

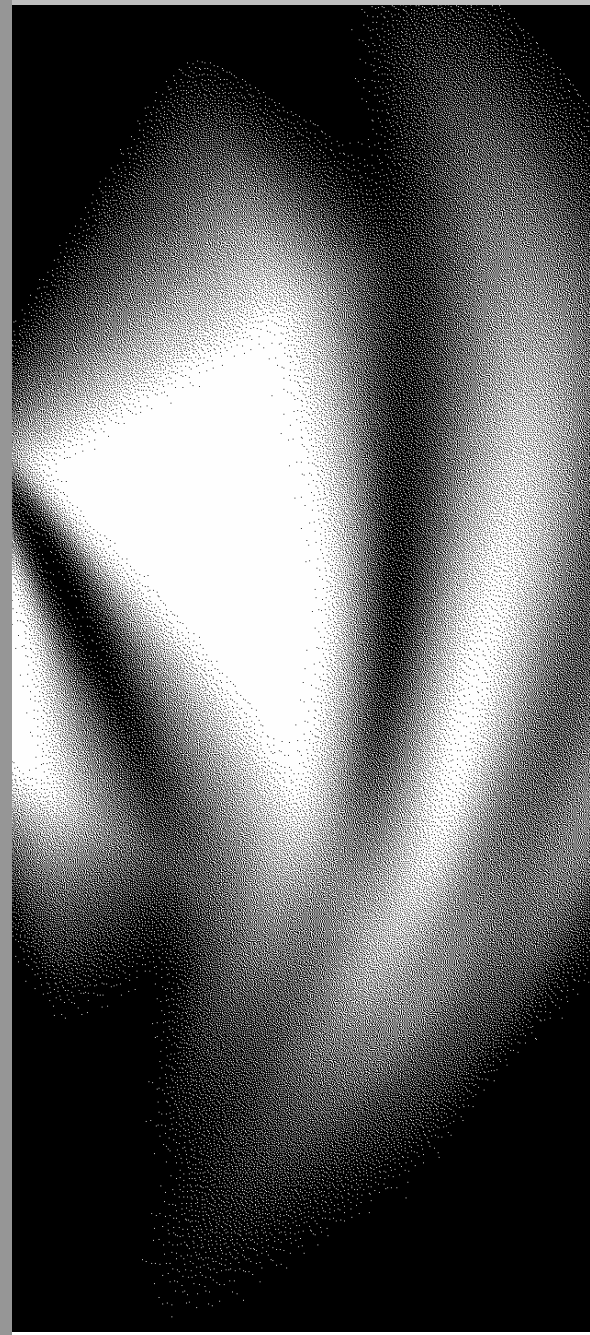


Australian Government
Productivity Commission

Impacts of Advances in Medical Technology in Australia

Productivity
Commission
Research Report

31 August 2005



© Commonwealth of Australia 2005

ISBN 1 74037 182 8

This work is subject to copyright. Apart from any use as permitted under the *Copyright Act 1968*, the work may be reproduced in whole or in part for study or training purposes, subject to the inclusion of an acknowledgment of the source. Reproduction for commercial use or sale requires prior written permission from the Attorney-General's Department. Requests and inquiries concerning reproduction and rights should be addressed to the Commonwealth Copyright Administration, Attorney-General's Department, Robert Garran Offices, National Circuit, Canberra ACT 2600.

This publication is available in hard copy, CD or PDF format from the Productivity Commission website at www.pc.gov.au. If you require part or all of this publication in a different format, please contact Media and Publications (see below).

Publications Inquiries:

Media and Publications
Productivity Commission
Locked Bag 2 Collins Street East
Melbourne VIC 8003

Tel: (03) 9653 2244
Fax: (03) 9653 2303
Email: maps@pc.gov.au

General Inquiries:

Tel: (03) 9653 2100 or (02) 6240 3200

An appropriate citation for this paper is:

Productivity Commission 2005, *Impacts of Advances in Medical Technology in Australia*, Research Report, Melbourne.

The Productivity Commission

The Productivity Commission, an independent agency, is the Australian Government's principal review and advisory body on microeconomic policy and regulation. It conducts public inquiries and research into a broad range of economic and social issues affecting the welfare of Australians.

The Commission's independence is underpinned by an Act of Parliament. Its processes and outputs are open to public scrutiny and are driven by concern for the wellbeing of the community as a whole.

Information on the Productivity Commission, its publications and its current work program can be found on the World Wide Web at www.pc.gov.au or by contacting Media and Publications on (03) 9653 2244.

Foreword

Medical technology is generally seen as an important driver of increased healthcare expenditure. The prospect that spending pressures will intensify with the ageing of the population raises questions about the benefits and costs of new technologies and processes for evaluating them.

The Australian Government accordingly asked the Commission to undertake a research into the impact of advances in medical technology on healthcare expenditure, and the associated costs and benefits for the community.

In preparing its report, the Commission has drawn on information from submissions, consultations with governments, other relevant organisations and research groups, as well as a wide array of studies examining the impacts of advances in medical technology. The Commission thanks the many people who have contributed for their co-operation in providing information, including in response to a progress report.

The study was overseen by Commissioners Helen Owens and Philip Weickhardt and conducted by a research team in the Commission's Melbourne office headed by Lisa Gropp.

Gary Banks
Chairman

August 2005

Terms of reference

THE IMPACT OF ADVANCES IN MEDICAL TECHNOLOGY ON HEALTHCARE EXPENDITURE IN AUSTRALIA

PRODUCTIVITY COMMISSION ACT 1998

The Productivity Commission is requested to undertake a research study detailing and explaining the impact of advances in medical technology on public and private healthcare expenditure, and the associated costs and benefits for the Australian community. Technology is defined here in broad terms, encompassing physical equipment, instruments and pharmaceuticals, clinical procedures, knowledge and support systems within which health care is provided.

In undertaking the study the Commission is to:

- a) Identify the key drivers of medical technology demand.
- b) Identify the net impact of advances in medical technology on healthcare expenditure over the past ten years.
- c) As far as practicable, identify the likely impact of advances in medical technology on healthcare expenditure over the next five to ten years, and identify the areas of significant potential growth.
- d) Identify existing mechanisms and processes for ensuring cost-effectiveness in the use of medical technology, and any gaps in these processes.
- e) Examine the impact of changes in medical technology on the distribution of costs and financial incentives across different parts of the health system, including whether advances in one technology area result in reduced costs in others.
- f) Investigate the net impact of advances in overall and individual health technologies on:
 - economic, social and health outcomes, including exploring which demographic groups are benefiting from advances in health technology; and
 - the overall cost effectiveness of healthcare delivery.

The Commission is to have regard to:

- recent substantive studies undertaken elsewhere;
- international experience in ensuring cost effectiveness of health care;
- the established economic, social, health and environmental objectives of the Government; and
- community expectations of appropriate healthcare provision.

The Commission is required to produce a final report within 12 months of the receipt of the reference.

ROSS CAMERON

31 August 2004

Contents

Foreword	III
Terms of reference	IV
Abbreviations and explanations	XV
Glossary	XXI
Key Points	XXVI
Overview	XXVII
1 Introduction	1
1.1 About this study	1
1.2 Background to the study	2
1.3 Medical technology and the Australian healthcare system	5
1.4 Scope of the study	7
1.5 Conduct of the study	8
1.6 Report structure	9
2 The market for medical technology	11
2.1 Key demand drivers	11
2.2 Supply of medical technology	37
2.3 Conclusion	41
3 Aggregate impact of medical technology on expenditure	43
3.1 Techniques to measure the impact of technology	43
3.2 The residual approach	44
3.3 The direct approach	57
4 Individual technology expenditure impacts	63
4.1 Which technologies have driven the increase in healthcare expenditure?	64
4.2 Expenditure impacts of individual technologies	72

4.3	Funding responsibilities and expenditure on technology	87
4.4	Summing up	96
5	Benefits of advances in medical technology	99
5.1	Measuring outcomes	100
5.2	Health outcomes in Australia	107
5.3	Linking outcomes to advances in medical technology	108
5.4	Conclusions	127
6	Distribution of the benefits of new medical technology	129
6.1	Defining appropriate access	129
6.2	Measurement issues	131
6.3	Who has access to new medical technology	134
6.4	Explaining differences in utilisation rates	152
6.5	Conclusion	163
7	Cost effectiveness of advances in medical technology	165
7.1	Assessing aggregate net benefits of advances in medical technology	165
7.2	Cost-effectiveness analysis	168
7.3	Cost effectiveness of broad categories of technology	170
7.4	Cost effectiveness of individual technologies	172
7.5	Conclusion	175
8	Health technology assessment in Australia: an overview	177
8.1	Defining health technology assessment	178
8.2	Identifying gaps in HTA processes	179
8.3	Overview of HTA arrangements	180
8.4	Key gaps	195
8.5	Summary	209
9	Health technology assessment: pharmaceuticals	211
9.1	Assessment processes	211
9.2	Methodological issues	216
9.3	Procedural issues	230
9.4	Post-assessment processes	238

10	Health technology assessment: procedures, devices and ICT	245
10.1	Key differences in HTA between pharmaceuticals and other technologies	245
10.2	Medical procedures	246
10.3	Prostheses and devices	254
10.4	Information and communications technology	259
10.5	Post-assessment processes	263
11	Future advances in medical technology	267
11.1	Background	268
11.2	Technology development process	272
11.3	Projected disease burden	275
11.4	Likely advances in medical technology	277
11.5	Illustrative expenditure impacts of some future advances in medical technology	301
11.6	Conclusions	307
12	Conclusions and future policy challenges	309
12.1	Conclusions	309
12.2	Future policy challenges	311
APPENDIXES		
A	Public consultation	317
B	Measuring health and economic outcomes	321
C	Health technology assessment in other countries	363
D	Case studies: an overview	381
E	Joint replacement surgery	385
F	Statins	403
G	Selective Serotonin Reuptake Inhibitors	417
H	Drug eluting stents	431
I	<i>Trastuzumab</i> (Herceptin)	445
J	PSA tests for prostate cancer	465

K	Information and communications technology	479
L	Genetic testing of women for breast cancer	511
M	Cataract surgery	527
	References	539

TECHNICAL PAPERS

1	Modelling aggregate expenditure impacts	CD/web only
2	Estimating individual technology expenditure impacts	CD/web only
3	Future expenditure impacts	CD/web only
4	Distributional data	CD/web only

BOXES

Box 1.1	Productivity Commission study into the economic implications of an ageing Australia	4
Box 1.2	Productivity Commission: operating principles	8
Box 2.1	Policies promoting private health insurance membership	17
Box 3.1	The choice of health expenditure series: a stylised example	47
Box 3.2	Interaction between income growth and technological change	52
Box 3.3	The non-demographic growth rate in the Commission's ageing report	54
Box 3.4	Derivation of the technology residual, 1992-93 to 2002-03	55
Box 4.1	Improvements in HIV/AIDS and asthma medications	71
Box 4.2	Cost savings generated by new pharmaceuticals	76
Box 4.3	Offsetting cost savings from selected new technologies	77
Box 4.4	Per patient costs vs treatment prevalence: some empirical studies	80
Box 4.5	Improved diagnostic technologies for prostate and breast cancers	82
Box 4.6	Estimating the expenditure impacts of selected advances in technology	85
Box 4.7	Growth patterns in public hospital separations	90
Box 4.8	Participants' comments on cost shifting in the Australian healthcare system	92

Box 4.9	Funding arrangements for genetic testing	93
Box 5.1	Health outcome indicators — an overview	101
Box 5.2	Potential uses of summary health outcome measures	102
Box 5.3	Burden of disease	103
Box 5.4	Potential problems using QALYs in economic evaluation	104
Box 5.5	Some economic impacts of advances in medical technology	106
Box 5.6	Impacts of specific pharmaceutical advances	116
Box 6.1	Selected government policy statements relating to access to the health system	130
Box 6.2	The impact of using different systems for classifying socioeconomic status — hospital admissions	134
Box 6.3	Socioeconomic status and interventions for heart disease	139
Box 6.4	Surgery for breast cancer by demographic group	146
Box 6.5	The impact of comorbidities and severity of disease on the use of medical technology	153
Box 6.6	Private and public patient access to new technology	156
Box 6.7	Socioeconomic status, private health insurance coverage and use of private hospitals	157
Box 6.8	Education and access to healthcare	158
Box 6.9	Impact of proximity to more specialised staff and facilities	161
Box 6.10	GP consultations	162
Box 7.1	Sensitivity and limitations of cost-effectiveness analysis — the example of dual chamber pacemakers	169
Box 7.2	Cost effectiveness of classes of technology	170
Box 8.1	Medicare Benefits Schedule	189
Box 8.2	Victorian Policy Advisory Committee on Technology	193
Box 8.3	Overseas approaches to HTA coordination	197
Box 8.4	HTA chronology of the drug eluting stent (DES)	206
Box 8.5	Diagnostic-treatment combinations: bone mineral density testing and Fosamax	207
Box 9.1	Study designs	217
Box 9.2	Disease registries in Australia	241
Box 10.1	HealthConnect — studies and trials	262
Box 11.1	Pharmaceutical development process	272
Box 11.2	Horizon scanning	275
Box 11.3	Robotic-assisted surgery	284

Box 11.4	Telemedicine in practice — an example	299
----------	---------------------------------------	-----

FIGURES

Figure 1.1	Real health expenditure per capita, 1992-93 to 2002-03	2
Figure 2.1	Total health expenditure by source, 2002-03	14
Figure 2.2	Health expenditure by individuals, in current prices, by area of expenditure, 2002-03	16
Figure 2.3	Private health insurance coverage, 1983–2005	17
Figure 2.4	Private health sector: prostheses services performed and total benefits paid	18
Figure 2.5	Population ageing and government health spending, 2002-03 to 2044-45	23
Figure 2.6	Trends in cataract surgery amongst Australia's aged	25
Figure 2.7	Trends in hip and knee replacement amongst Australia's aged	25
Figure 3.1	The residual over time	56
Figure 4.1	Real healthcare expenditure by area of expenditure, 1991 to 2001	64
Figure 4.2	Average price per script of PBS drugs	67
Figure 6.1	Age-standardised CHD separation rates by remoteness area	141
Figure 6.2	CHD separation rates by funding status, 1993-94 to 2003-04	145
Figure 8.1	Stylised process of health technology assessment	179
Figure 8.2	HTA agencies and committees, by broad type of technology and jurisdiction	184
Figure 8.3	Proportion of PBS drugs subjected to economic evaluation	189
Figure 8.4	Broad types of technology assessed by MSAC	190
Figure 9.1	Type of evaluation in submissions to PBAC, 1993 to 2002	223
Figure 9.2	PBS items, by type of restriction, 1997-98 to 2003-04	230
Figure 9.3	Average time taken to process drug submissions	232
Figure 10.1	Applications and references to MSAC, 1998-2000 to 2002-03	247
Figure 10.2	Indicators of MSAC processes, 1998-99 to 2003-04	252
Figure 11.1	Medical advances — possible future developments?	301

TABLES

Table 1.1	Health expenditure in selected OECD countries	3
Table 2.1	Health expenditure and mortality by major disease category	21

Table 2.2	Average rate of change in age-specific utilisation of seven procedures, United States, 1987–1995	24
Table 3.1	Some key residual studies	46
Table 3.2	The technology residual 1992-93 to 2002-03	53
Table 4.1	Real cost to government of subsidised PBS prescriptions, 1993-94 to 2003-04	66
Table 4.2	Hospital costs, 1996-97 to 2002-03	69
Table 4.3	Net expenditure impact of selected advances in medical technology, 2000-01	84
Table 6.1	Changes in inequality in death rates over time, 1985–87 to 1998–2000	136
Table 6.2	Rates of death from ischaemic heart disease, 2003	138
Table 6.3	Age-specific CHD separation rates and annual growth	140
Table 6.4	Ratios of CHD separation rates by socioeconomic status	143
Table 6.5	Age-standardised CHD separation rates by Indigenous status	144
Table 7.1	Median cost-effectiveness ratios by technology type	171
Table 7.2	Cost effectiveness of selected technologies	174
Table 8.1	Technologies covered by the NHSU	181
Table 8.2	Coverage of medical technologies by horizon scanning agencies, selected countries	182
Table 8.3	Key assessment criteria, national HTA mechanisms	185
Table 8.4	TGA classification system for medical devices	186
Table 8.5	Pharmaceutical expenditure, public and private sectors, Australia, 2002-03	188
Table 9.1	High-cost pharmaceuticals, Victorian public hospitals, 2003-04	212
Table 9.2	NHMRC levels of evidence	218
Table 9.3	Summary analysis of cost-effectiveness ratios, selected submissions to PBAC, 1991 to 1996	228
Table 9.4	Statutory processing times for drug evaluations by the TGA	232
Table 9.5	New submissions of prescription medicines to the TGA	234
Table 9.6	Distribution of clinical trial activity by phase of trial, Victoria	240
Table 10.1	Differences between medical devices and pharmaceuticals	246
Table 11.1	Pharmaceuticals in pipeline, by condition	274
Table 11.2	Top 10 ranking of disease burden, major disease groups by gender	277

Table 11.3	Estimated net expenditure impacts of selected advances in medical technology	307
------------	--	-----

Abbreviations and explanations

Abbreviations

AAT	Administrative Appeals Tribunal
ABS	Australian Bureau of Statistics
ACCHSs	Aboriginal Community Controlled Health Services
ACE	angiotensin-converting enzyme
AD	Alzheimer's Disease
ADA	adenosine deaminase
ADEC	Australian Drug Evaluation Committee
ADHC	attention deficit and hyperactivity disorder
ADIA	Australian Diagnostic Industry Association
ADRAC	Adverse Drug Reactions Advisory Committee
AF	atrial fibrillation
AFR	Australian Financial Review
AHA	Australian Healthcare Association
AHIA	Australian Health Insurance Association
AHIC	Australian Health Information Council
AHMAC	Australian Health Ministers Advisory Council
AHSA	Australian Health Service Alliance
AHWAC	Australian Health Workforce Advisory Committee
AHWOC	Australian Health Workforce Officials' Committee
AIDS	acquired immune deficiency syndrome
AIHW	Australian Institute of Health and Welfare
AIMD	active implantable medical device
ALRC	Australian Law Reform Commission

AMA	Australian Medical Association
AMAC	Australian Medical Advisory Committee
AMI	acute myocardial infarction
AMWAC	Australian Medical Workforce Advisory Committee
ANF	Australian Nursing Federation
ANZHSN	Australia and New Zealand Horizon Scanning Network
AOA NJRR	Australian Orthopaedic Association National Joint Replacement Registry
ART	assisted reproductive technology
ARTG	Australian Register of Therapeutic Goods
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
ASGC	Australian Standard Geographic Classification
ASVS	Australian Standard Vaccination Schedule
ATAGI	Australian Technical Advisory Group on Immunisation
AUSFTA	Australia–United States Free Trade Agreement
BCG	Boston Consulting Group
BMD	bone mineral density
BMS	bare metal stents
BNG	Benefit Negotiation Group
BPH	benign prostatic hyperplasia
CABG	coronary artery bypass grafting
CAGs	Clinical Advisory Groups
CAS	computer-aided surgery
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CDR	Common Drug Review
CEA	cost-effectiveness analysis
CeNTIE	Centre for Networking Technologies for the Information Economy
CETAP	Canadian Emerging Technology Assessment Program

CHD	coronary heart disease
CHERE	Centre for Health Economics Research and Evaluation
CIS	clinical information system
COPD	chronic obstructive pulmonary disease
CRT	cardiac resynchronisation therapy
CT	computed tomography
CVD	cardiovascular disease
DACEHTA	Danish Centre for Evaluation and Health Technology Assessment
DALE	disability-adjusted life expectancy
DALY	disability-adjusted life-year
DDDs/1000/day	defined daily doses per 1000 people per day
DES	drug eluting stents
DIMCs	Diagnostic Imaging Management Committees
DM	diabetes mellitus
DoFA	Department of Finance and Administration
DoHA	Department of Health and Ageing
DRE	digital rectal examination
DRG	Diagnostic Related Group
DSEB	Drug Safety Evaluation Branch
DUSC	Drug Utilisation Sub-Committee
DVA	Department of Veterans Affairs
ECCMHS	Expert Committee on Complementary Medicines in the Health System
EDS	electronic decision support
EFI	equivalent family income
EHR	electronic health records
ESC	Economics Sub-Committee
ESRD	end-stage renal disease
FDA	Food and Drug Administration (United States)
FISH	fluorescence in situ hybridisation

FSIOS	Federal Social Insurance Office of Switzerland
GAP	Global Access Partners
GDG	Guideline Development Group (England and Wales)
GDP	gross domestic product
GP	general practitioner
HDL	high-density lipoprotein
HealthPACT	Health Policy Advisory Committee on Technology
HER2	human epidermal growth factor receptor-2
HIC	Health Insurance Commission
HIV	human immunodeficiency virus
HoR	House of Representatives
HRQoL	health-related quality of life
HTA	health technology assessment
IADs	implantable atrial defibrillators
IC	Industry Commission
ICD	implantable cardioverter defibrillator
ICT	information and communications technology
IFF	Institute for the Future
IM	information management
IMRT	intensity modulated radiation therapy
IOLs	intraocular lenses
IRSD	index of relative socioeconomic disadvantage
IT	information technology
IVF	in-vitro fertilisation
LDL	low-density lipoprotein
LVAD	left ventricular assist device
MBCC	Medical Benefits Consultative Committee
MBS	Medicare Benefits Scheme / Schedule
MDEC	Medical Device Evaluation Committee
MIAA	Medical Industry Association of Australia

MoU	memorandum of understanding
MRI	magnetic resonance imaging
MSAC	Medical Services Advisory Committee
NATSEM	National Centre for Social and Economic Modelling
NCC	National Collaborating Centre (England and Wales)
NCCH	National Centre for Classification in Health
NCE	new chemical entity
NEHRT	National Electronic Health Records Taskforce
NEHTA	National E-Health Transition Authority
NET-S	New and Emerging Technologies - Surgical
ng	nanogram
NHF	National Heart Foundation
NHIG	National Health Information Management Group
NHIMAC	National Health Information Management Advisory Council
NHMDS	National Hospital Morbidity Data Set
NHMRC	National Health and Medical Research Council
NHS	National Health Service (United Kingdom)
NHSC	National Horizon Scanning Centre (United Kingdom)
NHSU	National Horizon Scanning Unit
NICE	National Institute for Health and Clinical Excellence (England and Wales)
NICS	National Institute of Clinical Studies
NOIE	National Office for the Information Economy
NPS	National Prescribing Service
NSAIDs	non-steroidal anti-inflammatory drugs
OA	osteoarthritis
ODBT	Office of Devices, Blood and Tissues
OECD	Organisation for Economic Cooperation and Development
OTC	over the counter
PAS	patient administration system

PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme/Schedule
PC	Productivity Commission
PCI	percutaneous coronary interventions
PDC	Prostheses and Devices Committee
PET	positron emission tomography
phaco	phacoemulsification
PHIAC	Private Health Insurance Administration Council
PHIMDEC	Private Health Industry Medical Devices Expert Committee
PhRMA	Pharmaceutical Research and Manufacturers of America
POCT	point-of-care testing
PPP	purchasing power parity
PSA	prostate specific antigen
PSD	Public Summary Document
PSTC	Pathology Services Table Committee
PTO	person tradeoff
QALY	quality-adjusted life-year
QHDAC	Queensland Hospitals Drug Advisory Committee
QoL	quality of life
RACS	Royal Australasian College of Surgeons
R&D	research and development
RANZCP	Royal Australian and New Zealand College of Psychiatrists
RANZCR	Royal Australian and New Zealand College of Radiologists
RP	robotic prostactectomy
RPBS	Repatriation Pharmaceutical Benefits Scheme
RS	rating scale
SCID	Severe Combined Immune Deficiency
SCNT	Sub-Committee for New Technologies under the Clinical Senate

SCRGSP	Steering Committee for the Review of Government Service Provision
SG	standard gamble
SID	supplier-induced demand
SSRI	selective serotonin reuptake inhibitor
SWARH	South West Alliance of Rural Hospitals
SWPE	standardised whole patient equivalent
TCA	tricyclic antidepressant
TGA	Therapeutic Goods Administration
TTO	time tradeoff
UHC	University HealthSystem Consortium (United States)
UK	United Kingdom
US	United States of America
VDHS	Victorian Department of Human Services
VDUAC	Victorian Drug Usage Advisory Committee
Viccu™	Virtual Critical Care Unit
VMAC	Victorian Medicines Advisory Committee
VMSC	Victorian Medication Safety Committee
VPACT	Victorian Policy Advisory Committee on Technology
WADEP	Western Australian Drug Evaluation Panel
WAMTC	Weighted Average Monthly Treatment Costs
WHO	World Health Organization
YOLS	year of life saved
ZDV	Zidovudine

Explanation

Findings

FINDING

Findings in the body of the report are paragraphs highlighted using italics, as this is.

Glossary

Advances in medical technology	See medical technology
Comorbidity	The presence of coexisting diseases or conditions (see also morbidity).
Co-payments	A payment made by the user at the time of service as part of the total payment for that service (DoHA 2003c).
Cost effectiveness	A new treatment is cost effective if it provides a defined level of benefit at lower cost than existing treatments, or more units of benefit for a given cost. Units of benefit include improvements in health outcomes such as length of life and quality of life. Costs cover additional outlays of resources by governments, insurers, patients and carers.
Dispensed price of prescription	The dispensed price of a prescription is the government-approved dispensed price of a drug listed on the Pharmaceutical Benefits Scheme (PBS). Pharmacists participating in the PBS agree to dispense medicines at the dispensed price. The consumer pays a set co-payment, and the government pays the difference up to the dispensed price. In agreeing to a dispensed price, the government includes allowances for the manufacturer's price, a margin for the wholesaler, a mark-up by the pharmacist and the pharmacist's dispensing fee. All components of the dispensed price are paid direct to participating pharmacies who make their own pricing arrangements with wholesalers and/or manufacturers for particular medicines (DoHA 2005c).
Efficacy	A therapy is efficacious if it produces a health benefit in a defined population in controlled or ideal conditions (DoHA 2003c).

Effectiveness	A therapy is considered effective if it produces a health benefit in uncontrolled or routine circumstances (DoHA 2003c).
Gap payments	A contribution to the overall payment for a service made by a patient, in addition to contributions by governments and insurers.
Incidence	The proportion of the population suffering from a disorder or illness for the first time during a given period.
Indication	A circumstance which points to or signifies the cause, pathology or treatment of a condition or disease.
Leakage	The prescription of drugs to cases that do not meet the criteria approved by the Pharmaceutical Benefits Advisory Committee.
Morbidity	Illness or disease, or the incidence or prevalence of illness or disease.
Medical technology	<p>The terms of reference define medical technology in broad terms to encompass physical equipment, instruments and pharmaceuticals, clinical procedures, knowledge and support systems within which healthcare is provided.</p> <p>The Commission also has interpreted this definition to encompass general technologies that are applied in the health industry (such as information and communications technologies), as well as technologies developed specifically for applications in the healthcare sector.</p> <p>Advances or innovations in medical technology are understood to encompass innovations in products (for example, new or improved pharmaceuticals) and processes (for example, new or improved surgical procedures or patient management systems).</p>
Prevalence	The number of cases of a disease present in a population at a given time or during a given period.

Separation

The discharge, transfer, death or change of episode of care of an admitted hospital patient. An admitted patient is a patient who has formally undergone an admission process in a hospital to begin an episode of care.

Technology diffusion

The process of adoption of new technology (including the speed of adoption, and the way in which new technology is distributed across different groups).

OVERVIEW

Key points

- Advances in medical technology have brought large benefits but have also been a major driver of increased health spending in recent years.
 - In many cases, increased expenditure on new medical technologies reflects improved treatment and a significant increase in the number of people treated.
- Overall, advances in medical technology arguably have provided value for money — particularly as people highly value improvements in the quality and length of life — but the cost effectiveness of individual technologies in practice varies widely and for some is simply unknown.
- Variations in cost effectiveness, and relatively low use by some demographic groups, suggest scope for expanding use of some technologies and possibly reducing use of others to increase net community benefits.
- Better coordinated, more systematic health technology assessment (HTA) with transparent objectives, underpinned by the principle of enhancing overall community wellbeing, would be a good step forward. HTA can help to target use of new technologies and promote overall cost effectiveness of healthcare spending.
 - Evidence and needs based access to new technologies is preferable to existing, often blunt, rationing mechanisms.
 - Systematic reviews of efficacy and cost effectiveness of new technologies once they are in use could promote overall cost effectiveness of healthcare, without unduly delaying their introduction.
 - Greater procedural transparency and community involvement in HTA have the potential to foster greater acceptance of technology funding decisions and to help ensure that HTA is not used simply to restrain expenditure.
- The next decade or so could see the emergence of revolutionary technological advances based largely on knowledge of the human genome. Many are expected to provide significant benefits to the Australian community, but at significant cost.
- Such technological advances, interacting with (and encouraged by) increasing demand for health services driven by income growth, accelerating population ageing, community expectations that new technologies will be accessible to all, the commitment of doctors to offer the best-available treatments, and subsidised consumer prices, will make for a potent mix, placing increasing pressures on the private and public health systems.
- These pressures underscore the need for better information about the costs and benefits of technology. But technology is only one input in healthcare. Problems related to technology use often reflect broader structural, incentive and resourcing issues in the health system.
- There is a pressing need to explore what the community considers is an appropriate level of subsidised access to healthcare and the technology it embodies, and the institutional and incentive structures that will deliver it efficiently and equitably.

Overview

‘Within policy circles, high-technology medical care has been viewed as a curse and a blessing because of its capacity to consume an ever-increasing share of resources and the wonders it works in the diagnosis and treatment of disease.’ (Gelijns and Rosenberg 1994, p. 28)

1 Background

The Australian Government has asked the Commission to undertake a research study detailing and explaining the impact of advances in medical technology on public and private healthcare expenditure, and the associated costs and benefits for the Australian community.

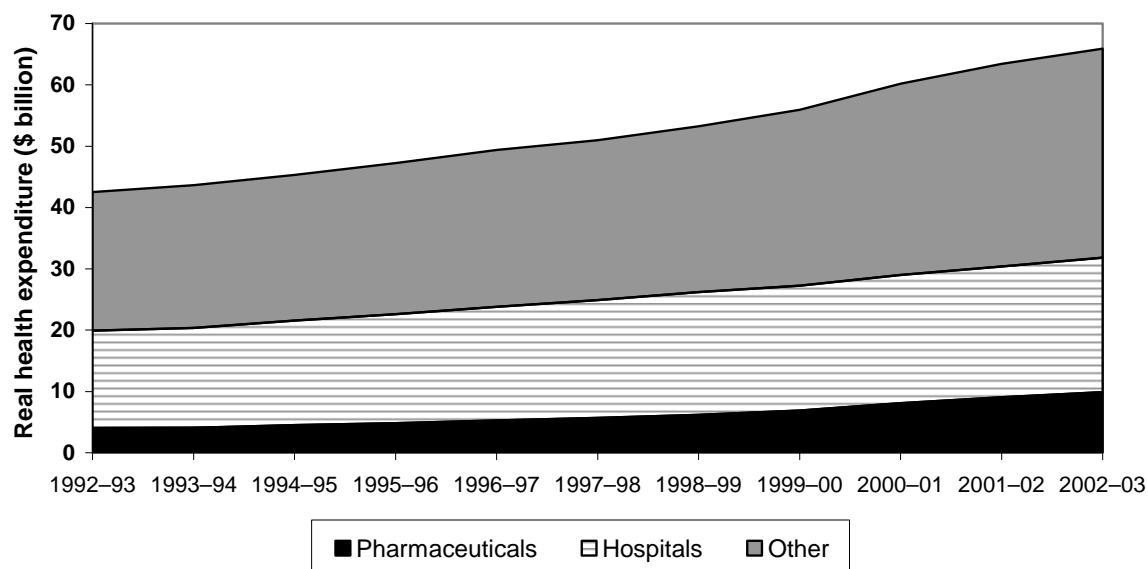
Recent decades have brought major advances in medical technology in diagnostics, procedures, prostheses, devices and medicines (box 1).

Box 1 Some major advances in medical technology	
MRI and CT scanning	‘Phaco’ cataract removal & foldable lenses
ACE inhibitors for high blood pressure	Hip and knee replacement
Angioplasty to unblock arteries	Inhaled steroids for asthma
Statins to reduce cholesterol	Laparoscopic surgery
SSRI and non-SSRI antidepressants	Tamoxifen to treat breast cancer

At the same time, health expenditure has increased rapidly. Real total expenditure on healthcare (public and private) rose by almost 70 per cent between 1992-93 and 2002-03. Real total spending on pharmaceuticals increased by 145 per cent over the same period, or by around 9 per cent per year (figure 1).

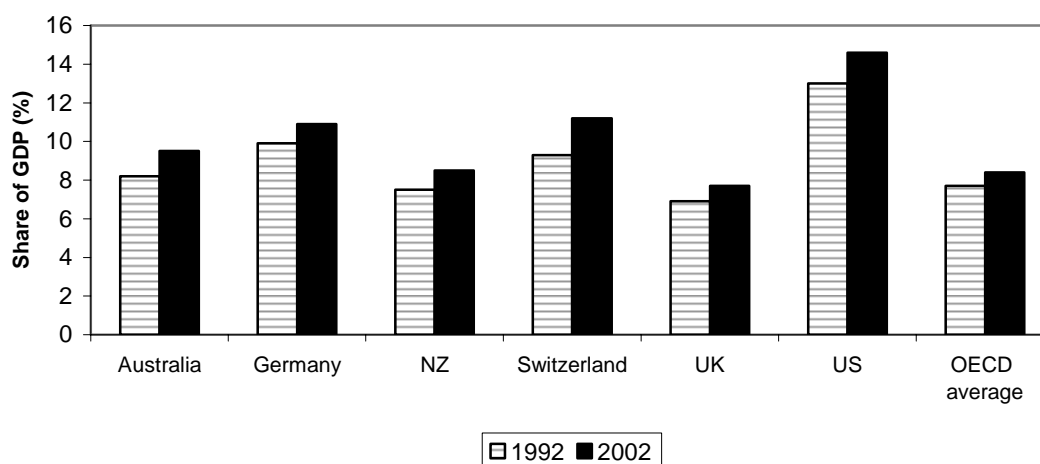
Figure 1 Real total healthcare expenditure in Australia has grown strongly

2001-02 prices



Total health spending in Australia expressed as a proportion of GDP reached 9.5 per cent in 2002, compared with 8.2 per cent in 1992. This is higher than the average for industrialised countries — the OECD average in 2002 was 8.4 per cent — and has risen proportionately more than in most other countries, including the United States (figure 2).

Figure 2 Australia's total health spending exceeds the OECD average



Medical technology is considered a significant, if not *the* most significant, driver of increased healthcare expenditure. There are concerns that these trends will continue,

even accelerate, with the anticipated rapid increase in the average age of the population and with emerging advances in medical technology, based on knowledge of the human genome, offering the potential to revolutionise treatments of major diseases.

Yet even if advances in medical technology drive increased healthcare expenditure, the critical question is whether the benefits outweigh the costs. In other markets increased expenditure generally would indicate increased consumer benefits. But because the direct purchase of healthcare in Australia is mostly undertaken by third parties — governments and private health insurers — normal market tests for ensuring value for money generally do not apply.

On the one hand, there are incentives for consumers and doctors to use medical technologies to the point where benefits are negligible — the most important being limited price signals. On the other, institutions that fund healthcare — particularly governments and public hospitals — face incentives to ration access to new technology to contain their budgetary outlays. The final level of technology use — and whether it is too high or too low relative to the level that delivers maximum community net benefits — will reflect the interplay of these and other pressures.

About this study

The terms of reference for this study are wide ranging:

- The definition of medical technology is very broad, including diagnostics, pharmaceuticals, medical devices and equipment, as well as knowledge and administrative support systems.
- In contrast to the Treasury's *Intergenerational Report* and the Commission's study into the economic implications of ageing, which both focussed on impacts on government spending, this study is required to consider past and potential future expenditure impacts of medical technologies for both the government and private sectors.
- The benefits as well as the costs of these technologies are to be assessed, as well as their overall impact on the cost effectiveness of healthcare.
- The Commission is also asked to review health technology assessment (HTA) processes and identify any 'gaps' in those processes.

In short, the study is intended to help assess whether medical technology is being used in a way, and to an extent, that delivers the maximum net benefits to the community and whether there is scope to deliver better outcomes in future.

2 What drives use of medical technology?

While the supply of new medical technology is an obvious prerequisite for its use, the final level of use and expenditure will reflect consumer demand for such technology, doctors' preferences and incentives, and externally-imposed rationing.

Individuals are willing to pay for good health and to achieve this they consume health services and, indirectly, the intermediate input 'medical technology'. Decisions to use a particular technology will be driven largely by medical practitioners, albeit in consultation with their patients and influenced by the incentive structures and constraints imposed by the healthcare system. In particular, governments and institutions that fund technology limit or guide where and when technologies can be used.

Consumer demand for health services

In recent years, the strongest drivers of consumer demand for health services and medical technology appear to have been income growth, rising community expectations, population growth and the interaction of low consumer prices and new technologies in both the private and public systems. Changes in the burden of disease have influenced demand for particular treatments. In the past decade, ageing of the population — which is a strong predictor of the burden of disease — has had a limited effect on health spending, but this will change as the average age of the population rises rapidly over the next few decades.

People consume more health services as they become wealthier

As their incomes grow, people demand more, and better quality, health services. This relationship is evident over time and across countries. Intuitively, this makes sense because good health is an essential ingredient for the improved quality of life and additional leisure and consumption made possible by increased income. Intuition is broadly supported by analysis: quantitative assessments of income elasticities are generally positive but range widely from 0.2 to more than 1.0. Commission modelling suggests that income growth accounts for at least 10 per cent (assuming an elasticity of 0.2) and potentially as much as half (assuming an elasticity of 1) of the growth in Australia's real healthcare spending over the last decade.

Escalating consumer expectations have also played a role ...

The amount and quality of health services demanded by the community will be influenced by what is considered a desirable level of health. For example, what is today considered an acceptable level of chronic pain or discomfort is likely to be significantly different from a few decades ago. Changing community perceptions of what is acceptable are strongly linked to education and lifestyle which, in turn, are strongly linked to income levels.

Greater awareness of medical technologies via internet access and media, and simply greater acceptance of, and belief in, the benefits of technology are also likely to have been strong drivers of expectations and demand. However, while there is broad agreement that community expectations are important in driving demand for health services, it is virtually impossible to quantify their impact.

... as have population growth, disease prevalence and ageing

The demand for health services and the technologies embodied in those services is inextricably linked to the nature and extent of illness and disease. Changes in the number of new cases (incidence) of disease, and total numbers affected (prevalence of disease), will reflect many factors, including:

- changes in population size;
- ageing of the population;
- new diseases and epidemics;
- improved screening and diagnostics;
- environmental factors (for example, air pollution);
- socioeconomic factors; and
- lifestyle/behavioural changes including, for example, changes in alcohol and tobacco consumption and obesity levels.

The link between population growth and aggregate demand for health services is reasonably straightforward — the greater the number of people, the greater the demand for health services, all else given. Population growth in Australia between 1992-93 and 2002-03 was 1.2 per cent per year, which explains roughly one-fifth of real average annual total health expenditure growth over the same period.

Recent changes in total expenditure in Australia for various diseases are partly attributable to lifestyle and increases in the average age of the population.

- Direct expenditure growth of 26 per cent for cardiovascular disease was below average health expenditure growth for all diseases of 37 per cent, reflecting the declining incidence of the disease attributable to lower smoking rates and other lifestyle changes, as well as improved preventative technologies (for example, statins and treatments for angina and high blood pressure).
- Substantially above average expenditure growth on treatment of diabetes probably reflects a combination of greater awareness of the disease and improved screening, and also ageing of the population combined with increasing obesity levels.

As highlighted in the Commission's report *Economic Implications of an Ageing Australia*, health spending increases with age. Across all health expenditure types, expenditure per person aged 65 years and over per year is around four times higher than expenditure per person under 65 years.

Yet to date, population ageing does not appear to have been a major driver of increased demand for health services — Commission estimates suggest that ageing has contributed at most about 0.7 percentage points of growth in total real health expenditure of 5.2 per cent per year, or around 13 per cent of expenditure growth over the past ten years. Once hospital costs associated with death are accounted for, a dip in death rates in recent years reduces further the past impact of ageing.

However, ageing of the population, and death rates, are set to accelerate. The Commission's report *Economic Implications of an Ageing Australia* estimates that the anticipated rise in the average age of the population will add 25 per cent to projected government health spending by 2044-45 (figure 3).

And because older age groups consume comparatively more health services, they consume more medical technology. There is also evidence that technology use by older age groups is increasing at a faster rate:

- treatment costs of prostate cancer rose by more than 150 per cent between 1993-94 and 2000-01 for males aged 65 years and over, compared with 79 per cent for those aged under 65 years;
- the use of cataract surgery increases with age, and the rate of increase is strongest for the 75–79 year age group (figure 4); and
- the number of hip replacements per 100 000 people also increases progressively with age. The rate of hip replacement surgery in the oldest age groups is also increasing, and is growing fastest for those aged 70–74 years (figure 4).

Figure 3 Population ageing and government health spending

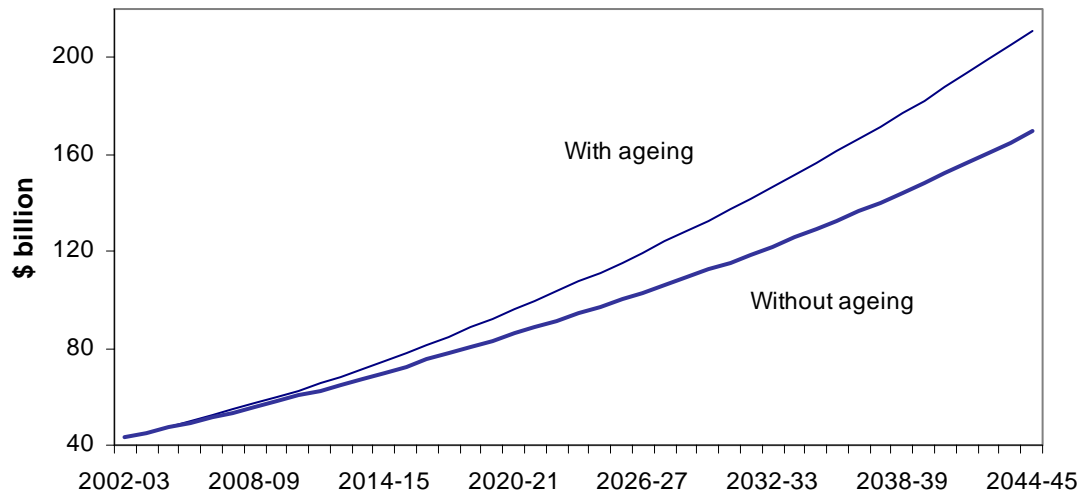
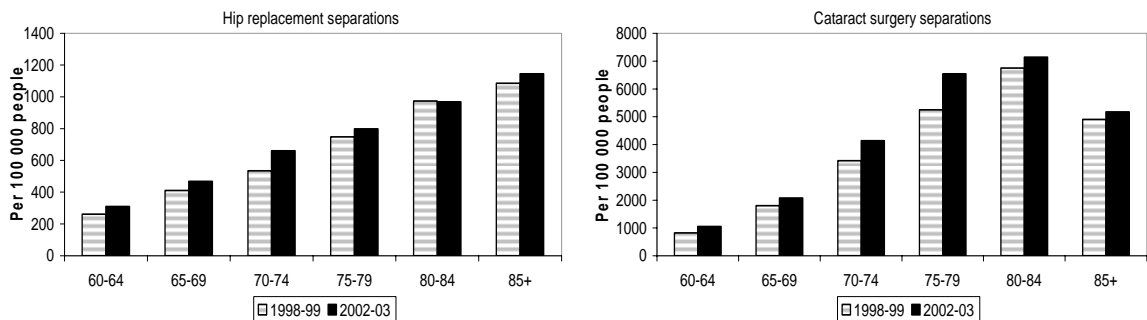


Figure 4 Hip replacement and cataract surgery increase with age



Universal access encourages demand for new technologies ...

The Australian, State and Territory Governments fund more than two-thirds of total healthcare expenditure, using funds raised from taxes and levies. Subsidised healthcare allows access on the basis of need rather than capacity to pay — in effect, health risks are spread across the community.

Affordable, needs-based access to healthcare has many desirable features. However, subsidised healthcare is a potentially bottomless pit — individuals have incentives to use new technologies provided they are perceived to deliver some benefits to them, regardless of their cost to the community.

... and, inevitably, rationing

This incentive structure has profound implications when new, more expensive technologies and treatments become available, particularly where these technologies facilitate an expansion in the range of conditions, indications and age groups that can be treated. Either all the increased demands must be met to maintain universal access, generating significantly increased healthcare spending, or rationing mechanisms must be brought into play.

Consumer co-payments are a form of limited price rationing for some technologies such as pharmaceuticals and technologies embodied in medical services. To the extent that co-payments have increased in recent years, demand for these services will have been dampened somewhat, though ‘safety net’ arrangements cushion their impact. Many non-price rationing and ‘gate-keeping’ mechanisms are also used.

- Public hospitals generally impose waiting periods, usually combined with prioritisation of treatment based on assessed clinical urgency.
- The Australian Government increasingly has attempted to contain its expenditure on new pharmaceuticals by restricting subsidised access to them to certain indications or according to disease severity, or by limiting the aggregate subsidy amount via price–volume agreements with pharmaceutical manufacturers.
- New drugs and procedures must be assessed as cost effective to be subsidised — that is, listed on the Pharmaceutical Benefits Schedule (PBS) and Medicare Benefits Schedule (MBS) in the first place.

Private insurance reimbursements have increased rapidly ...

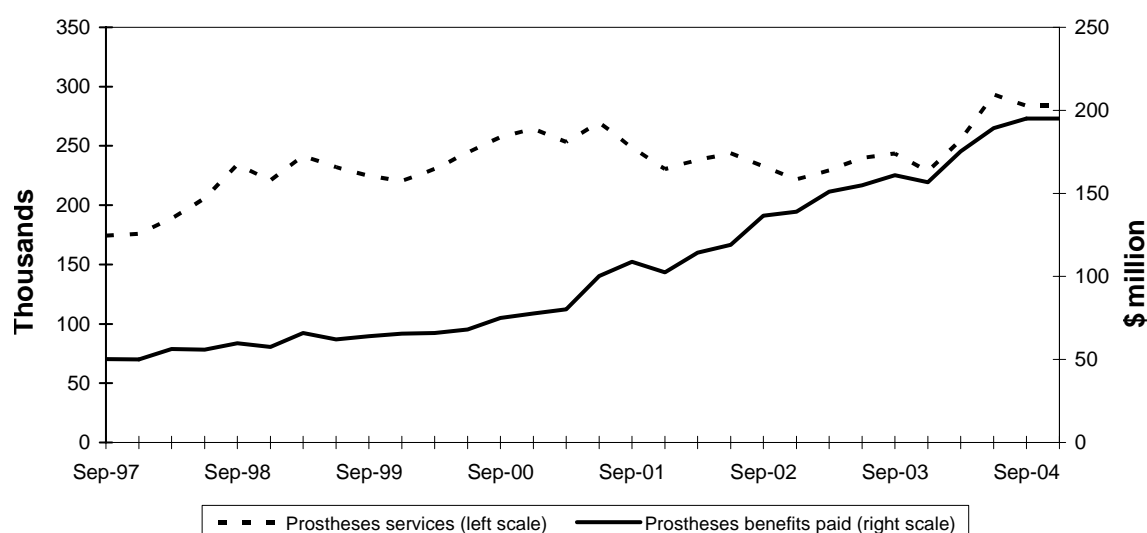
In Australia, private health insurance essentially provides insured patients with greater choice of clinician and a means of by-passing public hospital waiting periods. Increasingly, private health insurance is also facilitating access to new technologies.

The proportion of the population privately insured has risen to around 43 per cent from a low of 30 per cent in 1998, and reflects several policy initiatives including: the 30 per cent rebate on premiums; lifetime community rating; and penalty Medicare levies for uninsured high-income earners. Increased levels of private health insurance membership have been associated with a marked increase in the number of services performed and reimbursements for those services.

... especially for prostheses

The strongest area of growth has been in benefits paid for prostheses — an increase of more than 200 per cent between 1997 and 2004 (figure 5). The number of services involving prostheses has also increased, but by much less. This increase in benefits partly reflects the uptake of private health insurance by younger age groups (who are more likely to receive more sophisticated and expensive joint prostheses), and partly the introduction of ‘gap cover’ arrangements in 2001. These arrangements (until changes were introduced in early 2005) included a prohibition on private health insurers charging patients a gap for listed, implantable prosthetic items, such as artificial hips and knees, drug eluting stents (DES) and implantable cardiac defibrillators.

Figure 5 Health insurance benefits paid for prostheses have increased rapidly



Without any gap payable for prostheses by insured patients, there is little incentive to select less expensive items. Indeed, for both the individual and his or her doctor, there is an incentive to select the best prosthesis available, without much regard for its cost. For example, a large majority of angioplasty procedures for private patients now involve DES. While DES delay restenosis (re-narrowing of the blood vessel or heart valve) and the need for future surgery compared with bare metal stents for some patients, they cost much more.

Drivers of medical technology diffusion

General practitioners and specialists prescribe drugs and order diagnostic tests. Surgeons and other specialists select appropriate procedures, prostheses and devices, while hospitals purchase large diagnostic and surgical equipment and administrative support systems. All of these decisions are influenced by a range of factors, some of which have promoted demand for new technologies and some of which have constrained it (box 2).

Box 2 Drivers of technology decisions of clinicians and hospitals

- Awareness of new technologies and their potential benefits from company marketing, conferences, scientific journals and peers.
- Skills, capabilities and supply of clinicians and other inputs.
- Clinician assessment of patient clinical need.
- Financial and other incentives or constraints facing clinicians and institutions.
- Regulations and guidelines.

Arguably, the overriding objective of clinicians is to do the best for their patients. If arrangements are such that price is not a significant factor for the patient, then clinicians may feel remiss if they do *not* choose what they consider to be the best available technology. Indeed, they may consider themselves potentially legally liable if they do not choose the ‘state of the art’ technology on the market.

Substantial increases in use of more expensive prostheses in the private sector following the legislated removal of gap payments in 2001 provide some evidence of this. Diffusion of new technologies in private sector practice then drives adoption of (or, at least, pressure to adopt) these technologies in the public sector.

So-called ‘leakage’ of prescription medicines to patients where benefits are positive yet marginal (for example, prescribing of statins to people with very low absolute risk levels) could also suggest a lack of focus on costs. To the extent that clinician rewards are enhanced by use of newer technologies (if, for example, a new technology allows them to perform more procedures for the same level of reimbursement per procedure), then those demand pressures may be amplified.

At the same time, technology decisions of clinicians are influenced by government budget constraints (which, for example, limit the availability of subsidised MRI services), assessment and listing processes (which control the subsidisation of new medical procedures and pharmaceuticals), and restrictions on the prescription of around 80 per cent of all medicines listed under the PBS. The supply, distribution

and training of specialists and general practitioners will also affect technology diffusion.

Hospital technology decisions are strongly influenced by financial incentives — budget constraints in the case of public hospitals, which tend to encourage adoption of technologies that reduce hospital costs and, for private hospitals, the imperative of attracting scarce specialists — and their patients.

3 Have advances in medical technology increased or decreased spending?

‘Advances in medical technology have made it feasible and desirable to do more for each patient and to intervene with more patients.’ (Fuchs 1998, p. 2)

Whether advances in medical technology have led to reductions or increases in overall health expenditure will depend on:

- the impact of new technologies on unit treatment costs, including whether they substitute for, or complement, existing treatments;
- their level of use, for example, whether they generate new treatments for previously untreatable medical conditions, provide more intensive or prolonged treatments, or allow wider diagnosis and application of treatments (for example, to allow treatment of older age groups); and
- their impact on spending on other services such as aged care.

To gauge net expenditure impacts of advances in medical technologies over the past ten years, the Commission used two approaches. ‘Top down’ modelling (direct and residual) was used to assess aggregate technology impacts. ‘Bottom up’ case studies of some individual technologies were used to explore and explain the net expenditure impact.

‘Top down’ modelling

Net aggregate impacts of advances in medical technology were modelled using both direct and residual techniques (box 3).

Both methodologies have substantial limitations — most notably, they treat each explanatory variable as being independent of the others when this clearly is not the case. For example, higher incomes and changing expectations send signals to suppliers to produce better quality or higher-cost technologies, but without the availability of newer technologies, higher incomes may not translate into significantly higher health spending.

Box 3 ‘Top down’ modelling

Residual approach This approach subtracts the impact of known variables from health expenditure, leaving a residual. The size and sign of the residual is highly sensitive to assumptions made about the variables determining health expenditure and their elasticities. This residual is only a rough proxy for the effect of technology on healthcare expenditure, because it also captures the effect of other factors that are not possible to quantify, such as changes in lifestyle, tastes and the institutional environment.

Direct approach The direct approach is based on specifying a proxy for technological change. In this case, US health R&D expenditure was used since the US accounts for over half of total world health R&D and there are no time series data for global health R&D.

Bearing these caveats in mind, both modelling approaches — consistent with recent overseas studies — suggest that technology has been a significant factor driving increased real health expenditure in Australia over the past ten years:

- For the period 1992-93 to 2002-03, an income elasticity of 0.6 (midway between the upper and lower estimates) implies that the residual incorporating technology has contributed around one-third of the growth in real total healthcare spending. However, the residual exhibited a wide range, depending on the assumed income elasticity.
- The direct approach likewise estimates that technology has contributed a little more than one-third of the increase in real total healthcare expenditure over the same period.

‘Bottom up’ analysis

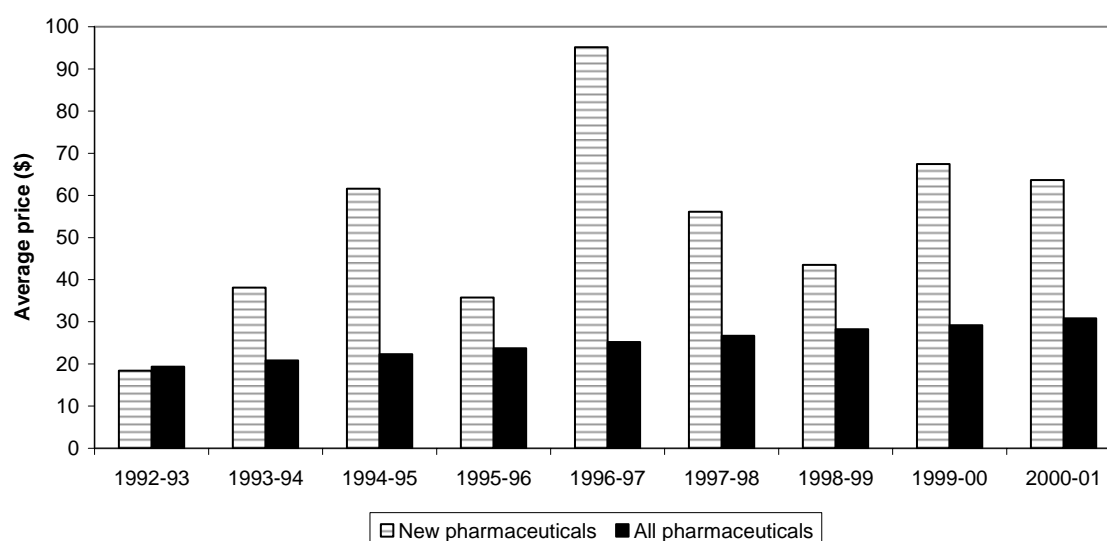
Technology has played a key role in driving spending in two key areas — inpatient (hospital) care (which accounts for about 40 per cent of health spending) and pharmaceuticals (a significant item for which spending growth has been consistently high).

For inpatient care, most of the increase in expenditure has been driven by rises in the average cost of treatment, fuelled at least in part by growth in spending on newer technologies used in critical and emergency care, new pharmaceuticals and more advanced prostheses. But some new technologies have reduced hospital treatment costs, mainly by reducing the length of hospital stays (for example, improved anaesthetic agents and minimally invasive surgical techniques).

New technologies appear to have had broadly offsetting effects on the *number* of hospital separations. On one hand, some less invasive and more effective procedures have *increased* the number of patients treated (for example, improved anaesthesia and minimally invasive surgery, such as lens extraction techniques combined with foldable intraocular lenses, have facilitated an increase in the number of surgical procedures). On the other, improvements in pharmaceuticals have *reduced* hospital separations for some other diseases, such as asthma, HIV/AIDS, and depression.

Though they may reduce hospital costs, new pharmaceuticals generally are more expensive than older drugs. Since 1993-94, the average (real) dispensed price of new PBS-listed drugs per script has been significantly higher than for older drugs (figure 6). In addition, many new drugs have facilitated expansion of treatment.

Figure 6 Average dispensed prices of new PBS-listed drugs exceed prices of older drugs

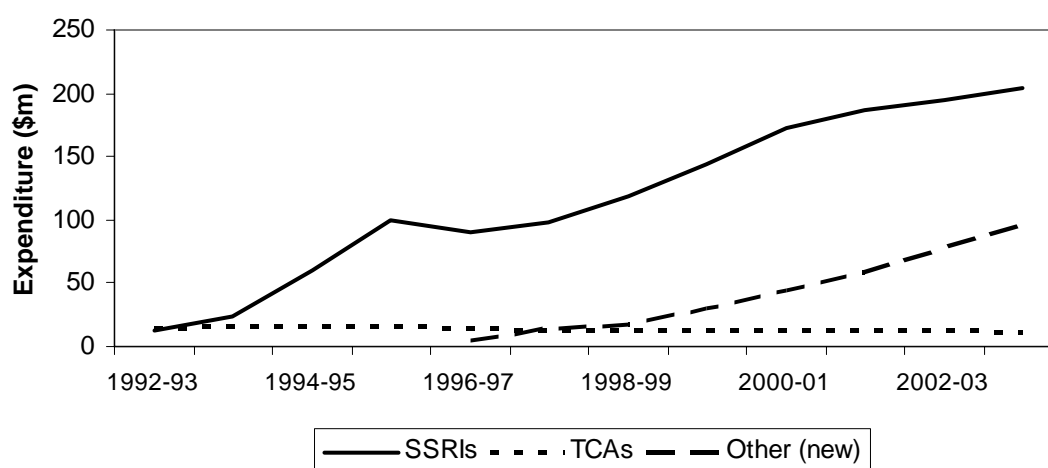


For example, though costing no more than earlier cholesterol-reducing drugs, statins are more effective and have fewer side effects. As a result, annual prescriptions for statins have grown from around 2 million to 15 million, making them the single-largest expenditure item on the PBS (just under \$900 million). Co-payments add another \$100 million. To the extent that statins reduce heart disease and strokes, there should be some savings in hospitals and aged care, but as yet these do not appear to have been large enough to offset higher direct outlays.

Selective serotonin reuptake inhibitors (SSRIs) (including Prozac and Zoloft) are more expensive than earlier tricyclic antidepressants (TCAs), but are less toxic and better tolerated. As a result of these improvements and an increase in reported

disease prevalence, annual prescriptions for SSRIs increased from fewer than 250 000 in 1992-93 to almost 7 million in 2003-04, and annual PBS spending from about \$12 million to \$200 million over the same period (figure 7). In 2003-04, private spending on SSRIs totalled more than \$70 million. Spending offsets are argued to include fewer visits to the doctor and shorter hospital episodes. However, whether SSRIs have been expenditure reducing or increasing overall depends on the extent to which they are being used to treat people with severe or mild depression (offsetting hospital savings are much lower for people in the latter group).

Figure 7 Government PBS/RPBS antidepressant prescription costs have soared



Some individual technologies, such as coronary stents, have increased unit costs of treatment because they complement angioplasty procedures. New higher-priced DES increase costs compared with the earlier model bare metal stents. However, the introduction of stents is unlikely to have increased angioplasty procedures, and is likely to reduce future hospital episodes and, therefore, hospital costs to the extent that restenosis is prevented or delayed.

By increasing the number of cases of diseases diagnosed, diagnostic imaging technologies such as MRI, CT and PET scans have increased healthcare expenditure, both through the cost of these imaging technologies themselves, and in the treatment of diseases which would otherwise have been undiagnosed. Diagnostic technologies may deliver cost offsets over time if early detection and treatment reduces the need for more intrusive (and expensive) treatments once the disease has progressed, or if expensive treatments can be better targeted.

4 The benefits and who gets them

A key factor driving the use of many new technologies has been their perceived benefits over alternative treatments. However, while there have been measurable improvements in various indicators of health and mortality — for example, between 1993 and 2003, life expectancy at birth in Australia increased by 2.7 years — it is difficult to attribute these to health spending, let alone particular technologies, with any degree of precision.

This is not to say that benefits of advances in medical technology have not been large, simply that measuring and attributing benefits is challenging:

- Observable indicators of health improvement may not capture all the benefits. Even indicators that attempt to incorporate quality of life (for example, using quality-adjusted life-year (QALY) measures) are highly subjective and sensitive to underlying assumptions and applied discount rates.
- There may be long, uncertain lags between the application of technology and health benefits, especially for diagnostic and preventative technologies.
- Estimates of benefits are often based on clinical trials but results from controlled settings may not translate to real life where patients have multiple conditions, different disease indications from those in the trial, or do not comply with treatment regimes.
- A lack of longitudinal patient data in Australia limits the study of benefits.

One Australian study, using US-based methodology, attributes 50 per cent of the improvements in ‘healthspan’ (QALYs) to medical innovations, with the remainder reflecting regulatory and other changes such as lifestyle. (Indeed, it could be argued that some health-promoting changes in lifestyle reflect advances in knowledge and consequently fall within the broad definition of medical technology used in this study.) Other studies attribute up to 70 per cent of observed reductions in mortality from cardiovascular disease to medical technology (drugs and acute interventions). Studies of particular technologies also suggest substantial health benefits (box 4).

Box 4 Health benefits of selected technologies

- New cancer drugs account for 50 to 60 per cent of the gains in US cancer survival rates (which have increased from 50 to 63 per cent) since 1975.
- New and innovative medications for asthma have resulted in a 28 per cent decline in mortality from the condition in Australia over the 1990s.
- Cataract surgery results in an average gain of 1.25 QALYs.
- Insulin pumps for diabetes patients improve patient quality of life and prolong life by an average of five years by reducing diabetes-related complications.

Use of advances in medical technology by demographic groups

While care must be taken in drawing conclusions because there may be sound clinical reasons for different treatment regimes, Australian and international studies suggest that people in more disadvantaged groups are less likely to receive some types of services — encompassing both old as well as newer technological interventions (box 5).

Box 5 Some examples of disparities in healthcare

- Men living in highly advantaged socioeconomic areas of Australia have higher rates of statin prescribing relative to their cardiovascular risk compared with other men.
- In Western Australia, women who are younger, in metropolitan areas or in more advantaged groups and not of Indigenous descent, are more likely to receive breast reconstructive surgery. Women with private health insurance, or who are treated in a private hospital at the time of their primary breast cancer surgery, are also more likely to receive breast reconstructive surgery.
- Residents of highly advantaged socioeconomic areas are more likely to undergo angiography and angioplasty in public hospitals than residents of disadvantaged socioeconomic areas.
- In New South Wales, patients from higher income families have marginally higher rates of hospital use (after adjusting for age and gender), even though patients in more disadvantaged socioeconomic groups tend to have poorer health.
- Indigenous people are less likely to undergo treatment including heart procedures, lung cancer surgery, renal transplant, cervical cancer screening and most diagnostic and therapeutic procedures in public hospitals.

The Commission analysed patterns of use of several new technologies and reached broadly similar conclusions although, in some cases, observed differences in use are not large or have narrowed in recent years (box 6).

Box 6 Differences in use of selected new technologies in Australia

- Age-adjusted rates of Herceptin use for the treatment of advanced breast cancer are higher for women in more highly-advantaged socioeconomic groups.
- Despite the greater prevalence of coronary heart disease amongst Indigenous people, they are significantly less likely to undergo heart procedures such as angioplasty with stent.
- People in the most disadvantaged groups in New South Wales, Victoria and South Australia are less likely to present to cancer clinics and, therefore, are under-represented in genetic testing for breast cancer.

For the technologies examined, it seems that capacity-to-pay may limit access to new technologies in their early stages of diffusion, especially prior to subsidisation, as well as access to elective procedures such as hip and knee replacement and cataract removal, which are rationed via public hospital waiting lists.

For more acute interventions, use by those in regional and remote areas, Indigenous people and the elderly living in socioeconomically disadvantaged areas was found to be frequently less than indicators of need would suggest was appropriate. For other types of services, there is some evidence that males and those in socioeconomically-disadvantaged areas may not receive treatments that could benefit them.

But reasons for differences in use are complex. For example, there is some evidence that people from more disadvantaged socioeconomic groups may have comorbidities that limit opportunities for some (especially acute) interventions (because of lifestyle or because they do not present for treatment until complications set in). (The Commission was unable to adjust the results for comorbidities, or link treatments with diagnoses.) In other words, there may be demand as well as supply side explanations and simply making technologies more widely available may not necessarily increase cost-effective use by some groups.

5 Have advances in medical technology delivered value for money?

Real total annual healthcare expenditure increased by around \$30 billion over the decade to 2002-03. Commission modelling suggests that advances in medical technology might have accounted for additional real spending of between \$220 to \$820 per person in 2002-03 compared with 1992-93. Though the range is wide, this puts into some perspective the order of magnitude of the benefits required to have

made the extra spending worthwhile. The question is whether advances in medical technology delivered benefits at least of this order of magnitude.

Hypothetical exercises using reasonable assumptions about the value of additional life expectancy and improved quality of life, and the contribution of advances in medical technology to these observed improvements, suggest that the benefits of technological advances to the Australian community have outweighed the costs.

For instance, if an additional year of healthy life is valued at \$100 000, then extra spending per person per year of \$820 (the Commission's upper estimate of the expenditure impact of advances in medical technology) would need to extend their life expectancy by about three days for each year of the ten-year period analysed, or by 30 days in total for that decade. Obviously, such calculations are highly sensitive to the value placed on additional life years — lower values would require advances in medical technology to extend life expectancy further. Yet halving the statistical value of an additional life year to \$50 000 increases to six the extra days required (per year) to make additional spending on those advances worthwhile. Such outcomes are well within feasible limits — numerous studies demonstrate strong links between observed improvements in life expectancy and quality of life and advances in medical technology. Overall, life expectancy at birth has increased by almost three years over the past decade or by more than three months for each of those ten years.

One US study suggests that benefits from advances in treatment of cardiovascular disease and low birth weight/premature infants together equal the entire increase in US medical spending over 50 years. However, it is not possible to provide a *precise* estimate of the impact of advances in medical technology on overall cost effectiveness of the healthcare system.

Analysis of categories of technologies supports this general conclusion. Given rigorous cost-effectiveness assessment of most new pharmaceuticals and many new medical and diagnostic procedures in Australia, it is reasonable to conclude that advances in these technology categories have been broadly cost effective.

In addition, estimates of cost effectiveness of individual technologies, where they are available, also suggest that many advances used in Australia are likely to have been cost effective relative to alternative treatments. Technologies that deliver both cost savings and additional health benefits clearly provide value for money — examples include some new vaccines, anaesthetic agents and laparoscopic surgery. For other new technologies, the estimated cost is low per unit of benefit — for example, cataract removal and hip and knee replacements. Many new drugs also appear to be relatively cost effective for their targeted patient group — statins, anti-hypertension drugs and SSRIs, for example.

While these examples provide *prima facie* evidence that use of these treatments will have been relatively cost effective, their cost effectiveness in practice may be less favourable. When consumer price signals are limited and medical practitioners also face incentives to use newer technologies, treatment may expand to people for whom the perceived benefits are negligible.

So even though cost effectiveness of all new drugs and most medical procedures is assessed prior to listing for reimbursement, cost-effectiveness outcomes in practice and over time are likely to differ from assessments based on controlled trial settings. Indeed, it is virtually impossible to conclude that a particular technology will *always* be cost effective or, for that matter, not cost effective — this will depend on who is receiving it and the cost effectiveness of available alternative treatments.

There is evidence that some technologies are not being used as cost effectively as they might. In some cases, this is because they are supplied to low-risk groups or used inappropriately, in others, because they are being under-used by some patient groups with apparent clinical need. There is also evidence that some technologies diffuse into practice without assessment and with little known about their cost effectiveness.

In some cases, side effects may emerge over time, diminishing benefits. The cost effectiveness of many technologies will also depend on the quality and availability of complementary inputs, including the skills of doctors. Cost-effectiveness measures of some technologies might also be affected by a constrained choice of alternative treatments — for example, it has been suggested that SSRI therapy may be less cost effective for some patients than cognitive behavioural therapy but the latter is not subsidised.

On the other hand, simply because the estimated cost per QALY is high for some new technologies (such as DES or Herceptin treatment of metastatic breast cancer), does not mean that curtailment of their use would necessarily increase social benefits:

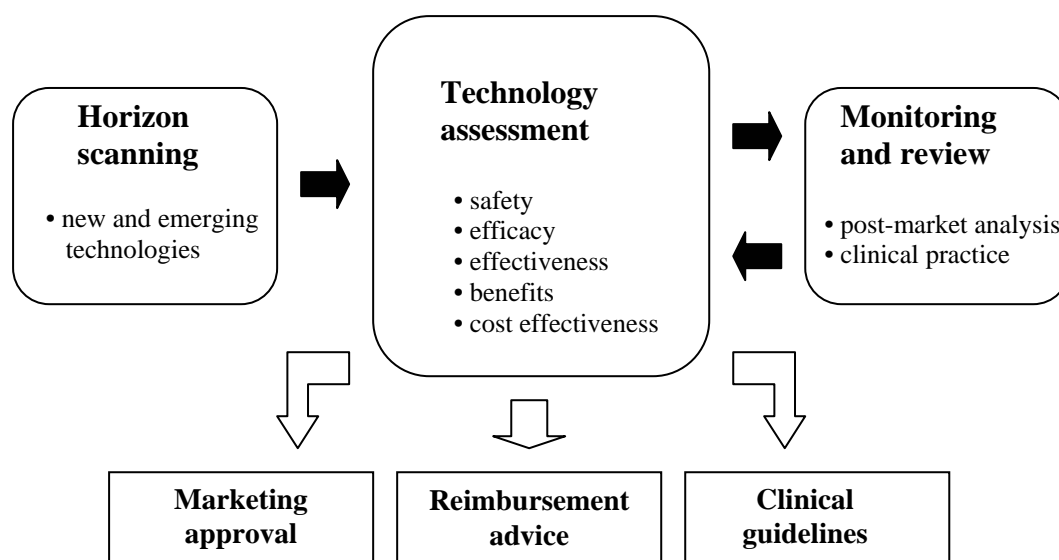
- Measuring benefits is inherently subjective and some aspects of health improvements (for example, shorter recovery time, greater convenience or ability to work) may not be fully accounted for in summary health measures. The community may also value life-saving treatments more highly than those that improve quality of life, especially where no alternative treatments are available. Measuring the benefits of improved diagnostic technologies is difficult because health outcomes depend on access to appropriate treatment.
- It is quite possible, even probable, that cost-effectiveness ratios of many new technologies will improve over time as the technology is refined and as clinicians develop their skills and techniques. For many procedures,

development can only occur ‘on-the-job’. Further, for many drugs and devices, competition will induce prices to fall over time. New diagnostic technologies may spur the development of effective treatments.

6 Health technology assessment: scope to do better

HTA encompasses processes and mechanisms to assess efficacy and cost effectiveness in health service delivery (figure 8). It is a very important mechanism for informing and guiding decisions of patients, practitioners, hospitals and other purchasers of technology, as well as informing governments and health insurers about appropriate levels of reimbursement for technological advances.

Figure 8 **Stylised process of health technology assessment**



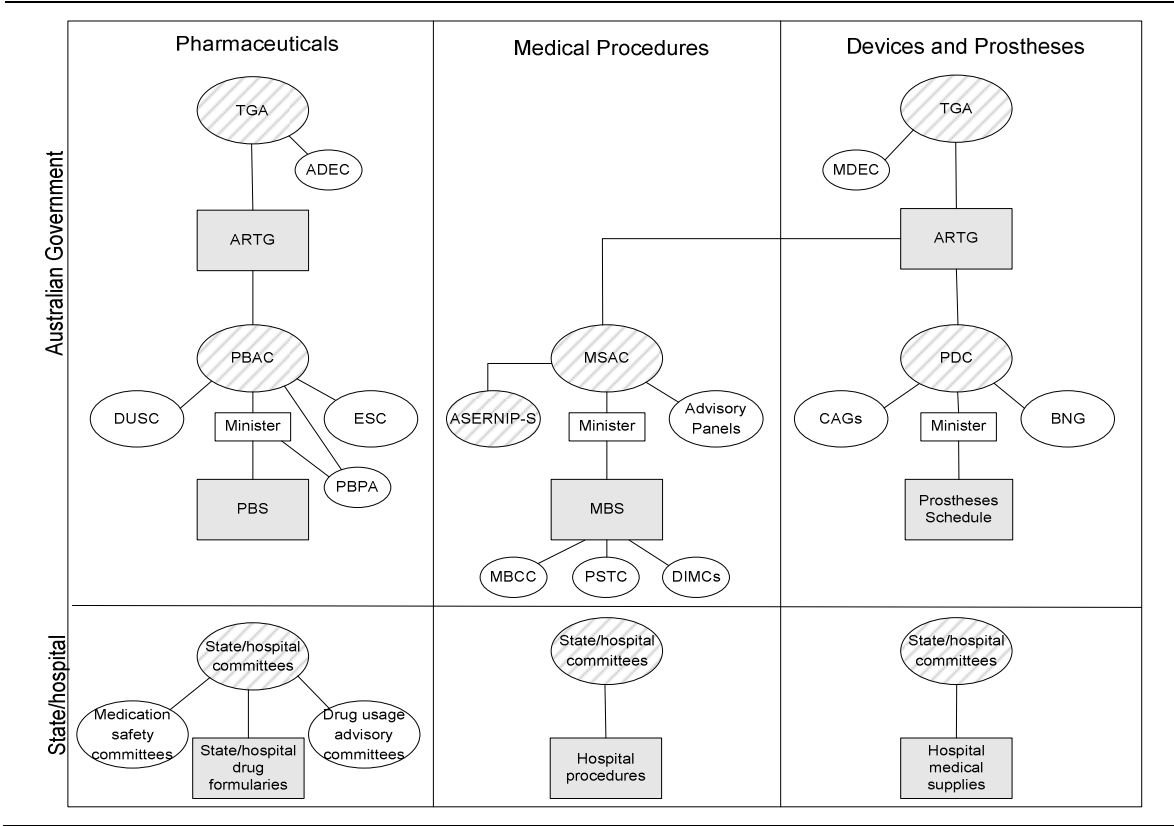
For this study, the Commission has been asked to identify gaps in HTA processes, begging the question of what is a ‘gap’? In the Commission’s view, the principal criterion for identifying a gap should be where improved HTA processes could efficiently facilitate the socially-optimal use of medical technologies.

In other words, the limitations and costs of HTA itself (including the potential cost of delaying the introduction of the technology to the Australian community), as well as the potential benefits, have to be considered. Full assessment of every technology regardless of the cost and delay would not be desirable.

With this criterion in mind, and drawing on international experience, there are several areas where there may be scope for improvement:

- Existing HTA processes are quite sophisticated compared with international counterparts, but they are complex (figure 9). In part, this complexity reflects overlapping responsibilities of different levels of government and, in part, different assessment processes and skill requirements for different categories of technology. Arguably, it also reflects development of HTA in reaction to rapid technological developments which have placed pressure on healthcare budgets. While there are differences between types of technology that may warrant different assessment processes and expertise, there appears to be scope for a more coordinated and systematic approach across the public and private sectors and across levels of government. A system-wide review looking at overlaps and opportunities for greater efficiency would seem to have merit.
- Also, in the future, the existing ‘silo’ approach to assessment may inhibit efficient assessment of emerging converging technologies, including targeted therapies that combine screening, diagnosis and treatment, and drugs and device combinations.

Figure 9 Just some of the HTA agencies and committees in Australia



- Cost-effectiveness assessment of medical devices and prostheses is not as well developed as for pharmaceuticals and medical procedures.

-
- There is no systematic, prioritised process for reviewing efficacy and cost effectiveness of new technologies once they are in use. Post-release monitoring and reviews can allow conditional introduction of new technologies and may be particularly suited to assessment of new medical procedures and devices as well as new biological drugs.
 - There is no national, coordinated approach for development of clinical guidelines based on cost-effectiveness assessment, to inform decisions by clinicians or, indeed, their patients.
 - There seems to be potential for greater use of overseas efficacy, effectiveness and, to some degree, cost-effectiveness analysis and related clinical guidelines. This seems particularly relevant considering the relatively small size of the Australian health budget in a global context and bearing in mind that most medical technology is imported. While there are cross-country differences (including costs, prevailing treatment regimes and patient profiles), this seems unlikely to justify in all cases the apparent strong preference for Australian trial data, especially given the delays and additional costs this entails.
 - It is important that HTA is used to encourage optimal purchasing and use of technology, not simply to restrain expenditure. Transparent processes and decision making and community consultation could promote acceptance of the analysis and decisions guiding the level of subsidised access, and avoid claims that HTA is merely being used as a tool for controlling spending by governments or particular institutions.
 - Increased use of information and communications technology (ICT) has the potential to improve access to health services (for example, via telemedicine), to improve health outcomes (via improved hospital management systems and, hence, fewer errors), to reduce supply costs (by improving administrative systems), and to improve data collection, analysis and monitoring. However, some ICT initiatives costing millions of dollars are being introduced with little prior assessment or ongoing evaluation. Introduction of costly ICT systems should be based on sound evaluation and good process.

These are very ‘broad brush’ findings. A comprehensive review of HTA arrangements would be required to formulate detailed recommendations for change. In some areas, changes are already underway — for example, the Pharmaceutical Benefits Advisory Committee (PBAC) processes will be made more transparent under the Australia–United States Free Trade Agreement, and there are some moves to improve coordination of HTA across technologies and jurisdictions.

7 What does the future hold?

The Commission is asked to identify likely future impacts over the next ten years. Because many heralded advances in medical technology are in the early development stage and are unlikely to have significant clinical impact within that timeframe, the study has also looked beyond ten years where relevant information is available.

On past experience, whatever anybody predicts about future technology is likely to be wrong. That said, there are some broad themes emerging from current research and development including:

- genomics research has the potential to provide a revolutionary set of tools for tackling disease, such as the development of biological treatments;
- increased targeting or ‘personalisation’ of medicine linked to the development of biological therapies;
- convergence of technologies such as drugs and devices (DES are an example), and blurring of the distinction between techniques traditionally used for diagnosis and for delivering treatment will continue; and
- the prospect of significant developments in the treatment of the major diseases of ageing (cancers, diabetes, dementia and arthritis), which are expected to impose the greatest disease burdens in future (table 1). It is no coincidence that the majority of new drugs in the pipeline are aimed at these major diseases (table 2).

Table 1 Victorian Government estimates of the top 10 disease burdens
Victoria — past and projected

<i>Males</i>	<i>Rank 2016</i>	<i>Rank 1996</i>	<i>Females</i>	<i>Rank 2016</i>	<i>Rank 1996</i>
Ischaemic heart disease	1	1	Dementia	1	4
Diabetes mellitus	2	5	Ischaemic heart disease	2	1
Prostate cancer	3	8	Breast cancer	3	3
Lung cancer	4	3	Depression	4	5
Dementia	5	11	Lung cancer	5	11
Heroin dependence & poly drug use	6	16	Chronic obstructive pulmonary disease	6	6
Hearing loss	7	12	Osteoarthritis	7	7
Bowel cancer	8	6	Diabetes mellitus	8	8
Depression	9	7	Stroke	9	2
Stroke	10	2	Bowel cancer	10	10

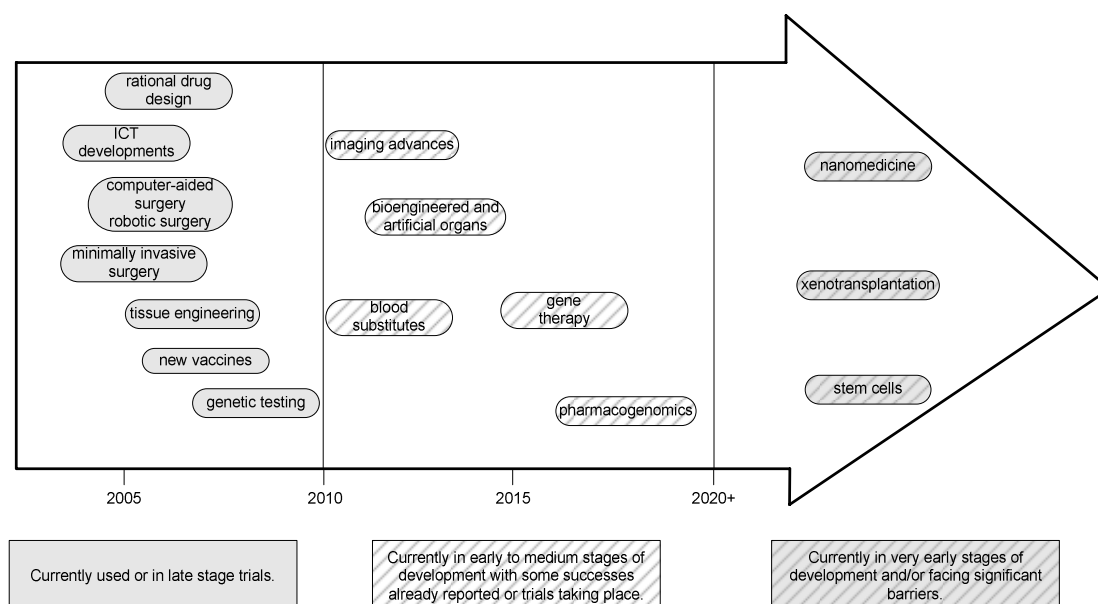
Examples of some emerging technologies are outlined in box 7. Many of these technologies have already started to appear in the marketplace (biological drugs such as Enbrel for arthritis, robotic surgery for prostate and heart surgery, and

genetic screening for breast cancer), though are not yet broadly applied. Others, such as gene therapy and nanomedicine, appear to be somewhat further away from introduction but, nonetheless, could have far-reaching effects (figure 10). Many of these tools aim to treat the same diseases — thus, they will compete in the marketplace and some will supersede others. If they are successful in overcoming the huge hurdles to get to the marketplace (including, in some cases, complex ethical issues), some of these technologies could have substantial impacts on the projected major disease burdens.

Table 2 Pharmaceuticals in the international ‘pipeline’, by condition
November 2004

<i>Condition</i>	<i>Clinical trials</i>			<i>US FDA application</i>	<i>Other</i>	<i>Total</i>
	<i>Phase I</i>	<i>Phase II</i>	<i>Phase III</i>			
Cancer	56	122	62	4	1	245
Arthritis	24	27	17	9	4	81
Cardiovascular	18	35	20	0	2	75
Diabetes	18	20	9	6	3	56
Mental health	9	16	12	6	3	46
Asthma	8	20	4	5	1	38
Injury prevention	1	0	3	0	0	4
Total	134	240	127	30	14	545

Figure 10 Medical advances — what does the future hold?



However, the broad consensus is that like recent medical advances, they will increase expenditure rather than reduce it. This is because many new technologies are likely to:

- be expensive to develop, gain approvals for and produce (such as biological medicines);
- be effective in treating diseases that are currently untreatable; and
- entail ongoing treatment of chronic conditions for people who will live longer.

They are also likely to require development of new skills (such as, robotic surgery) and entail changes in the delivery of healthcare and, hence, the workforce structure.

Box 7 Some future advances in medical technology

- **Rational drug design** — computer search techniques could reduce the trial and error of random search for identifying likely drug candidates.
- **Imaging and diagnostic advances** — will likely expand the range of diseases that can be detected using imaging techniques. Advances in miniaturisation of imaging devices could improve portability. There may be a reduced need for surgery to examine the structure and function of organs.
- **Minimally invasive surgery, robotics and virtual surgery** — particularly for neurological and coronary procedures.
- **Genetic testing, gene therapy and pharmacogenomics** — testing could allow identification of genetic susceptibility to diseases and more effective, targeted use of pharmaceuticals (pharmacogenetics); gene therapy could correct the genetic cause of the disease rather than treating the symptoms.
- **New vaccines** — could prevent cancers and may also offer less intrusive and costly ways to treat some cancers by stimulating patients' own immune systems.
- **Xenotransplantation and bioengineered organ, joint or tissue replacement** — in theory, xenotransplantation (from non-human species) could provide an increased supply of organs for transplantation; biomaterials have been used to improve artificial joints; and there has been progress in creating more complex organs, such as artificial pancreas and artificial hearts.
- **Stem cell therapies** — could be based on adult or embryonic stem cells and possibly used to patch damaged hearts, restore pancreatic function in diabetes patients and to treat patients with Parkinson's Disease.
- **Nanotechnologies and nanomedicine** — involve the production and application of materials at an atomic scale. Nanodevices could deliver medicines directly to the site of the body in need and reduce required dosages.
- **Information and communications technology** — even current ICT could be applied to improve healthcare administration and delivery, with appropriate system redesign of management practices.

There are some forces pulling in the other direction — for example, improved targeting of treatments (potentially reducing ‘leakage’), and the prospect of successful prevention of, or cures for, some chronic conditions that currently involve costly management, could reduce future healthcare spending. Application of ICT to health systems and healthcare delivery also has the potential to improve both productivity and health outcomes (including from improved accessibility) in the longer term, but initial outlays could be substantial.

8 Summing up ...

Advances in medical technology can bring both large benefits and increased outlays. Increased spending — by governments, insurers or individuals — is not necessarily a problem. The critical issue is whether the additional benefits outweigh the costs.

The weight of evidence suggests that advances in medical technology over the past ten years, in the aggregate, have increased private and government expenditure, though other factors such as income, population growth and community expectations have also been important. In most cases, increased expenditure on medical technology is reflecting improved treatments resulting in longer and/or better quality of life for more people. This trend is likely to continue.

While the benefits of many advances in medical technology also appear to be large — especially given the high value people place on preserving or improving their health — it is not possible to say *precisely* what impact advances in medical technology have had on the overall cost effectiveness of the health system. That said, advances in medical technology arguably have provided value for money overall, although the estimated cost effectiveness of individual technologies varies widely in practice and, in some cases, is unknown.

Evidence that some technologies are not being used as cost effectively as they might, and a lack of any evidence about the cost effectiveness of others, suggest that there may be room for better targeting of some technologies to improve net social benefits.

... and some future policy challenges

The next decade or so could see the emergence of what can be described as revolutionary technological advances based largely on knowledge of the human genome. Many of these are expected to provide significant benefits to the Australian community, but at significant cost.

Advances in medical technology, interacting with (and encouraged by) growing demands for health services driven by an acceleration in the average age of the population, as well as income growth, strong community expectations that new technologies should be accessible to all, and medical practitioners' desire to offer the best treatment to their patients, will make for a potent mix. This will place increasing pressures on both the private and public health systems.

These pressures underscore the need for more systematic technology assessment to facilitate evidence and needs based access. Addressing existing gaps and improving HTA processes, underpinned by the principle of enhancing overall community wellbeing, could identify, facilitate access to and use of beneficial technologies, especially compared with alternative rationing mechanisms that are not evidence based. In particular:

- There appears to be scope for a more coordinated and systematic approach to HTA across the public and private sectors and across levels of government, as well as more systematic reviews of efficacy and cost effectiveness of new technologies once they are in use.
- Greater procedural transparency and community involvement in HTA processes has the potential to foster greater acceptance of technology funding decisions and to improve those decisions so that they promote community wellbeing.

However, technology is only one input in healthcare and HTA is not a panacea. Concerns about technology use often reflect broader structural, incentive and resourcing problems in Australia's healthcare system. For instance, under a regime of continued universal access to most healthcare, where incentives to use technology are divorced from the need to pay for it, advances in medical technology will perpetuate tensions between community expectations and demands and budgetary priorities.

So although better evidence of the relative cost effectiveness of technologies has the potential to facilitate improved health outcomes by informing purchasing and funding decisions by governments, hospitals, medical practitioners and individuals, appropriate *use* of technology ultimately depends on the incentives facing consumers, clinicians and those funding purchases of technology, and the availability of medical professionals and other inputs. If public hospitals, for

example, are driven by annual budget constraints, they may have little incentive to purchase more broadly cost-effective technologies that reduce costs elsewhere in the health system, and which have long-term pay-offs for the community. If the supply of medical professionals is constrained, so too will be access to new technologies.

In the Commission's view, there is a pressing need to explore the institutional and incentive structures that will deliver most efficiently what the community considers is acceptable and appropriate access to new healthcare technology.

Findings

Chapter 2 The market for medical technology

FINDING 2.1

There are a number of drivers of demand for advances in medical technology. Key drivers are income growth, community expectations, population ageing, disease prevalence, the desire of and incentives facing medical practitioners to provide what they consider to be the best-available treatments, combined with limited consumer price signals.

The use of medical technology will reflect both the demand for and supply of medical technology, including the impact of constraints imposed by regulations and rationing mechanisms, such as budget constraints and waiting periods and any restrictions on the availability of skilled labour and other complementary inputs.

FINDING 2.2

The supply of medical technology does not take place in a vacuum. As in any commercial market, private R&D medical technology investment undertaken by 'for-profit' organisations largely responds to potential demand and profit expectations and is influenced by funding and insurance arrangements and regulation.

Advances in medical technology increasingly are being aimed at diseases of ageing (for example, cancers, dementia, arthritis) and diseases associated with lifestyle (for example, obesity-related diseases such as cardiovascular illnesses and diabetes).

Chapter 3 Aggregate impact of medical technology on expenditure

FINDING 3.1

The Commission's modelling provides support for the proposition that advances in medical technology have been a major driver of the growth in real healthcare expenditure over the past ten years. Advances in technology are estimated to have contributed about one-third of the average annual growth in real health expenditure

over the period. Other important contributors to the increase in health expenditure include population and income growth and, to a lesser extent, past ageing of the population and rising private health insurance coverage.

Chapter 4 Individual technology expenditure impacts

FINDING 4.1

Technological advances have played an important role in increasing expenditure on pharmaceuticals and inpatient care:

- *For pharmaceuticals, direct expenditure has increased due to the higher unit cost of new drugs and increases in the number of patients treated.*
- *For inpatient care, expenditure growth has been driven by increases in the average cost of treatment fuelled in part by the adoption of expensive new technologies.*
- *New technologies have had offsetting effects on hospital separations:*
 - *for some diseases, improved pharmaceuticals have reduced the need for hospitalisation; and*
 - *less invasive and more effective procedures and improved anaesthetics have led to increased separations for some conditions, but have also reduced the length of hospital stays.*

FINDING 4.2

Analysis of the expenditure impacts of some of the major advances in medical technology over the past decade suggests that most have increased net health expenditure:

- *For some, the expenditure impact has been unambiguous because they have higher unit costs; complement or add to the existing mix of technologies; or treat an entirely new disease.*
- *Others have reduced unit treatment costs or have generated offsetting savings elsewhere in the health system, but have often facilitated significant increases in the volume of treatment.*

FINDING 4.3

The division of funding responsibilities in the health sector influences expenditure on new technologies:

- *The technology choices of individual public agencies and institutions are often constrained by short-term budget caps. Hence, they have little incentive or*

ability to take into account the impacts of their treatment choices on either their own future spending or on consequent expenditure in other parts of the health system.

- *This creates a bias toward technologies that produce short-term cost savings in particular parts of the health system, possibly at the expense of technologies that are more cost effective but have higher upfront costs.*

FINDING 4.4

Increases in the proportion of patients using private hospitals (reflecting in part increased private health insurance coverage), combined with regulatory restrictions on gap payments for prostheses, have increased spending on medical technologies by inducing faster diffusion of more advanced and expensive technologies and apparently higher unit prices in the private sector. Diffusion in the private sector appears to place pressure on public hospitals to adopt the technology.

Chapter 5 Benefits of advances in medical technology

FINDING 5.1

Although it is not possible to quantify and attribute benefits in overall terms, the available evidence suggests that specific advances in medical technology have delivered substantial benefits across a range of areas in the past decade. They appear to have contributed to improved health status, observed increases in longevity and improved wellbeing.

Chapter 6 Distribution of the benefits of new medical technology

FINDING 6.1

The Commission found evidence that rates of use of some medical technologies were lower for Australians living in more socioeconomically disadvantaged areas (particularly the elderly in these areas), those residing in rural and remote areas, males, and Indigenous people. The reasons for this are complex and relate to both the demand for and supply of technology and healthcare more generally. Unequal use may be accentuated, at least initially, as new higher-cost technologies are introduced.

Chapter 7 Cost effectiveness of advances in medical technology

FINDING 7.1

While it is not possible to establish with precision the overall net benefits of new technologies or their net impact on the overall cost effectiveness of the healthcare system, arguably they have provided value for money, particularly given the high value people place on maintaining good health.

But the cost effectiveness of particular technologies varies widely and is highly sensitive to use of the technology — some technologies range from being highly cost effective for some patient groups but not for others compared with available alternative therapies. The cost effectiveness of some technologies in use in Australia is unknown. Evidence suggests that there may be scope to improve net social benefits from advances in medical technology through better targeting of those technologies.

Chapter 8 Health technology assessment in Australia: an overview

FINDING 8.1

Existing horizon scanning units in Australia — in contrast to practices in a number of overseas countries — do not cover new and emerging pharmaceuticals (including drugs, vaccines and blood products).

FINDING 8.2

Australia's health technology assessment (HTA) effort is fragmented along jurisdictional (national and State/Territory) and sectoral (public and private) lines. Complexity and duplication also reflects ad hoc development of HTA in reaction to technological advances and the budgetary pressures they have brought. This has led to apparently inefficient duplication of HTA effort and fragmented diffusion of knowledge and experience, creating unnecessary additional costs and delays.

While recognising the need for some flexibility in the application of HTA at the State/Territory and individual institutional level, there is potential for a more coordinated approach to assessing and sharing information about new technologies. A system-wide review looking at overlaps and opportunities for greater efficiency would seem to have merit. There would appear to be significant benefits available from adopting an over-arching framework for coordinating HTA activities at a national level.

FINDING 8.3

Where HTA is undertaken by organisations that also have expenditure responsibilities, this may lead to tensions between different objectives: that is, between facilitating optimal use of medical technology and controlling health expenditure.

FINDING 8.4

The level of information disclosure by the Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Advisory Committee (PBAC) regarding drug evaluations generally has been poor compared with some processes overseas and accepted good regulatory practice. Improved disclosure by PBAC is expected to result from new arrangements under the Australia–United States Free Trade Agreement.

While MSAC is somewhat more transparent than PBAC, MSAC tends to disclose information only when the assessment process has been completed.

FINDING 8.5

A stated intent of restrictions on Pharmaceutical Benefits Scheme (PBS)-listed items is to improve cost effectiveness based on clinical grounds. However, as the deliberations of PBAC are not public, it is difficult to determine whether it has imposed restrictions on certain drugs purely for fiscal reasons.

FINDING 8.6

Unlike some overseas HTA processes, Australian drug approval processes — including the Australian Drug Evaluation Committee (ADEC) and PBAC — currently provide little opportunity for consultation with patient groups or the general public. ADEC also lacks a consumer representative.

The Medical Services Advisory Committee (MSAC) assessment process, like the PBAC process, allows little opportunity for consultation with patient groups or the general public.

FINDING 8.7

As different HTA agencies and committees examine particular types of medical technology, conducting effective HTA of combined technologies (such as new drug/device combinations and targeted therapies combining diagnosis and treatment) can pose challenges and lead to delays. With greater technology convergence expected in future, coordination difficulties and delays are likely to be magnified.

FINDING 8.8

There appears to be no systematic national process for the development of clinical practice guidelines linked to HTA processes and cost-effectiveness assessment.

Chapter 9 Health technology assessment: pharmaceuticals

FINDING 9.1

PBAC does not assess all medicines used in hospital settings for clinical and cost effectiveness. This has led to duplication of HTA effort across and within States.

FINDING 9.2

While validation of surrogate indicators is clearly important, it can add to the costs and duration of the HTA process with the potential to delay the introduction of some beneficial drugs. Where drugs hold significant promise of being cost effective, they could be listed on the PBS on the condition that special post-market monitoring of cost effectiveness be undertaken over a defined period.

FINDING 9.3

The extent to which PBAC takes into account potential indirect benefits of medicines, such as hospital or aged care cost savings or the ability of patients to return to work, is unclear. While a lack of hard and relevant data and methodological issues complicate measurement of these impacts, discounting them on the grounds that unrealised savings should not be counted (because freed up hospital beds are used for other patients), or that any individual can be withdrawn from and replaced in the workforce without cost, is misconceived.

FINDING 9.4

Where the choice of discount rate heavily influences the results of an economic evaluation, there is a strong argument (accepted in several other countries) for considering sensitivity analysis using a range of discount rates. This analysis would be in addition to the base case using the discount rate recommended by PBAC.

FINDING 9.5

Although mutual recognition has the potential to fast-track drug approval by the TGA, there has been limited use of these processes. While transferring pharmacoeconomic evaluations across countries is likely to be difficult, there are strategies available to facilitate the transfer of clinical evidence.

The appropriate use of overseas clinical studies potentially could generate resource savings and accelerate the preparation of submissions to the TGA and PBAC.

FINDING 9.6

The use of a fixed dollar threshold that is not periodically adjusted for the effects of inflation, is likely to see a greater number of drugs being considered by Cabinet, possibly creating delays in the PBS-listing process and limiting transparency of decision making.

FINDING 9.7

A major risk with governments at times bypassing existing HTA processes is that it may lead to a proliferation of different programs which could result in funding inconsistencies, additional administrative costs, and limit transparency of decision making.

FINDING 9.8

Once pharmaceuticals are listed on the PBS, there appears to be no systematic process for monitoring and re-assessing their clinical and cost effectiveness by PBAC. This represents an opportunity for improving existing processes.

Chapter 10 Health technology assessment: procedures, devices & ICT

FINDING 10.1

Some new medical technologies deemed to fit under existing Medicare Benefits Schedule (MBS) codes may not have been assessed or have been assessed only after significant diffusion has occurred.

FINDING 10.2

The use of formal economic evaluation, such as cost-effectiveness analysis, is hampered by the generally weaker clinical evidence base that exists for medical procedures and devices, compared with that for pharmaceuticals. MSAC may commission further work in order to assess new technologies more fully.

FINDING 10.3

The MSAC assessment process appears lengthy, taking 13–15 months on average to complete evaluations. This may reflect the fact that MSAC assesses the safety as well as cost effectiveness of new medical procedures and some devices, and that it may need to commission further analysis if applications do not provide sufficient information.

FINDING 10.4

An overseas economic assessment of medical procedures is unlikely to obviate the need for an economic evaluation that incorporates Australian factors and conditions. That said, it may be possible to use overseas clinical studies and experience — with appropriate adjustments — as a basis for preparing Australian economic evaluations.

FINDING 10.5

Prior to the introduction of the Prostheses Act, medical devices and prostheses were subject to little, if any, assessment or re-assessment of their clinical or cost effectiveness.

Unlike PBAC and MSAC, a major focus of the new Prostheses and Devices Committee will be relative clinical efficacy rather than cost effectiveness. There appears to be greater scope for prostheses and devices to be assessed for cost effectiveness, bearing in mind that evaluation methods may need to differ from those applying to pharmaceuticals and medical procedures.

FINDING 10.6

Despite significant investment in health information and communications technology (ICT) projects at the State/Territory and national levels, and the potentially substantial benefits that appropriate use of ICT offers, these activities largely have been uncoordinated — for example, as evidenced by major interoperability problems between different sectors of healthcare. Moreover, the level and quality of project evaluation generally have been poor. ICT in healthcare represents a significant opportunity but also a significant challenge. It is far from clear that current and past approaches will ensure a good return for the substantial investments being made.

FINDING 10.7

Once listed on the MBS, medical procedures are not subject to systematic re-assessment of their clinical or cost effectiveness. While MSAC can undertake such re-assessments, its ability to do so is limited by its resources and by the types of reference it receives.

Appropriate monitoring and review processes could help to improve the overall cost effectiveness of medical technologies on the MBS and Prostheses Schedule. Such processes could facilitate the conditional introduction of new procedures and devices where evidence of cost effectiveness only becomes available over time.

Chapter 11 Future advances in medical technology

FINDING 11.1

New medical technologies in the pipeline have the potential to revolutionise the practice of medicine over the next 10 to 20 years. Significant benefits to the community could be delivered through the development of biological and targeted treatments, convergence of different types of technologies and application of new technologies to treat chronic diseases.

FINDING 11.2

New medical technologies in the pipeline are likely to have high unit costs and potentially wide application. When combined with significant demand pressures arising from higher incomes, an ageing population and increasing community expectations, these technologies have the potential to significantly increase health expenditure by governments, insurers and the wider community.

FINDING 11.3

ICT developments have significant capacity to improve health outcomes in their own right, or by providing architecture for the development and diffusion of other medical technologies and more efficient and safer delivery of health services through greater connectivity. Realising this potential will require better upfront assessment, planning, coordination and more investment.

1 Introduction

1.1 About this study

The Australian Government commissioned the Productivity Commission to undertake a research study detailing the impact of advances in medical technology on public and private healthcare expenditure, and the associated costs and benefits for the Australian community. The study was designed to:

... assist governments and other health sector stakeholders by improving the level of understanding about the relationship between advances in medical technology, health outcomes and health expenditures. (Cameron 2004)

The Commission was required to report within 12 months of receipt of the terms of reference, that is, by 31 August 2005.

Specifically, the Commission was asked to:

- Identify the key drivers of medical technology demand.
- Identify the net impact of advances in medical technology on healthcare expenditure over the past ten years.
- As far as practicable, identify the likely impact of advances in medical technology on healthcare expenditure over the next five to ten years, and identify the areas of significant potential growth.
- Identify existing mechanisms and processes for ensuring cost-effectiveness in the use of medical technology, and any gaps in these processes.
- Examine the impact of changes in medical technology on the distribution of costs and financial incentives across different parts of the health system, including whether advances in one technology area result in reduced costs in others.
- Investigate the net impact of advances in overall and individual health technologies on:
 - economic, social and health outcomes, including exploring which demographic groups are benefiting from advances in health technology; and
 - the overall cost effectiveness of healthcare delivery.

In examining these matters, the Commission was to have regard to:

- recent substantive studies undertaken elsewhere;

- international experience in ensuring cost effectiveness of health care;
- the established economic, social, health and environmental objectives of the Government; and
- community expectations of appropriate healthcare provision.

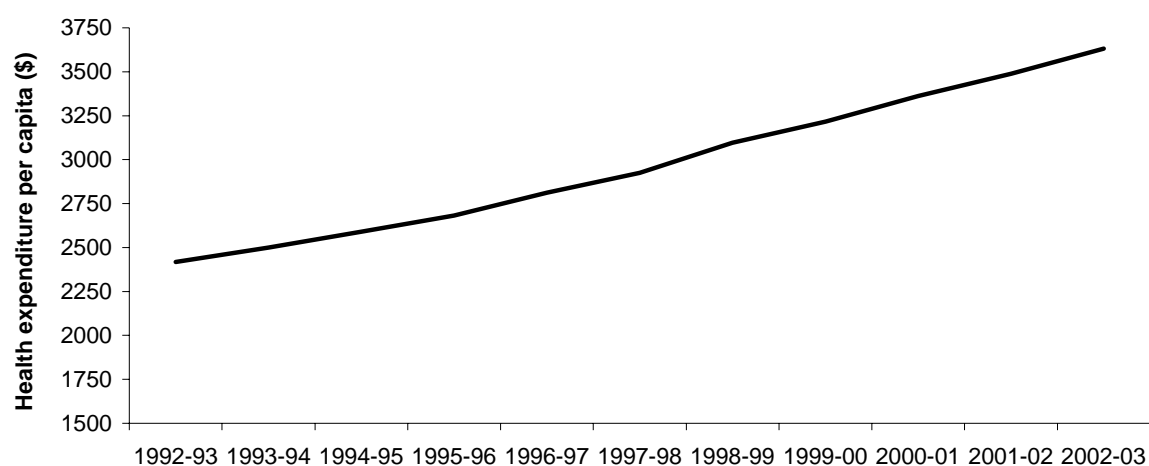
The terms of reference are reprinted in full at the beginning of this report.

1.2 Background to the study

Recent years have brought major advances in medical technology in screening and diagnostics, in preventative medicines such as cholesterol and hypertension reducing drugs, and in new procedures and devices such as coronary stents, minimally-invasive surgical procedures and hip and knee replacement.

At the same time, real expenditure on health has risen significantly — by around 50 per cent between 1992-93 and 2002-03 on a per capita basis (figure 1.1).

Figure 1.1 Real health expenditure per capita, 1992-93 to 2002-03
2002-03 prices



Data sources: ABS (2004b, 2004c); AIHW (2004d).

Health expenditure expressed as a proportion of Gross Domestic Product (GDP) reached 9.5 per cent in 2002, compared with 8.2 per cent in 1992. This is somewhat higher than the average for industrialised countries — the OECD average in 2002 was 8.4 per cent — and has risen faster than in most other countries (table 1.1). Growth in expenditure on pharmaceuticals in Australia has been particularly pronounced — by rising by around 9 per cent per year in real terms over the last decade (see chapter 4, figure 4.1).

Table 1.1 Health expenditure in selected OECD countries
Share of GDP

<i>Country</i>	<i>1992</i>	<i>2002</i>	<i>1992–2002</i>
	<i>% GDP</i>	<i>% GDP</i>	<i>% change</i>
Australia	8.2	9.5	15.9
Canada	10.0	9.6	-4.0
Finland	9.1	7.3	-19.8
France	9.0	9.7	7.8
Germany	9.9	10.9	10.1
Ireland	7.1	7.3	2.8
Italy	8.4	8.5	1.2
Japan	6.2	7.8	25.8
Netherlands	8.4	9.1	8.3
New Zealand	7.5	8.5	13.3
Norway	8.2	8.7	6.1
Sweden	8.3	9.2	10.8
Switzerland	9.3	11.2	20.4
United Kingdom	6.9	7.7	11.6
United States	13.0	14.6	12.3
OECD average	7.7	8.4	9.1

Source: AIHW (2004d).

There are concerns that these trends will continue, even accelerate, especially with ageing of the population and emerging advances in medical technology. The study of genomics is one such area that is likely to provide a new set of tools and approaches for tackling disease, such as the development of ‘biological’ medicines and treatments such as gene and stem cell therapies.

Advances in medical technology are frequently cited as a major, if not *the* major, cause of increased health expenditures and consequent pressure on government budgets. For example, the *Intergenerational Report 2002-03* concluded that growth attributable to non-demographic factors had been the key driver of real health spending by governments over the past decade, with technological change accounting for a significant proportion of this. Moreover, it was observed that: ‘non-demographic factors (such as listing new medications on the Pharmaceutical Benefits Scheme (PBS) and greater use of diagnostic procedures) are likely to generate the greatest cost pressure in the future’ (CoA 2002, p. 35).

The Commission’s study into the economic implications of an ageing population likewise projects that non-demographic factors, and technological advances in particular, together with population ageing, will continue to drive increased government health expenditure (box 1.1).

Box 1.1 Productivity Commission study into the economic implications of an ageing Australia

The study projects that government health expenditure as a proportion of GDP will increase from 5.7 per cent in 2002-03 to 10.3 per cent by 2044-45, based on the assumption that future expenditure will be conditioned by past trends and patterns.

Pharmaceutical expenditure is projected to increase by the largest relative amount, with the contribution of hospital expenditure expected to fall slightly. Other expenditure components are expected to maintain broadly stable shares of expenditure.

Anticipated ageing of the population is expected to increase projected government health spending by 25 per cent by 2044-45.

Source: PC (2005a).

Of course, even if advances in medical technology drive increased healthcare expenditure, the question then is whether the benefits outweigh the costs. Generally speaking, in competitive markets and in the absence of significant ‘spillover’ effects which indirectly affect others not party to the transaction, increased expenditure on technological advances can be presumed to deliver net private and social benefits. This is because consumers are assumed to know what is good for them. As a general rule, they buy goods and services only when the benefits outweigh, or at least equal, the costs incurred. In other words, consumers make purchases when they consider that they are obtaining ‘value for money’.

The market for healthcare is different. As discussed below, the direct purchase of healthcare in Australia is often undertaken by third parties (governments, hospitals and private insurers) rather than consumers of services. In addition, there are significant information asymmetries in the provision of healthcare. For this reason, patients typically rely on the knowledge and expertise of medical professionals. Even medical professionals may lack adequate information about the effectiveness of new technologies. This combination of a lack of information and the fact that patients generally do not pay directly for the full cost of the health services they consume, means that they have little ability or incentive to weigh the costs of advances in medical technology against the benefits.

In the absence of normal market ‘tests’ to ensure value for money, other allocation or rationing mechanisms will come into play, either by default or design. Governments and other providers may simply ration access to healthcare through a combination of budget constraints and ‘queuing’. Alternatively, they may facilitate evidence-based prioritised treatment by assessing clinical and/or cost effectiveness of technologies to promote ‘value for money’.

Against this background, this study is asked to shed some light on the questions of whether medical technology has delivered value for money in Australia and whether its use could be improved upon. How medical technology interacts with the Australian healthcare system is described briefly in the next section.

1.3 Medical technology and the Australian healthcare system

Decisions to use advances in medical technology are often divorced from the need to pay for it. Although direct out-of-pocket payments by individuals at the point of service delivery have increased as a proportion of total health spending, they still account for only around one-fifth of the total. (Of course, the community ultimately pays for all healthcare through general taxation, the Medicare levy, private health insurance premiums and compulsory third-party motor vehicle insurance premiums.)

Responsibility for funding the remaining 80 per cent of healthcare expenditure, including spending on medical technologies, is spread across different levels of government and private and public institutions:

- The Australian Government funds around 46 per cent of all healthcare expenditure. It directly subsidises access to both pharmaceuticals through the PBS and medical services (including procedures, diagnostics and pathology) through the Medicare Benefits Scheme (MBS). It also directly funds some high-cost drugs and other technologies for use in public hospitals. In addition, it provides funds to State and Territory Governments for the provision of public hospital services and provides a rebate equal to 30 per cent of private health insurance premiums.
- State and Territory Governments fund about 22 per cent of healthcare spending and are primarily responsible for providing public hospital services. Public hospitals provide free access to medical technologies such as surgical procedures and medical devices and prostheses.
- Private health insurers reimburse most hospital expenses (including the costs of prostheses and medical devices) for privately-insured patients in both private and public hospitals as well as the costs of some ancillary services. Overall, private health insurers fund almost 10 per cent of total health spending.
- Workers' compensation and compulsory motor vehicle third party insurers account for about 5 per cent of health spending.

Decisions to use particular medical technologies typically are made by individual medical practitioners, often in conjunction with their patients. Although their

decisions are not usually constrained by the patient's ability to pay, access to technologies (especially subsidised technology) is influenced by a range of regulatory requirements, guidelines and budgetary constraints:

- Pharmaceuticals are listed on the PBS only after assessment of their cost effectiveness. Increasingly, access to subsidised medicines under the PBS is restricted to certain conditions or disease indications. In some cases, the aggregate subsidy level is limited by price–volume agreements with manufacturers or made conditional on achievement of agreed performance targets.
- Prior to their listing for reimbursement on the MBS, the cost effectiveness of new medical procedures is assessed by the Medical Services Advisory Committee (MSAC).
- Public hospitals influence clinician decisions particularly in regard to their treatment of public patients by restricting the availability of some technologies. In some cases, simple budget constraints apply and access is rationed by waiting; in others, access may be prioritised and guided by technology assessment undertaken within the hospital or at a State/Territory or national level.

Out-of-pocket expenses paid directly by consumers include co-payments for medicines. Users of prescription medicine who do not qualify for a concession or who do not meet safety net thresholds, pay a co-payment of up to \$28.60 per script. Concession card holders pay \$4.60 per script.¹ Patients are also required to contribute to the cost of medical services where the fee charged by the doctor exceeds the level reimbursed by government. Other major categories of out-of-pocket expense include purchases of dental services, over-the-counter medicines such as painkillers and antihistamines, complementary medicines, and prostheses and appliances such as spectacles, hearing aids, and walking frames and sticks. While part of the cost of some of these items may be covered by private health insurance, privately-insured patients may be required to pay a 'gap' for these and other insured services such as hospital treatment.

The contribution of direct, out-of-pocket expenditure to total health spending increased from about one-sixth in 1992-93 to one-fifth in 2002-03, with annual average real growth of around 5 per cent per year over this period. More recently, annual average growth has reached around 8 per cent, largely reflecting increased spending on pharmaceuticals (including co-payments for PBS-listed items), dental services and aids and appliances.

¹ Co-payments were increased to these levels on 1 January 2005. In addition, concession and non-concession patients may be required to pay a 'brand premium' if a less expensive generic drug is available but not dispensed.

1.4 Scope of the study

The terms of reference for this study are wide-ranging. In contrast to both the *Intergenerational Report* (CoA 2002) and the Commission's study into the economic implications of ageing (PC 2005a), which focussed on impacts on government spending, this study is required to consider past and potential future expenditure impacts of medical technologies for both the government and private sectors, and also to assess the benefits of these technologies. In addition, the Commission is asked to identify processes for assessing advances in technology and any gaps in these processes. In short, the study is intended to help inform whether medical technology is being used in a way, and to an extent, that delivers the maximum net benefits to the community.

Defining advances in medical technology

The terms of reference define medical technology broadly to include physical equipment, instruments, pharmaceuticals, clinical procedures, knowledge and support systems within which healthcare is provided. This definition allows the Commission to explore a variety of direct and indirect impacts of advances in medical technology and, consequently, a range of technology assessment processes. That said, the breadth of the definition poses challenges. For example, the impact of advances in knowledge is virtually impossible to capture.

The Commission also has interpreted this definition to encompass general technologies that are applied in the health industry (such as information and communications technologies), as well as technologies developed specifically for applications in the healthcare sector.

Advances or innovations in medical technology are understood to encompass innovations in products (for example, new or improved pharmaceuticals) and processes (for example, new or improved surgical procedures or patient management systems).

Time horizon

The Commission was asked to identify net expenditure impacts of medical technology over the past ten years and likely future impacts over the next ten years. Because many heralded advances in medical technology are in the early development stage (for example, gene therapy and some nanotechnologies) and are unlikely to have significant clinical impact within a ten-year timeframe, the Commission has attempted to look beyond the next ten years in those cases where relevant information is available.

The market for medical technology

The terms of reference ask the Commission to identify key drivers of demand for medical technology. The Commission has also considered key drivers of supply, as well as regulatory and institutional arrangements, to build a more complete picture of the dynamics of the market for medical technology.

1.5 Conduct of the study

In accordance with its operating principles (box 1.2), the Commission encouraged and sought public participation in this study. Soon after receipt of the terms of reference, advertisements were placed in national newspapers and *The Medical Journal of Australia*. The first circular was sent to almost 600 individuals and organisations considered likely to have an interest in the study. An issues paper was released in early September 2004 to assist participants to prepare their initial submissions.

Box 1.2 Productivity Commission: operating principles

In undertaking its work, the Commission follows three fundamental operating principles:

- the provision of independent analysis and advice;
- the use of processes that are open and public; and
- to have over-arching concern for the community as a whole, rather than just the interests of any particular industry or group.

In conducting its commissioned work, the Commission facilitates transparency and consultation by seeking submissions from interested parties and by releasing draft reports to facilitate further comment and debate. Broad policy guidelines outlining how the Commission is to undertake its functions are contained in the Commission's founding legislation, the *Productivity Commission Act 1998* (Cwlth).

The Commission has held informal discussions with around 60 organisations including pharmaceutical and medical device manufacturers, medical research organisations, medical practitioners, health technology assessment (HTA) agencies, private health insurers, government agencies and departments, and health consumer organisations, to seek information and to canvass a wide range of views. Forty-one submissions were received in response to the issues paper. Another 21 submissions were received in response to the progress report, released in mid-April 2005. A roundtable (comprising 15 organisations including the Australian and some State governments, industry, clinicians, HTA agencies and healthcare consumer bodies)

was held in Melbourne on 8 July 2005 to discuss future technological advances and the implications of these for HTA.

Details of individuals and organisations visited, roundtable attendees and submissions received are provided in appendix A. All non-confidential parts of submissions are available on the Internet, at Commission and State libraries, and from Photobition Digital Imaging Centre.

Acknowledgements

The Commission engaged a consultant, Dr Susan Hurley of Bainbridge Consultants, to provide some initial assistance with case studies.

The Commission extends its thanks to Professor Hugh Taylor, Professor John McNeil, Associate Professor Richard Bell, Professor Garry Jennings, Professor Mark Cooper and Mr Simon Neil for their expert advice on aspects of various case studies.

Thanks also to Ms Rosemary Korda, National Centre for Epidemiological Research, Australian National University, who provided source material regarding distributional issues, Mr Jim Pearse for his general advice on data, and Dr Graeme Suthers, Dr Kathy Tucker, Dr Judy Kirk, Ms Mary-Anne Young and Ms Rebecca D'Souza who all provided data on genetic testing from their respective family cancer clinics.

The Commission also thanks all participants for their submissions and comments.

1.6 Report structure

This report is structured as follows:

- The market for medical technology in Australia is described in chapter 2, including an analysis of the key drivers of demand for and supply of medical technology and the impact of regulatory and institutional arrangements on the use of that technology.
- The net expenditure impacts of advances in medical technology over the past ten years are examined in chapter 3, using econometric modelling techniques to quantify the aggregate impact of medical technology. Chapter 4 considers the expenditure impact of major categories of technology and various individual technological advances.

-
- The benefits of advances in medical technologies are explored in chapter 5, including a brief discussion of methodological issues in measuring benefits.
 - Distribution of access to, and the benefits from, advances in medical technology are examined in chapter 6.
 - The impact of medical technologies on the cost effectiveness of healthcare delivery is examined in chapter 7.
 - Chapters 8, 9 and 10 explore HTA processes in Australia and identify potential gaps, with reference to overseas experience where relevant.
 - Potential future technologies and their potential costs and benefits are canvassed in chapter 11.
 - Conclusions and future policy challenges are presented in chapter 12.

Appendix B explores issues in evaluating benefits of medical technology. Appendix C summarises some overseas HTA arrangements.

Appendixes D to M bring together case studies of some advances in medical technologies, namely statins, selective serotonin reuptake inhibitors, artificial hip and knee joints, drug eluting stents, prostate specific antigen testing, Herceptin, genetic testing for breast cancer, information and communications technology and phacoemulsification and intraocular lenses for cataract surgery.

Four technical papers are available on the CD and from the Commission's website:

- Technical paper 1 provides additional details of the quantitative analysis estimating the aggregate impact of technology on past health expenditure.
- Technical paper 2 presents details of estimates of the net expenditure impacts of selected individual technologies summarised in chapter 4.
- Calculations and assumptions underlying the illustrative examples of expenditure impacts of four possible future technologies (chapter 11) are presented in technical paper 3.
- Unpublished data relevant to chapter 6 and appendixes E and M are presented in technical paper 4.

2 The market for medical technology

The terms of reference require the Commission to identify the key drivers of demand for medical technology. This chapter takes a somewhat broader perspective, discussing the demand for health services more generally, and demand and supply factors driving the use of advances in medical technology, as well as budgetary, regulatory and other external influences. The interaction of all these factors ultimately drives consumption of, and expenditure on, medical technology. Analysis of the drivers of demand for, and diffusion of advances in, medical technology also provides some insights into whether those advances are being used appropriately. Quantitative estimates of the impact of key demand and supply drivers on total health expenditure are presented in chapter 3.

2.1 Key demand drivers

People value good health and, consequently, health services that promote it. In turn, health services embody the intermediate input ‘medical technology’. Decisions to use a particular technology (once it becomes available) typically will be driven by medical practitioners, albeit increasingly influenced by the incentive structures and constraints imposed by the health system. Patients also have a role to play in the choice of technology. Accordingly, the demand for medical technologies is a ‘derived’ demand, driven both by the final demand for good health and health services by consumers and by the input decisions of doctors in conjunction with patients, all in the context of the institutional and regulatory environment.

Consumer demand for health services

The drivers of demand for any good or service are income, prices and other factors referred to as ‘tastes’ or ‘preferences’. In the case of the demand for health services, the latter catch-all category incorporates several factors, including the prevalence of disease and consumer expectations. Among other things, the prevalence of disease is a function of lifestyle and ageing. Demand for health services, and indirectly technology, is also affected by changes in expectations about levels and availability of treatment (for example, for the elderly) and changes in perceptions of what is ‘illness’ and ‘wellness’.

Income

It is generally accepted, and observed that, all else given, as incomes grow, people consume more, and better quality, health services. This relationship is evident over time and across countries. Intuitively, this makes sense because good health is prerequisite to the improved quality of life and additional leisure and/or consumption made possible by increased income.

The Department of Health and Ageing (DoHA) suggested that the rapid growth of out-of-pocket expenses (health services paid directly by consumers) demonstrated that health expenditure rose more than proportionately with income. It commented:

The fastest real growth within the non-government area in the last ten years was pharmaceuticals. More than three-quarters of the out-of-pocket expenditure on pharmaceuticals is on non-prescription medicines and alternative therapies. (sub. 34, p. 4)

While some growth in out-of-pocket expenses could reflect a change in subsidy arrangements (for example, de-listing of some medicines or increased co-payments), or a change in tastes away from traditional ‘Western’ medicine rather than income effects, strong spending growth is evident for largely unsubsidised medical services such as laser eye surgery and cosmetic surgery, dental services and aids and appliances (for example, spectacles).

The precise impact of changes in income on the demand for health services — the income elasticity — is difficult to measure. As discussed in chapter 3 and technical paper 1, the various techniques used to measure the linkage at the *aggregate* level, produce estimates ranging from 1.0 to 1.6 (for example, Newhouse 1977 and Parkin et al. 1987). In other words, a 1.0 per cent increase in income leads to an increase in the demand for health services and, assuming all else given, an increase in total health expenditure, of between 1.0 per cent and 1.6 per cent. However, isolating the effects of higher income on health spending from other factors, including the impact of new technologies, is a difficult exercise. Some have suggested that an inability to unravel the interaction of demand and supply factors may tend to inflate these estimates (chapter 3).

On the other hand, some estimates of the income elasticity for individuals are as low as 0.2 (Manning et al. 1987). Estimates of income elasticities at an individual level may be low because health services are funded substantially by insurance or taxes. This suggests that an individual’s budget constraint is unlikely to be the relevant constraint when measuring the aggregate relationship between income and the demand for health services.

The Commission has assumed a range of income elasticities (0.2, 0.6 and 1) in its residual analysis of the impact of technology on health spending (chapter 3), with the impact of income growth on spending increasing in line with the assumed elasticity — accounting for roughly 10 per cent, 30 per cent and 50 per cent of the real increase in health spending between 1992-93 and 2002-03 respectively.

Consumer prices, subsidies and private insurance

The demand for virtually all goods and services is inversely related to their price relative to other goods and services. Health services are no exception. It follows that because consumer prices for many health services are heavily subsidised, the quantity of health services demanded is higher than if consumers had to pay prices reflecting full costs of supply. This section discusses changes in co-payment, subsidy and private insurance arrangements, which may have affected prices and consumer demand for health services (and the technologies they embody).

Arguably, however, the greatest impact on demand has not come from changes in subsidy arrangements, but rather from the interaction of the availability of new technologies that expand the range of, or intensify treatments, and existing subsidy arrangements that potentially extend access to these new technologies at zero or negligible explicit prices. The extent to which this increased demand translates into increased consumption and expenditure depends on the effect of any externally-imposed rationing mechanisms.

Government subsidies

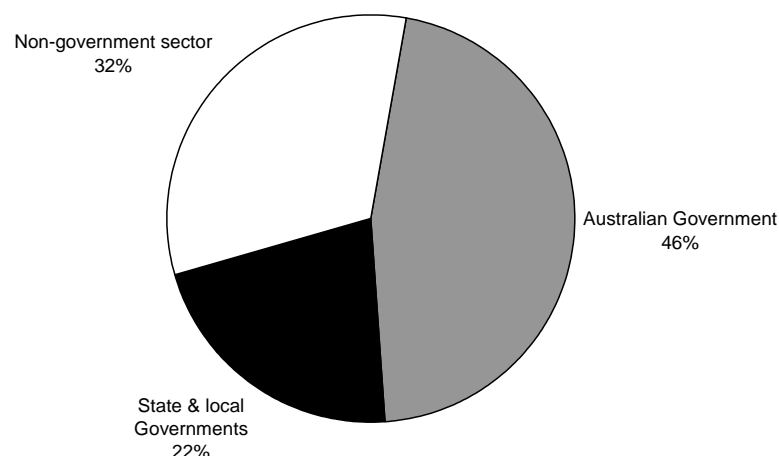
The Australian and State and Territory Governments are responsible for funding approximately 68 per cent of total healthcare expenditure, using funds raised from taxes and levies (figure 2.1). Subsidisation allows access to healthcare on the basis of need rather than capacity to pay — in effect, health risks are spread across the community.

While affordable and needs-based access to healthcare has many desirable features, individuals have an incentive to demand new technologies regardless of their cost because, from their private perspective, healthcare is a free, or relatively cheap, good. So long as technologies deliver some positive private benefits, they will be demanded.

This incentive structure has profound implications when new, inherently more costly technologies and treatments become available, particularly where these technologies facilitate an expansion in the range of treatable conditions, indications or age groups. In the context of subsidised access to health care, the introduction of

new technologies that expand the scope for treatment is equivalent in the consumer's eyes to reducing prices from prohibitive to negligible levels. Either all the increased demands must be met, generating significantly increased healthcare expenditure, or rationing mechanisms inevitably must come into play.

Figure 2.1 **Total health expenditure by source, 2002-03^{a,b,c}**



^a Expenditure by the Australian Government and the non-government sector has been adjusted for tax expenditures. ^b 'Non-government sector' includes expenditures by individuals, health insurance funds, workers compensation and compulsory motor vehicle third-party insurers. ^c Total health expenditure also includes expenditure on nursing homes and patient transport services.

Data source: AIHW (2004d).

The dilemma is noted by the Australian Health Workforce Advisory Committee (AHWAC), the Australian Medical Workforce Advisory Committee (AMWAC) and the Australian Health Workforce Officials' Committee (AHWOC):

A system where the full resource costs of treatment are generally not borne privately tends to result in an increase in private demand over what would otherwise occur. To what extent this is translated into additional public funding is a matter of continuing debate. (2004, p. 37)

Co-payments (discussed below) are a form of limited price signalling which may reduce demand for some technologies and services such as pharmaceuticals and medical services. However, for many services, non-price rationing mechanisms are used. For example:

- public hospitals generally impose waiting periods combined with prioritisation of treatment based on assessed clinical urgency;
- the Australian Government increasingly has attempted to contain its expenditure on new pharmaceuticals by restricting subsidised access to certain indications or

according to disease severity, or by limiting the aggregate subsidy amount for a new drug via price–volume agreements with manufacturers (chapter 8); and

- the Australian Government also limits access to subsidised magnetic resonance imaging (MRI) and some other diagnostic services.

Mechanisms for rationing subsidised access to new technologies are discussed in more detail below and in chapters 4, 8, 9 and 10.

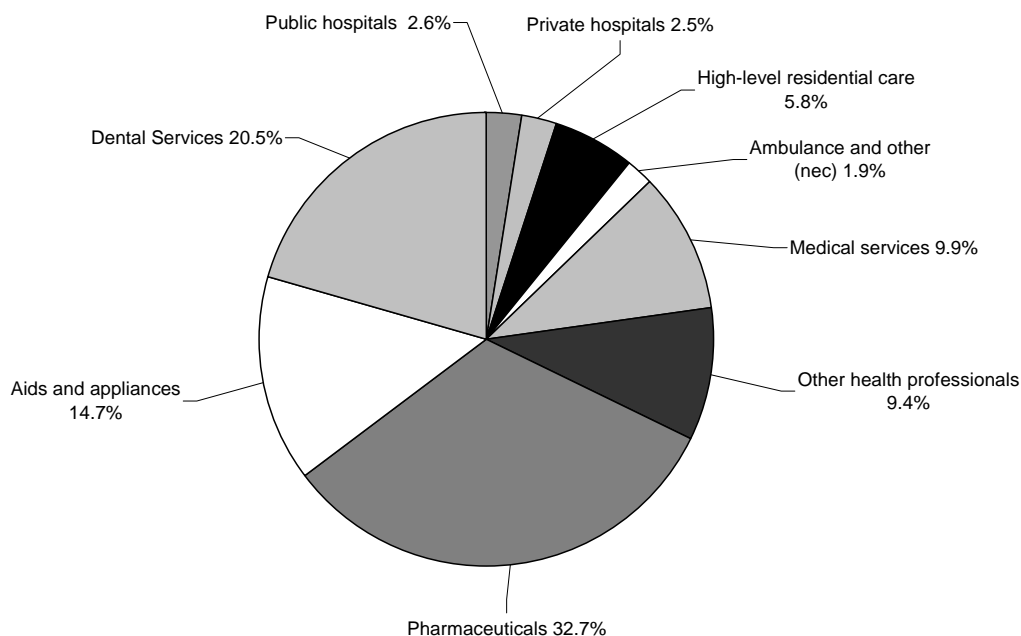
Co-payments and out-of-pocket expenses

About 20 per cent of total health expenditure is out-of-pocket — that is, direct payments by consumers at the point of service delivery.¹ Major components include: expenditure on prescription medicines (co-payments) and non-prescription medicines (including vitamins and complementary medicines); gap payments for medical services (for example, for visits to general practitioners (GPs) and some diagnostic services), gaps paid by privately-insured patients for private hospital and ancillary services, as well as payments for unsubsidised services (such as laser eye surgery and cosmetic surgery); and purchases of dental services and (non-implantable) aids and appliances, such as spectacles, external hearing aids and walking aids (figure 2.2).

Out-of-pocket expenditure will be sensitive to price changes or, in the case of co-payments, to the level of co-payment. Just how sensitive is difficult to say. Estimates of price elasticities with respect to increases in co-payments for prescription pharmaceuticals are generally ‘inelastic’ and in the range 0.1 to 0.3 (for example, McManus et al. 1996), suggesting that consumers regard prescription drugs as largely non-discretionary. Consumer behaviour may also be affected by the existence of safety nets which reduce co-payments to the concession level (currently \$4.60 per script) once an annual spending threshold is reached. If consumers expect that they will reach this threshold, an increase in co-payments may have little impact on their demand for prescription medicines. Overall, the implication is that to the extent higher drug prices feed through to higher co-payments, they will induce a less than proportional reduction in the quantity demanded. In other words, there will be some induced dampening of demand amongst those required to pay a co-payment, but not by enough to prevent a net increase in total expenditure.

¹ Under this definition, out-of-pocket expenses exclude health insurance premiums and hypothecated levies.

Figure 2.2 Health expenditure by individuals, in current prices, by area of expenditure, 2002-03^a



^a Individuals' expenditure not adjusted for non-specific tax expenditure.

Data source: AIHW (2004d).

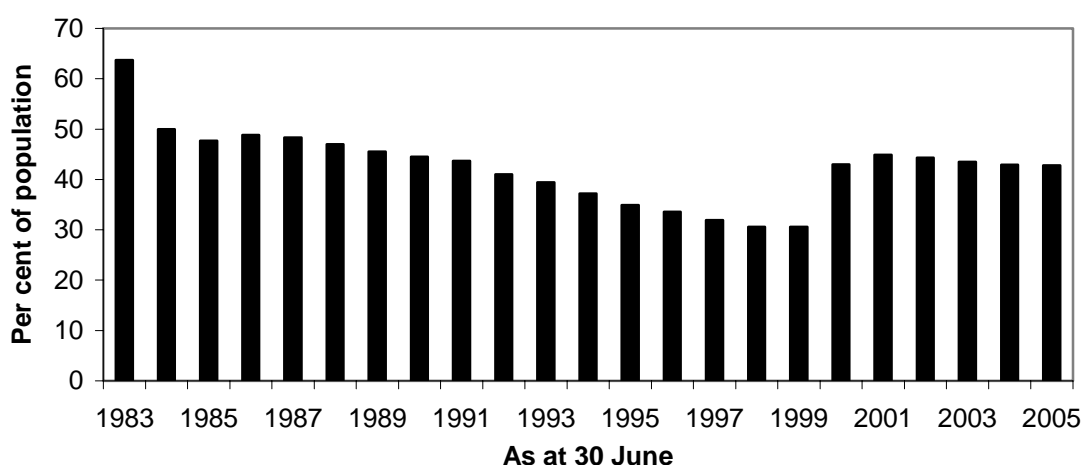
Private health insurance

In the context of universal, free access to public hospital services, private health insurance essentially provides insured patients with greater choice of doctor and a means of by-passing public hospital waiting periods. Increasingly, private health insurance may also be seen as facilitating access to new technologies. The Victorian Department of Human Services (VDHS) noted that:

One of the reasons people take out private insurance is so that they can access technological advances more readily than if they relied on the public system. (sub. 24, p. 24)

In the past few years, there has been a significant policy-driven shift to private health insurance after several years of decline. The proportion of the population covered has risen to around 43 per cent from a low of 30 per cent in 1998 (figure 2.3).

Figure 2.3 Private health insurance coverage, 1983–2005



Data source: PHIAC (2005a).

Policy changes include the introduction of penalty Medicare levies for high-income earners, the 30 per cent private health insurance rebate, lifetime community rating, and gap cover schemes (box 2.1). In essence, these changes have combined carrots and sticks to encourage membership — the net effect has been to make private health insurance premiums relatively cheaper and health insurance more attractive.

Box 2.1 Policies promoting private health insurance membership

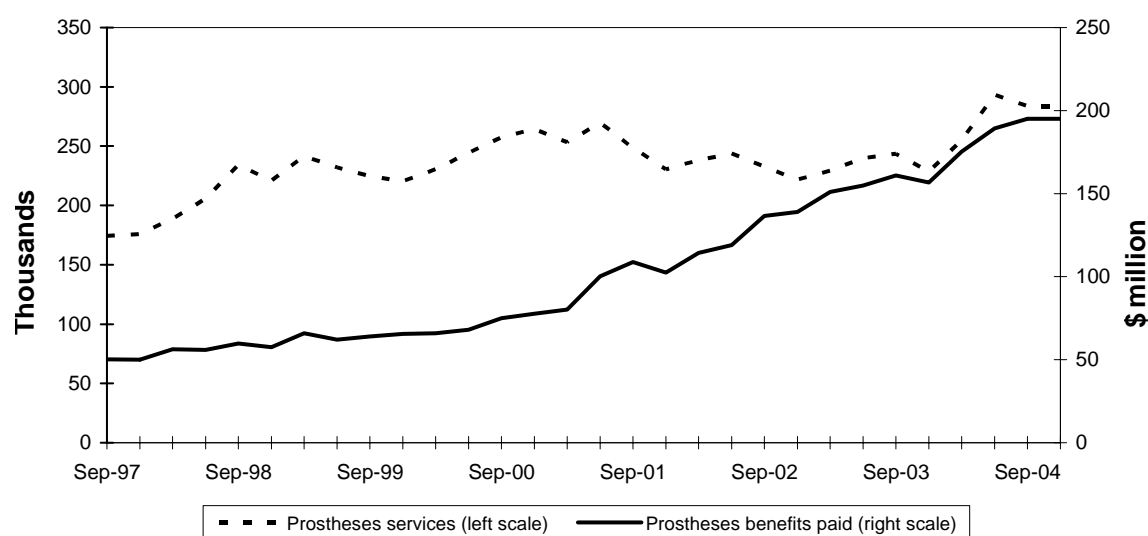
- July 1997 — Introduction of the Medicare surcharge (1 per cent of taxable income) for higher-income earners without an appropriate level of private health insurance.
- January 1999 — Introduction of the 30 per cent rebate on all private health insurance premiums for registered health funds.
- July 2000 — Introduction of Lifetime Health Cover. People who take out hospital cover earlier in life and maintain hospital cover pay lower premiums throughout their life compared to those who join when they are older.
- August 2000 — Gap cover schemes introduced.
- February 2001 — Removal of gap payments for prostheses and devices listed on Schedule 5.

Increased levels of private health insurance membership have been associated with an increase in the number of services performed and benefits paid. In particular, there has been substantial growth in the number of services provided and benefits paid by private health insurers above the Medicare Benefits Schedule (MBS) fee.

Separations in private hospitals increased by around 15 per cent or 253 000 between 1996-97 and 2002-03, with the increase in separations in private hospitals occurring largely since policy changes in 2000-01. Over the same period, separations fell by 94 000 in the public sector, although they have increased in the public sector in more recent years (see chapter 4, table 4.2).

In addition, there has been an increase in demand for more expensive services, particularly those involving prostheses. By 2002-03, prostheses accounted for more than 20 per cent of the average cost per separation in private hospitals (excluding overheads and most medical practitioner remuneration). Total private health insurance benefits paid for prostheses services increased by more than 200 per cent between 1997-98 and 2003-04. The number of services involving prostheses increased by around 50 per cent over the same period (figure 2.4).

Figure 2.4 Private health sector: prostheses services performed and total benefits paid



Data source: PHIAC (2005a).

In part, the shift towards use of more expensive items in the private sector may reflect clinical need. For example, younger patients who have taken out private health insurance in recent years may require more sophisticated knee or hip prostheses. But incentives are also likely to have played a role. Between early 2001 until mid-2005, no gap was payable for prostheses by insured patients and, thus, there was little incentive for them or their doctors to select less expensive items even when the latter may have been clinically adequate.²

² Although premiums will likely increase as a result, the increase is spread across the entire insured population.

For example, as discussed in appendix H, it is understood that a large majority (almost 90 per cent) of angioplasty procedures for private patients now involve drug eluting stents (DES) (compared with maybe fewer than half of all public patients undergoing angioplasty). While DES appear to have some benefits compared with bare metal stents for some patients,³ they cost several times more than bare stents. Largely as a result of the rapid uptake of DES after their approval by the TGA in 2002, the average cost of coronary angioplasty with stenting in private hospitals more than doubled between 2001-02 and 2002-03. Stent costs per private patient quadrupled over the same period. To the extent that recent changes to prostheses arrangements allow gaps for some prostheses, demand for items where gaps are payable may be dampened if some patients do not value the additional benefits offered as much as the additional payments required. This could place downward pressure on such prices and treatment costs.

Not only do private patients appear more likely than public hospital patients to receive newer, more expensive versions of devices and prostheses, it is claimed that private health insurers pay more for the same devices and prostheses than do public hospitals. Both BUPA Australia (sub. 28) and the VDHS (sub. 24) provided data and analysis suggesting that prices charged for items implanted in private patients were often around 25 per cent higher on average than prices charged to public hospitals and, in some cases, many times higher. If this is so, the cost impact of use of a more sophisticated prosthesis will be more pronounced for the private sector.

The Medical Industries Association of Australia (MIAA), representing device and prostheses suppliers, suggested that higher prices charged to the private sector for similar items reflected differences in the cost of supplying the public and private sectors (for example, because of sales volumes or differences in the level of support services provided) (sub. PR54). However, a lack of buying power on the part of private insurers (arising from legislated ‘no-gap’ arrangements), and/or the ability of suppliers to price discriminate using any market power conferred by patents or a first-to-market advantage, may also contribute to observed differences.

Incidence and prevalence of disease

The demand for health services and the technologies embodied in those services will be inextricably linked to the nature and extent of illness and disease. Changes in the number of new cases (incidence) of disease, and total numbers affected (prevalence of disease), will reflect many factors, including:

- changes in population size;

³ Nonetheless, as discussed in appendix H, because of the short time in which DES have been available, the incremental benefits are difficult to quantify.

-
- ageing of the population;
 - new diseases and epidemics;
 - improved screening and diagnostics;
 - environmental factors (for example, air pollution);
 - socio-economic factors; and
 - lifestyle/behavioural changes including, for example, changes in alcohol and tobacco consumption and obesity levels.

Major disease categories in terms of total treatment costs and mortality rates are presented in table 2.1.

Observed changes in total expenditure per disease category over the period 1993-94 to 2000-01 can be partly attributed to the influence of lifestyle and ageing:

- Direct expenditure growth of 26 per cent for cardiovascular disease was below average growth of 37 per cent, presumably reflecting the lower incidence of the disease, caused by lower smoking rates and other lifestyle changes, and improved preventative technologies (for example, statins and treatments for angina and high blood pressure).
- Substantially above average expenditure growth on treatment of diabetes probably reflects a combination of greater awareness of the disease and improved screening, but also ageing of the population combined with increasing obesity levels.

Over the next few decades, incidence and mortality rates for cancers and cardiovascular diseases are expected to decline,⁴ reflecting reduced smoking levels and better technology, although total *numbers* of cases will continue to increase as the general population ages. Incidence rates for, and prevalence of, dementia and diabetes are expected to increase significantly, attributable to population ageing and increased obesity respectively.

⁴ Although the increasing incidence of diabetes will tend to counter the decline in the incidence of cardiovascular disease.

Table 2.1 **Health expenditure and mortality by major disease category**
2000-01

<i>Disease</i>	<i>Total expenditure by disease \$m</i>	<i>% of total allocated expenditure</i>	<i>% of total deaths</i>	<i>Expenditure % change 1993-94 to 2000-01</i>
Cardiovascular	5393	11.0	38.3	26
Nervous system	4858	9.9	4.9	44
Musculoskeletal	4725	9.6	0.7	37
Injuries	4061	8.3	5.8	36
Respiratory	3533	7.2	8.3	22
Oral health	3376	6.9	0.0	52
Mental disorders	3018	6.1	0.7	32
Digestive system	2821	5.7	3.2	38
Neoplasms (cancers)	2764	5.6	29.3	31
Genitourinary	2081	4.2	2.5	na
Endocrine, nutritional & metabolic	1571	3.2	1.3	65
Skin diseases	1392	2.8	0.2	na
Maternal conditions	1318	2.7	0.0	9
Infectious & parasitic	1251	2.5	1.4	28
Neonatal causes & congenital anomalies	583	1.2	1.0	28
Diabetes mellitus	836	1.7	2.4	118
Signs, symptoms, ill-defined etc	5593	11.4	0.1	66
All diseases	49 174	100	100	37

na not applicable.

Source: AIHW (2004c).

Population growth

The link between population growth and aggregate demand for health services is reasonably straightforward — the larger the number of people, the larger the demand for health services, at any given price. The usual assumption is that population growth translates into a one-for-one increase in the demand for healthcare and health expenditure. In other words, a 1.0 per cent increase in the population is assumed to translate into a 1.0 per cent increase in the demand for health services and, hence, expenditure, all else held constant.

Population growth in Australia between 1992-93 and 2002-03 was 1.2 per cent per year, which explains roughly one-fifth of real average annual total health expenditure growth over the same period.

Population ageing

Health expenditure increases with age. Across all health expenditure types, expenditure per person per year on those aged 65 years and over is around four times higher than on those under 65 years, and rises to between six and nine times more for older age groups (PC 2005a).

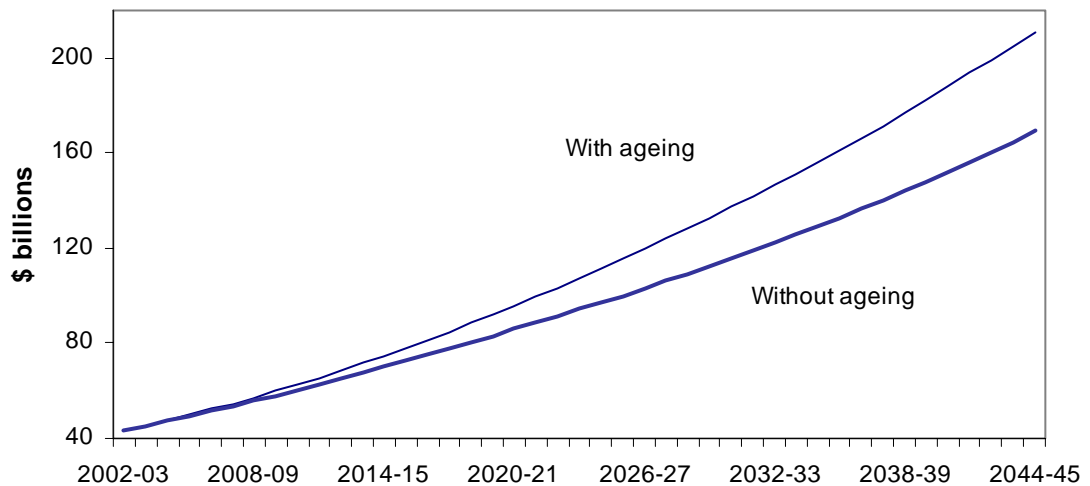
Nonetheless, to date, population ageing does not appear to have been a major driver of increased demand for health services — Commission estimates suggest that ageing has contributed at most about 0.7 percentage points of growth in total real health expenditure of 5.2 per cent per year, or around 13 per cent of expenditure growth over the past ten years. Once hospital costs associated with death are accounted for, a dip in crude death rates in recent years reduces further the past impact of ageing. However, ageing of the population, and crude death rates, are set to accelerate. The Commission's report *Economic Implications of an Ageing Australia* estimated that future ageing of the population will add 25 per cent to projected government health spending by 2044-45 (figure 2.5).

Because older age groups consume proportionately more health services, they consume commensurately more medical technology. Moreover, utilisation levels of some technologies are increasing faster for older age groups than for younger age groups. This is likely to be reflecting a combination of changing expectations, improved health status of the elderly, and improved technology. As Dr Stan Goldstein commented:

... not only is it safer to offer a treatment because the health status of many individuals remains reasonable despite their age, but as the life expectancy of older persons is greater, there is a greater perceived benefit, or anticipation of a greater longevity of benefit, in providing technology whose benefit may have, in the past, been appropriately restricted due to the potential risks and the perceived limited years of benefit for the individual. (sub. 5, p. 2)

Fuchs (1998) analyses United States data comparing utilisation of seven procedures by age groups (over 65 years) over time (table 2.2). Whilst utilisation rates rose significantly across all age groups, the largest increases were consistently found to be in older age groups (80–84 years and 85+ years).

Figure 2.5 Population ageing and government health spending, 2002-03 to 2044-45



Source: PC (2005a).

Table 2.2 Average rate of change in age-specific utilisation of seven procedures, United States, 1987–1995

Average percentage change per year

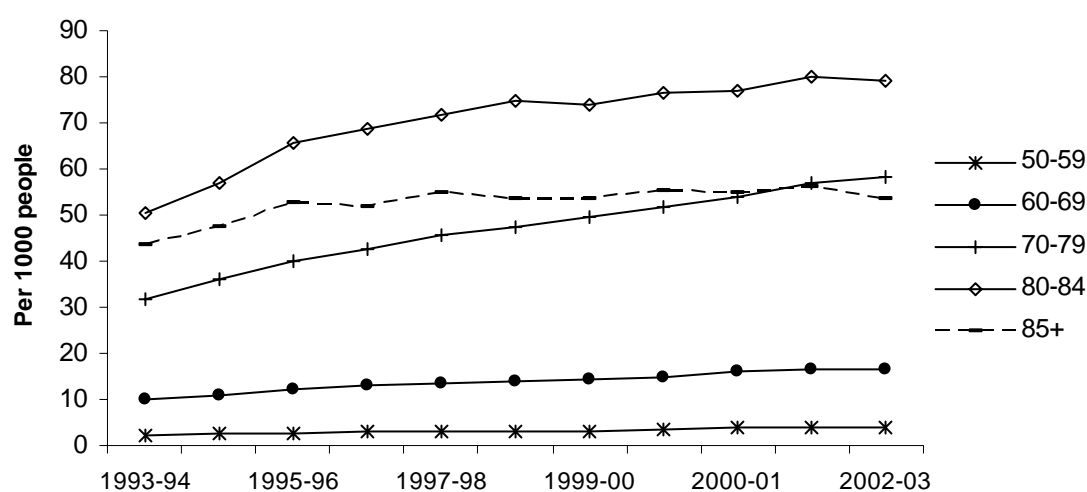
Procedure	Men by age group				
	65–69	70–74	75–79	80–84	85+
Angioplasty	13.1	15.7	19.7	21.3	22.3
Coronary artery bypass graft	3.7	5.5	8.5	11.1	14.6
Cardiac catheterisation	4.4	6.2	10.0	13.4	16.0
Carotid endarterectomy	7.1	5.9	10.1	11.4	10.6
Hip replacement	14.9	16.3	17.7	20.1	25.8
Knee replacement	11.5	12.1	11.8	8.2	10.6
Laminectomy	3.9	5.0	8.0	10.1	8.4
	Women by age group				
	65–69	70–74	75–79	80–84	85+
Angioplasty	12.6	14.9	17.1	18.4	20.0
Coronary artery bypass graft	4.4	7.3	10.7	13.3	11.0
Cardiac catheterisation	5.3	7.1	9.9	16.9	15.7
Carotid endarterectomy	8.6	6.9	9.1	10.3	11.8
Hip replacement	18.3	17.0	18.7	21.4	28.9
Knee replacement	10.9	10.8	9.1	8.4	10.7
Laminectomy	4.9	6.6	6.5	4.1	7.2

Source: Fuchs (1998).

Somewhat similar patterns of growth in costs of treatment of the elderly are evident in Australia. For example:

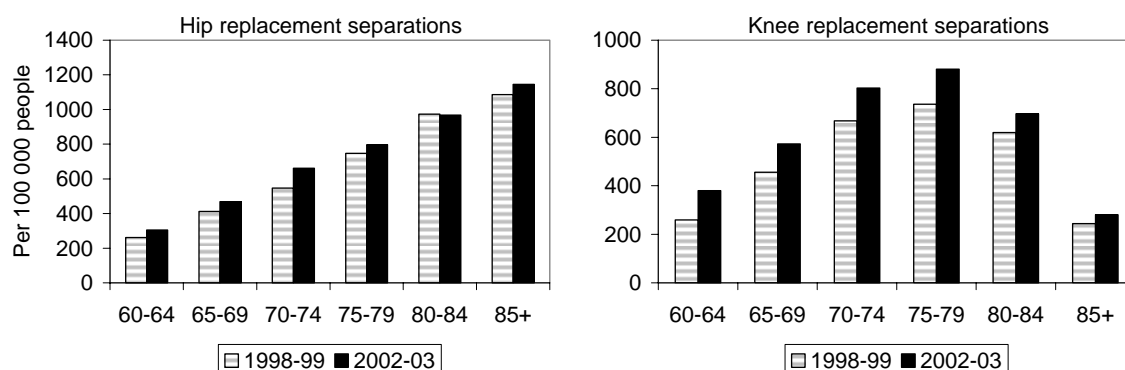
- the prevalence of cataract surgery increases with age and increases have been strongest for the 75–79 year age group (figure 2.6); and
- the number of hip replacements per 100 000 people increases progressively with age. Knee replacements are more heavily concentrated in the 75–79 year bracket. The rate of joint replacement surgery in most of the oldest age groups is also increasing (figure 2.7).

Figure 2.6 Trends in cataract surgery amongst Australia's aged



Data sources: AIHW (unpublished data); ABS (2004 unpublished estimated resident population data). Data available in technical paper 4.

Figure 2.7 Trends in hip and knee replacement amongst Australia's aged



Data sources: ABS (2004b); AIHW (2005d).

Community expectations and preferences

The amount and quality of health services demanded will reflect in part what is considered a desirable level of health. What is today considered an acceptable level of chronic pain or discomfort is likely to be significantly different from a few decades ago, given the availability of new treatments. Changing perceptions are likely to be strongly linked to education and lifestyle which, in turn, are strongly linked to income levels.

Greater awareness of medical technologies via Internet access, media and so on, and simply greater acceptance of or belief in the benefits of technology are also likely to have been strong drivers of expectations and demand. Queensland Health commented:

Consumers have greater access to information than ever before and are better informed and more likely to take an active role in the planning of their care. Armed with information from the internet and media, consumers often have an expectation that new technology will be introduced into the public sector as soon as it becomes available. Consumers' lobbying has been responsible for the introduction of technology especially where [it] can be very forceful about lack of access to new technology and for its introduction locally, via the media or by approaching politicians and driving demand for the uptake of new technology. (sub. 43, p. 4)

Technology may also be preferred by some consumers to preventative actions (for example, taking a pill rather than exercising and changing diet), though such preferences to some extent may also reflect distorted consumer price signals if new technologies are subsidised and preventative actions are not. Technological breakthroughs may be preferred simply because they receive more publicity than more prosaic forms of treatment.

Several participants considered that community expectations were being influenced in a way that was detrimental to the cost-effective provision of health services. Dr Jeff Brownscombe observed:

Many conditions may be treated by both technological (high unit cost) and conservative (low unit cost) means. Often these may achieve equivalent results, or the conservative option may be superior. However, frequently the technological solution is chosen in spite of this. Reasons include:

- The perception that technological solutions are superior despite doctors explanations to the contrary. People feel they have been better treated if they have been allowed to access expensive technology. This interacts with the placebo effect in a complex way and is linked to our value systems. It is an important topic for public education.
- Conservative management often necessitates lifestyle change, the need for which people may deny and which many people only do when there are no other options.

Technological treatments offer an alternative to these, yet this may be detrimental in the long term (example: medications for the management of smoking-related respiratory disease may delay quitting). (sub. PR55, p. 2)

And the Australian Nursing Federation commented that:

Products are marketed and profited from like any commodity and developers are often focused on trials and producing evidence of success for their products rather [than] on appropriate or responsible use. The public often falls ‘victim’ to promotional campaigns, learning of new technological advances from these rather than from properly performed detailed analysis. This can have a direct impact on demand and expectations of treatment by the general public and can result in a lack of understanding regarding the existence of more cost effective alternatives. (sub. 26, p. 2)

In similar vein, *Choice* (2004) magazine argues that pharmaceutical companies sometimes circumvent bans on direct-to-consumer advertising through advertisements advising that patients ask their doctor about new treatments, ‘news’ stories about new drugs and various other awareness-raising campaigns. It is claimed that patients then pressure doctors to prescribe new treatments.

A contrary view was put by the National Association of People Living with HIV/AIDS which considered that:

... consumers themselves can and do exercise rational judgement — and contrary to one popular view, are more than capable of resisting marketing ploys or other pressures when making decisions about their health care. (sub. PR58, p. 7)

Even if consumers filter marketing and other pressures to use new technologies, the availability (or absence) of clinical information may affect their choices. The role of information in influencing patient (and doctor) demand for technology is highlighted by a recent trial conducted in regional South Australia. Education of doctors and the community resulted in significant reductions in the use of antibiotics for upper respiratory tract infections (Dollman et al. 2005).

There will always be a debate as to whether information is appropriately provided and whether regulations are needed and/or appropriate. These issues are beyond the scope of this study. What is clear is that the Australian community appears to need little encouragement to embrace new technologies that it considers may be helpful in improving its health. However, while there is broad agreement that community expectations are important in driving demand for health services and access to new technologies, it is virtually impossible to isolate and quantify the impact.

Intermediate demand for, and diffusion of, advances in medical technology

The pattern and rate of technology diffusion differs significantly across countries with comparable income levels and health expenditures and after adjusting for disease patterns. From its study of heart attack care in 17 countries, the TECH Research Network found that differences in technology diffusion were greatest for costlier technologies, where budget and other constraints on use were more likely to apply. Technology diffusion in Australia was categorised as ‘late start/fast growth’, albeit with levels of diffusion converging over time towards the world leader, the United States (TECH Research Network 2001). This section outlines some key factors likely to influence the diffusion of medical technology in Australia.

While it is patients who are the ultimate consumers of health services, choices about the use of particular technologies — including new technologies — continue largely to be driven by medical practitioners, though often, and probably increasingly, in conjunction with their patients. A report prepared for the VDHS suggests that in Victorian public hospitals:

Clinician’s preference is the dominant influence on uptake of new technology in terms of both total investment and mix ... They influence pattern of uptake ... [including] those patients for whom a new technology is used and how the criteria for use changes over time. (KPMG Consulting 2001, Appendices, p. 29)

In competitive markets, producers of goods and suppliers of services generally will endeavour to select a combination of inputs — labour, capital and technology — that delivers the attributes desired by consumers, at the minimum cost. However, as discussed in chapter 1, the market for health services is not a normal, competitive market, partly because governments and health funds rather than consumers pay for most of the direct cost of those services. Increasingly, guidelines and regulations attempting to control budget outlays are affecting technology choices of clinicians and the rate of technology diffusion throughout the community. In addition, many technology choices will also be made directly by governments and/or hospital administrators. For example, hospitals purchase prostheses, devices and diagnostic and surgical equipment and implement administrative support systems.

Major factors influencing provider decisions to use newer technologies once they become available include:

- awareness of technological advances and their potential benefits;
- doctor assessment of patient clinical need;
- financial and other incentives provided to doctors and institutions, for example, by reimbursement arrangements and liability laws;

-
- budget and other constraints, such as regulations and guidelines, imposed by governments and institutions including hospitals; and
 - skills and availability of health professionals and other complementary inputs.

Awareness of, and willingness to adopt, new technologies

Medical practitioners become aware of new medical technologies in a variety of ways, including:

- international and local conferences;
- clinical trials;
- marketing and other information provided by manufacturers;
- practice in hospitals and influence of colleagues;
- horizon scanning and other health technology assessment;
- training; and
- medical journals.

The indirect and direct influence of technology suppliers on choices of doctors via conferences, clinical trials and marketing is especially contentious. Lopert and Henry suggest that marketing by pharmaceutical companies contributes to ‘leakage’ — that is, the prescription of drugs to cases which do not meet the criteria approved by the Pharmaceutical Benefits Advisory Committee (PBAC):

... pharmaceutical companies spend large sums promoting their products. A drug may be promoted for any or all of the indications approved by the Therapeutic Goods Administration. PBS-listed indications are however often narrower ... There is a strong case for requiring pharmaceutical promotion to provide information that is balanced to assist prescribers ... (2002, pp. 126–7)

Several submissions suggested that the availability and promotion of technologies tended to ‘medicalise’ conditions, leading to increased use of technological interventions. For example, Dr Jeff Brownscombe commented:

Medical evidence shows both SSRI [selective serotonin reuptake inhibitor] medications and six sessions of cognitive behavioural therapy [CBT] (delivered by psychologists) can have a similar impact on outcomes. SSRIs are widely available and a major expense for the PBS, yet doctors find it very difficult to refer for CBT due to lack of public funding. This may not be a cost effective decision, especially in the long term as SSRI scripts are often ongoing.

Similarly, many expensive cardiac drugs offer minimal survival benefits for high cost. However, brief interventions for smoking, with proven efficacy and more substantial survival benefits, remain at the periphery of treatment. (sub. PR55, p. 3)

Professor Lesley Barclay and Dr Robyn Thompson from Health Services Development, Institute of Advanced Studies, considered that childbirth likewise had become medicalised:

... current Australian health policy and medical insurance schemes encourage hospital birth for the majority of women under the care of a specialist obstetrician, who may not be present at the birth. In addition an increasing array of medical technology is becoming available to monitor the progress of pregnancy and fetal development, provide genetic screening of the fetus and newborn infants and, in the last few decades, to enable fetal surgery to correct a variety of anatomic and non-anatomic defects. (sub. PR48, p. 1)

Thus use of newer technologies may not only reflect differences in promotional efforts but also funding and listing arrangements that focus on particular technologies rather than disease prevention and management. Such arrangements may create a bias towards subsidisation and use of newer technologies.

Promotion of medicines is regulated through a code of conduct administered by Medicines Australia, the industry's umbrella organisation. In its submission to this study, Medicines Australia commented that:

Clearly, a major influence on the take-up of new medicines is the pharmaceutical industry itself. Having invested between US\$750 million and US\$1 billion to develop a new medicine from 'bench to bedside', a pharmaceutical company will seek to enter the market to obtain a return for that investment. However, there is increasing recognition that this requires balanced information and collaboration with a range of stakeholders. The industry continues to rely heavily on 'medical representatives' to promote products face to face with prescribers. Increasingly, the additional marketing activities undertaken by the industry are becoming aligned (both in content and delivery) with broader educational programs involving other partners such as the specialist colleges. As part of a Federal Budget initiative in 2003, the Australian pharmaceutical industry agreed to highlight details of any listing on the Pharmaceutical Benefits Scheme in any promotional materials, in an effort to ensure prescribers acted more in line with PBS listings. (sub. 30, pp. 62–3)

While the question of whether information provided by manufacturers promotes appropriate prescribing of medicines and use of other new technologies is beyond the scope of this study, there would seem to be little doubt that information campaigns increase awareness of pharmaceuticals and other treatments. Whether they increase overall use and expenditure is open to question — it may be the case that in some circumstances information merely switches use from one product to another. However, if a newer, more expensive drug or intervention is selected, expenditure will increase. The issue then is whether there are commensurate additional benefits.

Some cost-effective treatments may be under-used because of a lack of information and sponsorship. Fett (2000) cites the example of *Helicobacter pylori* (antibiotic) eradication therapy to treat peptic ulcers. He suggests that diffusion of this new treatment was very slow (imposing costs on patients and the community) because of professional scepticism and a *lack* of marketing effort reflecting the fact that there was no champion of (or pecuniary beneficiary from) the treatment. Fett also attributes low diffusion of immunisation to ‘a lack of institutional impetus to promote immunisation’ (2000, p. 24).

Several studies of the factors affecting doctors’ decisions to use new technologies suggest that the influence of local peers, rather than externally-provided marketing or scientific information, is a key influence. For example, Greer observes:

... it is intrinsically difficult for knowledge emanating from external sources to affect local medical behaviour. This is true irrespective of the esteem accorded the sponsors of the new knowledge. (1988, p. 23)

Wider diffusion thus tends to follow the lead of key ‘opinion leaders’ who are the most respected members of the medical community.

Several participants also identified the diffusion of new technologies in private sector practice as a significant driver of adoption of (or pressure to adopt) these technologies in the public sector (chapter 4). As observed by the Australian Hospitals Association, this may also reflect peer influence and that clinicians typically work in both the public and private sectors:

In particular, doctors who work in both public and private sectors cannot deny the latest technology to public patients if private patients are receiving these treatments. Senior medical staff form part of a global workforce that discusses the latest technology and promotes its introduction on [the] basis of quality and safety. In other words, if doctors decide that it is no longer safe to use a treatment considered as outmoded they create a demand for newer alternatives. Current examples are brain stenting, gamma knives and robotics. (sub. 25, p. 3)

Patient clinical need

Medical practitioners generally strive to do the best for their patients, a point stressed in several submissions to this study. The Royal Australian and New Zealand College of Radiologists, Faculty of Radiation Oncology observed:

Radiation Oncologists are committed to find the most effective methods of treating patients with cancer. This is the primary driver for the adoption of new technologies. (sub. 18, p. 2)

And Dr Michael Loughnan commented that:

As a General Medical Practitioner, I believe that any advances in medical technology, which may clarify diagnosis, and thereby influence outcomes, must be used or at least offered by me. (sub. 10, p. 1)

In response to a submission to this study from the health fund BUPA Australia, the Australian Medical Association stated: ‘It would be unethical not to offer patients the better health outcomes that can be achieved by the latest prostheses and drugs’ (AMA 2005).

This suggests that if arrangements are such that price is not a significant factor affecting the patient’s decision, then doctors may feel remiss if they do *not* choose what they consider to be the best-available technology, regardless of its cost. The increase in use of more expensive prostheses in the private sector following removal of gap payments in 2001 provides some evidence of this (see above). Gelijns and Rosenberg observe similar pressures in the United States:

As long as new technologies were seen as offering even small health benefits compared with existing practices, and as long as third-party payers covered the incremental costs, pressures arose in the system for adoption and regular use of these technologies. (1994, p. 34)

Financial and other incentives

The OECD observes that: ‘The type of reimbursement mechanism can have an important influence on the incentives for the uptake and diffusion of technology,’ (2005a, p. 23).

For example, as discussed in chapter 4, budget-constrained public hospitals have incentives to purchase, and encourage doctors to use, technologies that reduce hospital costs (or increase hospital receipts under casemix funding arrangements), and to constrain the use of technologies that raise costs, even though more expensive technologies may sometimes be more cost effective from a broader community perspective. The short-term nature of budgeting is also likely to encourage a focus on short-term outcomes. In other words, the narrow financial incentives facing public hospitals may not necessarily align with optimal use of technology in the community over time.

While budget-constrained public hospitals have an incentive to contain use of cost-increasing technologies, private hospitals may face incentives to do the opposite. To attract privately-insured patients, private hospitals compete for high-quality clinicians. To attract and retain the services of scarce clinicians they may purchase expensive technologies, such as robotic surgery. Analysis of decisions relating to five technologies bought by hospitals in Pennsylvania found that:

Hospitals have competed, in part, by acquiring technologies to attract and retain physicians and their patients ... The potential financial losses usually associated with an oversupply of services may have been mitigated by cost-based reimbursement used by payers and possible cost-shifting practices of providers to maximise reimbursement arrangements. (Bryce and Cline 1998, p. 221)

Teplensky et al. found in their study of the adoption of MRI that ‘the importance to the hospital of being a technological leader is one of the strongest determinants of hospital [MRI] adoption behaviour’ (1995, p. 459).

Supplier-induced demand

Financial incentives may also affect doctors’ choice and use of technology. The OECD has identified fee-for-service payments (in the context of universal health insurance), as encouraging possible oversupply of services in Australia (OECD 2005c). This, in turn, could generate commensurately greater use of some technologies. Richardson noted that:

Medical practitioners in both public and private hospitals gain financially, as well as professionally, from the adoption of new technologies, especially when they involve procedural work where reimbursement is significantly more generous than for consultations. (1988, p. 430)

The Royal Australian and New Zealand College of Radiologists cited international evidence that:

... non-radiologists performing their own imaging are two to seven times more likely to order imaging procedures than treating physicians with no stake in the radiology practice to which they are referring [patients]. (sub. 27, p. 2)

Just how important financial incentives are in driving use of new technology by doctors is difficult to establish, largely because other factors such as subsidised consumer prices serve to increase demand to the point that marginal benefits are very low. In this context, incentives provided by a system of fee-for-service payments for clinicians largely align with incentives provided to consumers to consume health services up to the point that benefits are negligible. In a study of supplier-induced demand in Australia, Bickerdyke et al. concluded that, on balance:

Empirical evidence on supplier-induced demand from Australia and overseas is inconclusive and incomplete. In practice, supplier-induced demand is difficult to identify because doctor behaviour and service patterns consistent with supplier-induced demand may also be consistent with appropriate medical treatments. Even so, on balance, the evidence suggests that supplier-induced demand is likely to be small relative to other influences on the provision of medical services. (2002, p. x)

It is conceivable that given a choice of two technologies with similar health benefits, doctors may favour the technology that generates a larger financial reward (for example, because of a higher scheduled reimbursement level), regardless of its cost relative to the other treatment. Whether doctors can or do induce demand for new technologies that increase their private returns, but which are inferior to other technologies or treatments (or, indeed, no treatment), will largely depend on the quality of information available to them and their patients. While it is unlikely that doctors would advocate treatments that they knew to be inferior, all else equal, uncertainty about the effects of new technologies may allow some bias towards use of technologies that bring greater rewards to doctors.

Defensive medicine

Several submissions pointed to the threat of successful litigation against medical practitioners if the latest technologies were not used. Dr Michael Loughnan claimed that:

The requirement to blame a practitioner or institution for compensation to be available when a patient suffers creates a focus on new technology. (sub. 10, p. 1)

And the Australian Healthcare Association observed that:

Doctors have to consider the legal risk whereas the cost issue is one for hospital management. Without evidence, hospitals have no real choice but to accept usage as a default measure of acceptability and quality. (sub. 25, p. 3)

In a study of the dynamics of technological change, Gelijns and Rosenberg likewise found that:

In an environment of considerable uncertainty concerning the real value of medical interventions, physicians have been able to expand the demand for medical services, an expansion that has been intensified by a concern over malpractice suits. (1994, p. 29)

Newhouse considers that growth of ‘defensive medicine’ in the United States could ‘only account for a trivial fraction of the expenditure increase’ (1992, p. 9). Yet a survey of Australian doctors found that between 38 and 85 per cent ‘often’ or ‘occasionally’ adopted ‘defensive’ practices. General practitioners were more likely to adopt such practices, with the main implication for technology use being referrals for non-invasive diagnostic procedures (Hancock 1993). In such cases, risks and costs incurred by patients would be low. As discussed in appendix J, in a survey of over 200 GPs in NSW, around 60 per cent perceived a risk of litigation if they denied PSA testing of asymptomatic men, while only 15 per cent were concerned about the risk of litigation arising from complications following PSA testing (Girgis et al. 1999). Dr Jeff Brownscombe observed that:

... the [diagnostic] tests ordered to cover medicolegal possibilities, whilst consistent with priorities established by our own legal justice system, would nonetheless be acknowledged by many doctors as “low yield”. The benefits to the population are marginal, impacting negatively on the cost-effectiveness of the use of medical technology, in addition to driving up costs in absolute terms. (sub. PR55, p. 2)

Legal liability is to some degree a function of what the community considers to be reasonable practice and, thus, responses by medical practitioners may broadly reflect changing community expectations and demands. In this vein, Gelijns and Rosenberg observe:

Such ‘defensive medicine’ has also, of course, not been inconsistent with the financial, socio-cultural, and professional incentives encouraging the widespread application of technology. (1996, p. 46).

In other words, as with supplier-induced demand, the incentives facing doctors to use the latest technologies to avoid legal liability may not deliver outcomes much different from those demanded by patients. This is not to say, however, that ensuing use of technologies will deliver net benefits. Brownscombe suggests that court decisions concerning individuals may ignore population-wide costs and benefits:

... [courts] tend to overstate the value of investigation findings (typically expensive, technological tests) over clinical findings, perhaps because they are seen to be more objective, their findings are less open to dispute and perhaps because of a misplaced faith we have in the reliability of findings generated through technological means. Courts also do not factor in other costs such as small increases in risk of cancer due to radiation exposure, which may be relevant at the population level but are difficult to measure and of little relevance when assessing an individual’s damages entitlements. (sub. PR55, pp. 1–2)

Regulatory and budget constraints

Gelijns and Rosenberg note that:

Differences in health care financing systems provide a partial explanation for the observed variations in the international diffusion of medical technology ... budgetary caps explicitly force choices among technologies. (1996, pp. 53–4)

While doctors in Australia are given a great deal of freedom to select treatments and technologies, their choice set is somewhat restricted, particularly where public funding of technologies is involved. For example:

- There are requirements for authorisation for and/or restrictions on prescribing many high-cost drugs (such as the biological arthritis drug Enbrel) under the PBS. Almost 80 per cent of all PBS-listed medicines currently either require authorisation, or their use is restricted, compared with around 65 per cent in 1997-98.

-
- Public hospital budget constraints may restrict the use of some high-cost technologies for public patients (for example, implantable cardioverter defibrillators), or ration access to them via clinical guidelines (as is the case for DES in Victorian public hospitals). More generally, public hospitals ration access to procedures and there is some evidence that waiting periods are increasing (Pirani 2005). As discussed in appendix E, in 2003-04, approximately 25 per cent of patients on waiting lists for knee replacement surgery waited for more than a year, with a median waiting time of 168 days (AIHW 2004a), compared with a median waiting time of 112 days in 1999-00 (AIHW 2000). Similarly, in 2003-04, 12 per cent of patients on waiting lists for hip replacement surgery waited more than a year. The median waiting time for hip replacement surgery increased from 88 days in 1999-00 to 91 days in 2002-03 (AIHW 2004a).

The Australian Government has also restricted subsidised access to new diagnostic equipment. For example, Lázaro and Fitch observe that:

Australia has a significantly larger number of CTs [computed tomography] ... than many other countries, and a smaller amount of MRIs; the introduction of MRIs in Australia was linked to a formal assessment associated with restrictions on governmental funding. Thus regulatory mechanisms — or the lack of them, which is the predominant case — may affect the diffusion and use of medical technologies. (1995, p. 565)

The impact of regulatory and budget constraints on the use of particular technologies is discussed further in chapter 4.

Skills and availability of health professionals and other complementary inputs⁵

The use of medical technology at the very least requires the services and knowledge of a medical professional and may also require other inputs, such as other skilled professionals (for example, technicians and nurses), capital equipment and infrastructure. To the extent that new technologies require more complementary inputs than technologies they replace, the impact on overall health spending will be amplified. On the other hand, if these inputs are limited, adoption of the new technology will likewise be constrained.

⁵ The Australian Government has asked the Commission to undertake a research study to examine issues impacting on the health workforce including the supply of, and demand for, health workforce professionals. A draft report is scheduled for release in September 2005. Details of the study are available from the Commission's website.

For example, the rate of diffusion, and effectiveness, of medical technology may reflect in part the time taken to acquire necessary skills and knowledge. The MIAA, which represents suppliers of medical devices and prostheses, the successful use of which largely depends on the skills of clinicians, observed that its:

Member companies invest heavily in ancillary services including training doctors and other medical personnel ... In 2003-04 MIAA conducted 50 professional development training programs for 1000 people employed in our highly specialised industry. (sub. 17, p. 80)

This role of skill development in technology diffusion is observed by Fuchs:

... as physicians developed greater confidence and capacity to perform the procedures on more patients, especially on older patients, utilisation steadily increased. (1998, p. 3)

The numbers, proportions and distribution of surgeons, specialists and GPs will also have a direct influence on the rate of diffusion of new technologies. Queensland Health observed that the uptake of new technology was influenced by the availability of qualified staff (sub. PR43). In Australia in recent years, the number of practising specialists has increased while the number of GPs has fallen.

The number of specialists increased from 16 524 to 22 553, or by more than one-third between 1991 and 2001. The percentage increase was around 20 per cent when controlling for population growth (OECD 2004). Of course, aggregate numbers can mask changes within particular specialities and do not reveal whether numbers are at appropriate levels. For example, Queensland Health noted that Queensland was poorly supplied with medical oncologists. That said, the overall increase in the numbers of specialists per 1000 of population may have facilitated increased use of new procedures and treatments. Moreover, some new technologies such as minimally-invasive techniques for eye surgery and hip and knee replacements have improved productivity of some specialists, allowing more procedures to be performed.

Over the period 1996-97 to 2001-02, the number of GPs per 100 000 people fell from 132 to 123, or expressed on a full-time workload equivalent basis, from 88 to 85, a reduction of roughly 3 per cent. Thus, to the extent that GP numbers influence prescribing and service levels, they may have exerted a limited constraining influence in recent years, particularly in regional areas where shortages are more acute.

The availability of nursing staff, operating theatres and hospital beds could also affect the use of technology by limiting access to hospital procedures. Although Australia had the second highest nurse–population ratios of any OECD country in 2000 — 11 726 nurses per 1 million population, second only to Ireland — some studies suggest that Australia has a shortage of nursing staff in rural and remote

areas (Simoens et al. 2005). This shortage in turn could contribute to unequal access to medical technologies in these areas (chapter 6).

2.2 Supply of medical technology

The supply of advances in medical technology largely reflects health research and development (R&D) effort and its subsequent commercialisation, after meeting safety and other regulatory requirements. However, there are other important sources of technological advance:

- advances in health treatments may also come from applications of technologies originally developed for non-health applications (for example, MRIs); and
- some advances will develop from clinical practice and observation. This is more likely to be the case for advances in procedures.

Globally, health R&D funding is roughly equally divided between the public and private sectors. In 2001, it was estimated that public sector funding of health R&D totalled US\$47 billion, and private sector funding US\$59 billion. Of private sector funding, about US\$8 billion was funded by not-for-profit organisations such as universities, foundations and charities. (Global Forum for Health Research 2004)

As in any commercial market, private R&D medical technology investment undertaken by ‘for-profit’ organisations largely responds to potential demand and profit expectations. Publicly-funded R&D investment will reflect the priorities of the government, typically filtered through a funding body. The Global Forum for Health Research observes:

The vast majority of R&D spending is done *by* high-income countries in high-income countries, aiming to generate products tailored to healthcare markets *of* high-income countries. (2004, p. x)

Thus, according to AHWAC et al.:

New technologies are not developed haphazardly, but they are induced by the incentive for developing specific kinds of technologies, and government regulation and the financial incentives of the market shape their development. (2004, p. 37)

Not surprisingly, then, advances in medical technology increasingly are being aimed at diseases of ageing (for example, cancers, dementia, arthritis) and diseases associated with lifestyle (for example, smoking and obesity-related diseases such as cancers, cardiovascular illnesses and diabetes). Medicines Australia (sub. 30) noted that of 579 drugs currently in clinical trials worldwide for eight diseases (included in Australia’s National Health Priority Areas), 245 are for cancer treatment, 81 for

arthritis, 56 for diabetes and 34 for dementia. Developments in other areas of medical technology appear to be similarly targeted (chapter 11).

Gelijns and Rosenberg stress the policy importance of understanding the link between R&D effort and incentives provided by the health market:

Today's changing health care market sends signals to different groups that operate under different time horizons, with different priorities, and that are subject to different incentives. Indeed, the research community that is in a profit-making mode — the drug and medical device industry — is often highly sensitive to market signals. (1994, p. 43)

At the time of their study, Gelijns and Rosenberg found some preliminary evidence of a shift in private R&D toward the development of more cost-reducing innovations — such as minimally-invasive devices — in the light of a shift to 'managed care' and heightened cost consciousness in the US health system. Although it does appear to be the case that many new technologies have reduced unit costs compared with existing treatments, by reducing risks and thresholds for intervention they typically have facilitated much greater levels of use and, hence, higher spending overall (chapter 4).

Australian health R&D and medical technology

Australia's total health R&D in 2002-03 was estimated at around \$1.3 billion, representing approximately 1.0 per cent of global health R&D. The non-government sector contributes around one-quarter of this amount, the Australian Government about 60 per cent, with the remaining 15 per cent being funded by other levels of government. Australia has led innovation in many areas in recent years, including:

- *in vitro* fertilisation;
- antibiotic treatment of stomach ulcers;
- cochlear implants; and
- tissue cultures and transplants for burns.

The key organisation responsible for directing public funding of health-related R&D is the National Health and Medical Research Council (NHMRC). This funding is prioritised in line with anticipated major disease burdens in Australia. According to the Department of Health and Ageing (DoHA):

Considerable public funding is committed through the NHMRC for researching all forms of diseases and assessing how best to prevent, treat and cure them. The Australian government has boosted its commitment to Australian researchers by over \$220 million spread over the period 2004-05 to 2008-09. The funds are to be used to research the nation's major health problems, including cancer and heart disease. Projects are also to be funded which will tackle the obesity epidemic, including a study

of the activity patterns of pre-school children. There will also be financial support for research to identify the genes responsible for high blood pressure, multiple sclerosis, anxiety and depression. (sub. 34, p. 16)

However, given the small amount of local health-related R&D, most advances in medical technology in Australia are sourced from overseas.

Medical technology costs and prices

The price at which technologies are supplied will be influenced by the costs of research and development, manufacture, marketing and distribution, as well the costs of meeting regulatory hurdles such as marketing approval. Supplier prices are also likely to contain premiums conferred by patents and other intellectual property. Whether market premia are obtainable will depend on the degree of competition in the relevant market.

Prices finally received by producers will also reflect the demand side of the market. For example, Australia's reimbursement arrangements for PBS-listed medicines award market premiums based on their relative cost effectiveness as assessed by the PBAC, regardless of patent status.

As discussed above, concerns have been expressed about price differences for medical devices and some prostheses in the private and public hospital sectors. Differences could relate to differences in sales volumes or service levels or reflect a lack of buying power on the part of private insurers (influenced by legislated 'no-gap' arrangements). Differences could also reflect price discrimination based on market power conferred by patents or first-to-market advantage. But such producer market power is likely to be eroded over time as substitutes emerge (for example, there is evidence that the price of DES has fallen significantly (by around one-third) since the introduction of a competing device). Persistent price differences for the same technology would suggest either cost differences or a regulatory impediment to price convergence.

Prices for procedures will largely reflect the supply prices of specialists and other medical professionals, plus the costs of providing, equipping and staffing operating theatres and hospital beds.

Cost-increasing or cost-reducing technologies?

The supply of medical technology does not take place in a vacuum. Some studies have suggested that development of medical technology is biased towards cost-increasing innovation because of the availability of health insurance (public or

private). In other words, producers have little incentive to produce less expensive technologies where consumers have little incentive to seek out lower-cost treatments. Fuchs and Garber observe:

Health insurance increases demand for health care generally, but its most important effect on health care spending may be through its long-term influence on the development of new forms of care. And health-insurance subsidized care not only raises investment in medical research, but also changes the character of that investment, encouraging research on quality-improving innovations, rather than on cost-reducing ways to accomplish the same health outcomes as older interventions. (2003, p. 46)

Goddeeris (1984) argues that this response by investors is not necessarily a problem, provided the insurance arrangements correct a market distortion — that is, correcting a bias to consume too few health services. On the other hand, if insurance-cum-subsidy arrangements are overly generous and encourage too much consumption relative to the socially-optimal level (which is difficult to determine), then the supply of technology is likely to respond to the inappropriate signals.

From a global perspective, the Australian market for medical technology is very small, suggesting that the influence of Australian funding and technology reimbursement arrangements on global R&D and innovation is likely to be commensurately small. That said, if other countries benchmark their technology reimbursement decisions on prices paid in other countries, Australian arrangements might have a somewhat greater influence.

2.3 Conclusion

The market for medical technology is complex and deeply embedded in the institutional and incentive structures of the health system. There are many factors driving the demand for and consumption of health services and medical technology and many factors working to constrain it. Some of these factors reflect the community's high, and growing, valuation of good health, others may reflect distorted price signals, institutional funding and reimbursement arrangements and imperfect information.

One area where expenditure has grown especially rapidly — procedures in the private sector involving some prostheses, for example — has implications about the importance of consumer price signals (or lack of them) coupled with the incentives facing doctors to provide what they consider to be the best technology available. Rising demand linked to income growth and expectations, combined with incentives for consumers and their doctors to consider mainly the perceived benefits of new technologies, make for a potent mix, especially when some new technologies are relatively high cost.

Given the high value people place on maintaining or improving their health, it may still be the case that the benefits perceived by individual consumers of increased spending on new technologies exceed the costs. However, where poor information or institutional and financing arrangements distort technology choices, there is a possibility that from a society perspective the cost–benefit ratio is not being optimised.

Quantitative estimates of the impact of key demand and supply drivers on healthcare spending are presented in the following chapter.

FINDING 2.1

There are a number of drivers of demand for advances in medical technology. Key drivers are income growth, community expectations, population ageing, disease prevalence, the desire of and incentives facing medical practitioners to provide what they consider to be the best-available treatments, combined with limited consumer price signals.

The use of medical technology will reflect both the demand for and supply of medical technology, including the impact of constraints imposed by regulations and rationing mechanisms, such as budget constraints and waiting periods and any restrictions on the availability of skilled labour and other complementary inputs.

FINDING 2.2

The supply of medical technology does not take place in a vacuum. As in any commercial market, private R&D medical technology investment undertaken by ‘for-profit’ organisations largely responds to potential demand and profit expectations and is influenced by funding and insurance arrangements and regulation.

Advances in medical technology increasingly are being aimed at diseases of ageing (for example, cancers, dementia, arthritis) and diseases associated with lifestyle (for example, obesity-related diseases such as cardiovascular illnesses and diabetes).

3 Aggregate impact of medical technology on expenditure

The Commission has been asked (terms of reference (b)) to identify the net impact of advances in medical technology on health expenditure over the past ten years. This chapter assesses the impact of changes in medical technology at the aggregate level. The techniques available to quantify the impact of advances in technology are outlined in section 3.1. Sections 3.2 and 3.3 present the methodology and results of the Commission's modelling using the residual and direct approaches to quantify the impact of technological change. A more detailed description of the modelling is provided in technical paper 1.

3.1 Techniques to measure the impact of technology

Since Newhouse (1992) estimated that technological change could account for as much as 75 per cent of the increase in US health expenditure over several decades, technology has been widely cited as a major driver of the growth in healthcare expenditure. For example, in a survey of almost 50 health economists, Fuchs (1996, p. 8) found that 81 per cent agreed with the statement 'the primary reason for the increase in the health sector's share of GDP over the past 30 years is technological change in medicine'.

A major difficulty in quantifying the impact of technology on health expenditure is that health technology, broadly defined, is not directly observable. Some partial measures are available — new pharmaceutical listings, for example — but these do not capture broader advances in technology such as improvements in clinical devices or procedures.

Two techniques have been devised that attempt to circumvent this problem (Pammolli et al. 2005):

- the residual approach — which quantifies the impact of other determinants of health expenditure and attributes the unexplained component to advances in medical technology; and
- the direct approach — which specifies a proxy measure for technology.

The Commission has attempted to model the impact of medical technology on Australian healthcare expenditure using both techniques. The limitations of these techniques — particularly their sensitivity to the choice of other determinants of health expenditure for which to control — should be kept in mind when considering the results. Nonetheless, both techniques provide support for the proposition that technological change has been an important driver of the growth in health expenditure over the past decade.

The impact of technology on healthcare expenditure is a function of the policy environment that prevailed over the decade. Policy constraints governing the adoption of new technologies — for example, health technology assessment arrangements and other externally-imposed rationing mechanisms — have influenced the magnitude of the impact of technology on expenditure (chapters 2, 8, 9 and 10). Further, the broader institutional framework of the health system, including the division of funding responsibilities, has also affected the uptake of new technology and the types of technology adopted (chapter 4). Therefore, the estimates presented in this chapter are estimates of the impact of technology on net health expenditure *given* these policy constraints.

Focusing on the aggregate impact of technology can obscure the ways in which individual technologies have affected healthcare expenditure. The impacts of individual technologies are discussed in more detail in chapter 4. The analysis in this chapter attempts to capture the broader impact of technological change across all technologies. Further, this chapter makes no attempt to canvass the benefits provided by medical technologies. Discussions of the benefits and cost effectiveness of new technologies are presented in chapters 5 and 7 respectively.

3.2 The residual approach

The impact of technology change on healthcare expenditure can be modelled as a ‘residual’. This approach was pioneered by Feldstein (1971) and Fuchs (1972). Using the residual approach, the impacts of changes in other factors — inflation, income and demographics, for example — are quantified and the unexplained or residual component is attributed to changes in medical technology.

The residual method is the most widely-used method for quantifying the impact of technology on healthcare expenditure. Its major attraction lies in the fact that it circumvents the need to specify a direct measure of technology. Also, it captures the impact of changes in general technologies that are applied in the health sector (such as information technology and knowledge).

The residual approach should only be considered a rough guide to the magnitude of the impact of technology on expenditure. It will never be possible to achieve a perfectly ‘clean’ estimate of the residual, because the impact of some other factors that cannot be quantified — lifestyle, environment and education, for example — will also be captured in the unexplained component along with technology.

A further limitation of the approach is the sensitivity of the sign and size of the residual to assumptions made about the elasticities (the responsiveness of healthcare expenditure to changes in its determinants). There is considerable uncertainty about these elasticities, even for the most important and widely researched determinants of expenditure such as prices and income (chapter 2).

An implicit assumption of the residual approach is that the growth rates of the determinants of healthcare expenditure are independent of one another. However, it is likely that there is interaction between the growth rates of these variables — between ageing and technological change and income growth and technological change, for example. This makes it very difficult to disentangle the impacts of particular components. These overlaps, and the potential impact on the Commission’s residual estimates, are discussed in more detail in the modelling section of this chapter.

Previous studies

Table 3.1 summarises a number of key previous residual studies, including Australian studies. There is a range of variables that have been controlled for across studies as well as a broad range of elasticities assumed for some of the factors, such as income. In general, the more factors considered and the higher the elasticities assumed, the smaller the resulting residual attributable to technology.

Care must be taken in comparing results across studies. The starting health expenditure series (nominal, real or real per capita) (box 3.1), the time period chosen and whether the residual is calculated as an average annual growth rate or percentage of the total increase (technical paper 1), will have a bearing on the magnitude of the estimated residual.

Many of the earlier residual studies presented in table 3.1 span time periods prior to 1970, when technological progress in medicine was arguably slower than it has been in more recent decades, see for example, Cutler (2004). Nonetheless, all the studies — with the exception of Mushkin and Landefeld (1979) — find that the technology residual has a significant and positive impact on health expenditure.

Table 3.1 Some key residual studies

<i>Study</i>	<i>Expenditure data</i>	<i>Determinants of growth</i>	<i>Magnitude of the residual</i>
Cutler (1995)	Real US healthcare expenditure per capita 1940–1990	<ul style="list-style-type: none"> • Excess health inflation • Private insurance • Income growth • Ageing • Administration costs 	49% of total percentage increase in health expenditure
Fuchs (1972)	Nominal US health expenditure 1947–1967	<ul style="list-style-type: none"> • Population growth • Inflation (general and excess health) • Income growth 	0.6 percentage points of the annual growth in health expenditure (7.5% of the average annual growth in expenditure)
KPMG Consulting (2001)	Nominal Victorian inpatient expenditure 1996-97 to 1999-00	<ul style="list-style-type: none"> • Population growth • Ageing and gender • Inflation • Dialysis 	1.7 percentage points of the annual growth in health expenditure
Mushkin and Landefeld (1979)	Nominal US health expenditure 1930–1975	<ul style="list-style-type: none"> • Population growth • Ageing • Inflation (general and excess health) • Income growth • Third-party payments 	-0.5 percentage points of the annual growth in health expenditure
Newhouse (1992)	Real US personal health expenditure per capita 1929–1990	<ul style="list-style-type: none"> • Ageing • Private insurance • Income growth • Supplier-induced demand 	>50% of the total percentage increase in health expenditure
Oxley and MacFarlan (1994)	Real health expenditure OECD countries 1960–1990	<ul style="list-style-type: none"> • Ageing • Income growth • Public insurance 	40% to 79% of total percentage increase in average OECD health expenditure (income elasticity of 1 and 0.2, respectively)
Mohr et al. (2001)	Real personal US health expenditure 1960–1998	<ul style="list-style-type: none"> • Population growth • Inflation (general and excess health) 	Estimates range from 4% to 64% of the average annual growth in health expenditure across years
Smith,S (2001)	Real per capita US health expenditure 1940–1990	<ul style="list-style-type: none"> • Excess health inflation • Income • Ageing • Insurance • Supplier-induced demand 	2.2 percentage points of the annual growth in health expenditure
Wanless (2001)	Nominal UK health expenditure 1977–2000	<ul style="list-style-type: none"> • Population growth • Ageing • Inflation (general and excess health) 	1.9 percentage points of the annual growth in health expenditure (19% of the average annual growth in expenditure)

Box 3.1 **The choice of health expenditure series: a stylised example**

The choice of health expenditure series used as a starting point for the residual approach needs to be taken into account when comparing estimates across studies. When residual estimates are expressed as a percentage of the growth in health expenditure, the magnitude of the residual will differ with the starting series.

Suppose that two residual studies were carried out using the same underlying health expenditure data over the same time period. One study (Study A) used nominal health expenditure as its starting point (with an average annual growth rate of 10 per cent per annum), while Study B used real health expenditure per capita (with an average annual growth rate of 5 per cent per annum).

Both studies control for the impact of ageing and income growth when estimating the residual. Study A also controls for the impact of inflation and population growth. In Study B, these are already controlled for by using real per capita health expenditure as the starting series. Thus, both studies produce identical estimates: the residual has accounted for 2 percentage points of the average annual growth in health expenditure over the period.

However, if the results are expressed as a percentage of the average annual growth in the original series, the residual estimate is 20 per cent in Study A and 40 per cent in Study B. So, even though the results of these studies are actually identical, the percentages differ because of the different starting series. Thus, estimates presented in this manner are not directly comparable across studies using different health expenditure series.

<i>Study A: Nominal health expenditure</i>		<i>Study B: Real health expenditure per capita</i>	
	Percentage points		Percentage points
Nominal health expenditure	10	Real health expenditure	5
Inflation	3		
Population growth	2		
Ageing	1	Ageing	1
Income growth	2	Income growth	2
Residual	2	Residual	2

The Commission's modelling

The Commission has applied the residual approach to real Australian healthcare expenditure (both public and private) to provide a rough guide to the impact of technology on expenditure over the previous decade. Real health expenditure has been chosen as the starting point for the residual calculation because it makes the 'real' impact of technology (independent of changes in economy-wide prices) more apparent. The residual is calculated for the period 1992-93 to 2002-03.

A more comprehensive discussion of the data and methodology is presented in technical paper 1.

Methodology

A key determinant of the magnitude of the residual is the choice of other determinants of healthcare expenditure for which to control. The justification for the inclusion of particular determinants may be based on data availability, theoretical grounds (Newhouse 1992) or drawn from prior quantitative analysis (Ringel et al. 2002).

The Commission has attempted to quantify the major drivers, decomposing the growth in real health expenditure into the impact of:

- population growth;
- ageing and gender shifts; and
- income (GDP) growth.

The justification for the inclusion of these determinants is presented in technical paper 1.

Other potential determinants of the quantity of healthcare demanded — private health insurance coverage and consumer out-of-pocket payments — were also investigated by the Commission. Increases in the proportion of the population covered by private health insurance since 2000 have been associated with an increase in the number of services performed and benefits paid (chapter 2). However, very little information exists about the magnitude of the relationship between private health insurance coverage and total health expenditure. Thus, there are considerable difficulties in choosing an appropriate elasticity for this variable (technical paper 1). For this reason, the estimates reported in the following section exclude the private health insurance coverage variable. Estimates of the residual controlling for this variable are reported in technical paper 1.

Increases in consumer out-of-pocket payments — for example, co-payments for medicines and gap payments for medical services — may moderate demand for some health services. The task of compiling an aggregate measure of out-of-pocket expenditure is complicated by the existence of safety nets for both pharmaceuticals and medical services. Further difficulties exist in choosing an appropriate price elasticity with respect to out-of-pocket payments, although the limited evidence available suggests that these are probably quite low (chapter 2). For these reasons the Commission has not controlled for the impact of out-of-pocket payments in calculating the residual. However, to the extent that these payments have grown

over the decade, the residual estimates reported may be understated (with the degree dependent on the price elasticity of demand).

Another potential demand-side driver of health expenditure is changes in the incidence and prevalence of disease over time. Growth in the prevalence of chronic diseases such as cancer, or conditions strongly related to ageing, such as cataracts, are controlled for to some degree in the residual analysis by controlling for the ageing of the population. However, changes in disease prevalence which are partly influenced by lifestyle — higher prevalence of diabetes in younger people, for example — are not controlled for in estimating the residual.

The Commission also investigated controlling for supply-side drivers of health expenditure, such as excess health inflation and the number of medical personnel. Factoring out excess health inflation controls for the growth in real health expenditure generated by the faster than average growth in the price of healthcare over the last ten years. A significant component of the health price index is medical wages, so the excess health inflation series may reflect the ability of healthcare professionals to raise their income relative to the rest of the economy (Oxley and McFarlan 1994).

However, there are well-documented concerns about the construction of health price indexes (Berndt et al. 2000). For this analysis, the major limitation of the index is that it does not adequately control for quality improvements over time (Wanless 2001). To the extent that improvements in quality are driven by advances in technology, this will imply that the expenditure impacts of new technologies are captured to some degree in the health price index. For this reason, the estimates reported in the following section exclude the excess health inflation variable. Estimates of the residual controlling for this variable are reported in technical paper 1.

Another factor often cited as a supply-side driver of health expenditure is the number of medical personnel, particularly practitioners. However, this will only impact on health expenditure to the extent that the number of practitioners influences servicing levels and behaviour. Newhouse (1992) and Oxley and MacFarlan (1994) claim that this may occur through supplier-induced demand (SID), in particular, if the number of practitioners provides incentives for them to over-service consumers to maintain their income levels.

In a review of the empirical evidence regarding the impact of SID in Australia, Bickerdyke et al. (2002) note:

There does not appear to be any robust and reliable evidence on the likely magnitude of SID, although most existing studies suggest that, where SID arises, it is small both in absolute terms and relative to other influences on the provision of medical services. (p. xiv)

Further, per capita numbers of general practitioners — arguably the group with the biggest potential to oversupply health services — have remained reasonably stable in the last decade (chapter 2). This suggests that SID is unlikely to be a significant determinant of health expenditure growth and thus is not controlled for when estimating the residual.

An increase in practitioners may also affect health expenditure if practitioner numbers were previously constrained, leading to unmet demand. In this case, relaxing the constraint will allow more patients to be treated, thus increasing expenditure. With specialist numbers increasing over the decade (chapter 2), it is possible that for some treatments or procedures supply-side constraints have been relaxed. However, without information about the location and particular specialities in which the increases have occurred, it is difficult to assess the impact on final health expenditure. For this reason, specialist numbers are not controlled for when estimating the residual.

Choice of elasticities

Assumptions made about the responsiveness of healthcare expenditure to changes in the determinants of expenditure also affect the magnitude of the residual. For population growth, the standard assumption is of a one-to-one pass through to healthcare expenditure, or an elasticity of one.

The impact of age and gender is modelled by assuming the present age and gender profile of expenditure applied in the past, consistent with the Commission's ageing study (PC 2005a). However, if technology has acted to steepen the age-cost profile over the decade — for example, if the availability of expensive new technologies to treat chronic diseases has increased per capita expenditure at a greater rate for older age groups compared to younger age groups — then the impact of ageing may be understated (and the residual overstated) using this assumption.

On the other hand, an alternative method of controlling for the impact of age on past health expenditure, taking into account the cost of death, finds that ageing has had a smaller impact on past spending. This method and the resulting residual estimates are presented in technical paper 1.

There is considerable uncertainty about the appropriate elasticity with respect to income (Getzen 2000). It is generally agreed that there is a positive relationship between income and healthcare expenditure. However, there is still considerable debate about the magnitude of the elasticity.

For this reason the Commission has estimated an upper and lower bound for the residual based on a plausible range of income elasticities. The upper bound of the residual is based on the assumption of an income elasticity of 0.2, based on the findings from the RAND health insurance experiment (Manning et al. 1987; Phelps 1992). The lower bound is based on an income elasticity of one, which has been widely adopted in other early studies (Fuchs 1972; Mushkin and Landefeld 1979; Newhouse 1992).

The higher income elasticity estimates (of one and greater) have tended to come from macro studies (using time series or international cross-section data) which are more relevant to the Commission's analysis than the micro level RAND study. However, adopting these higher elasticity estimates in the residual calculation may overstate the proportion of growth attributable purely to income (and understate the residual) because these estimates capture the interaction between income and technological change (box 3.2) The impacts of technological change and income growth on health expenditure are inherently interrelated:

- increased demand for better health outcomes can only be met by improvements in technology in the long run; but
- new, more expensive technologies will only be developed and used when society is willing to pay for improved health outcomes from their growing incomes (box 3.2).

In recognition of the fact that an income elasticity of one may be too high (because of the interaction between income and technological change), while an elasticity of 0.2 is probably too low (because it is based on individual decision making), a mid-range estimate based on an elasticity of 0.6 is presented as the preferred estimate.

Box 3.2 **Interaction between income growth and technological change**

The impact of technological change and income growth on health expenditure are inherently interrelated. Hall and Jones (2004) show that health expenditure growth will occur when rising incomes (and preferences that accommodate rising health share) are accompanied by advances in medical technology. Consider the following:

If incomes were to rise, yet technology were to remain static, it is unlikely that health expenditure would rise in proportion with the rise in income. Although willingness to pay for improved health outcomes could certainly rise proportionately with income (or even more) (Hall and Jones 2004), in the absence of new, improved technology, the desire for better health would remain largely unsatiated. Health expenditures may rise in line with incomes initially, as treatment thresholds are lowered and/or waiting lists reduced. However, eventually the benefits available from existing treatments would be fully exploited and health expenditures would rise less than income growth (everything else being equal).

Applying the example in the other direction:

If improved but highly expensive technologies were developed with incomes static, it is unlikely that there would be as much use of these technologies as expenditure on other goods and services would have to fall to accommodate their consumption. Growth in health expenditure in this case would be limited despite the new technologies. Further, profit-seeking manufacturers would have less incentive to develop cost-increasing technologies that improve health outcomes in the future.

Implications for estimates of income elasticities

Aggregate level studies (using time series or international cross sectional data) have tended to produce income elasticity estimates of one or greater (Gerdtham 1992 and Newhouse 1977, for example). This tendency for health expenditure to grow at least proportionately with income suggests:

- the willingness to pay for improved health outcomes has risen at least proportionately with income; and
- new or improved treatments have permitted these desired health expenditures to occur.

Thus, the magnitude of the historical relationship between income and health expenditure growth reflects the interaction of income growth and technological change (Oxley and McFarlan 1994; Ringel et al. 2002).

To adopt these high income elasticities to estimate the historical impact of income on health expenditure could lead to the role of technology (captured in the residual) being understated. However, any apportioning of increases in health expenditures between income and technology will be arbitrary. For this reason, the Commission has estimated the residual using a range of income elasticities.

The estimated residual

The residual, including technology, is estimated to have contributed 1.9 percentage points to the 5.3 per cent annual growth in real health expenditure over the past decade, equating to 36 per cent of the total growth in real health expenditure over this period (based on the preferred elasticity estimate of 0.6). However, the residual estimate is sensitive to the choice of income elasticity, ranging between a 0.9 and 2.9 percentage point contribution to annual growth (based on elasticities of 1 and 0.2 respectively). This equates to between 17 and 56 per cent of the average annual growth in health expenditure over the period (table 3.2).

In monetary terms, the mid-range estimate of the residual is equivalent to about \$510 of additional health expenditure per person in 2002-03 compared with 1992-93. Again, this figure falls within a wide range of \$220 to \$820 of additional spending per person, representing the lower and upper bound of the residual respectively.

Table 3.2 The technology residual 1992-93 to 2002-03^a

	<i>Annual growth in health expenditure attributable to the residual^b</i>	<i>Per cent of average annual growth in health expenditure attributable to the residual</i>
	Percentage points	%
Lower bound ^c	0.9	16.9
Mid-range ^d	1.9	36.4
Upper bound ^e	2.9	55.8

^a The residual is calculated from real health expenditure data. The effects of population growth, age and gender shifts and GDP growth have all been controlled for. ^b Represents the percentage point contribution of the residual to the annual growth in real health expenditure of 5.3 per cent. ^c The lower bound is based on the assumption of an income elasticity for healthcare of one. ^d The mid-range is based on the assumption of an income elasticity for healthcare of 0.6. ^e The upper bound is based on the assumption of an income elasticity for healthcare of 0.2.

Source: Commission estimates.

Using the alternative method for controlling for the impact of population ageing (see above) increases the mid-range residual estimate to 43.3 per cent. This is discussed in more detail in technical paper 1.

The estimates are in the broad range of previous studies (table 3.1). As the Medical Industry Association of Australia noted:

US studies using the residual method have shown wide variation in the ‘contribution’ of medical technology, from less than 5% to over 60%. (sub. 17, p. 18)

The Commission’s ageing report (PC 2005a) found that non-demographic drivers of health expenditure growth, including technology, accounted for

between 0.3 and 0.9 percentage points of the growth in *government* health expenditure (excluding Pharmaceutical Benefits Scheme (PBS) expenditure), depending on the time period chosen (box 3.3). These are not directly comparable to the estimates reported in table 3.2 because of differences in the time period and the starting health expenditure series (government health expenditure, excluding PBS compared to total health expenditure). In particular, excluding the impact of the PBS (which has grown more strongly than average health expenditure over the decade) will place a downward bias on the non-demographic growth rate.

Box 3.3 The non-demographic growth rate in the Commission's ageing report

The Commission's ageing report (PC 2005a) estimates the non-demographic growth in government healthcare expenditure (excluding PBS) over various periods. The non-demographic growth rate is calculated by controlling for the impacts of ageing and population growth on healthcare expenditure. The growth rate is reported as a 'premium above GDP', which also controls for the impact of income growth (implicitly an income elasticity of one). The non-demographic growth rate captures the impact of other determinants of healthcare expenditure, including technology.

The Commission's estimates suggest that the non-demographic growth rate contributed between 0.3 and 0.9 percentage points to the 4 to 5 per cent real growth in government healthcare expenditure, depending on the time period chosen.

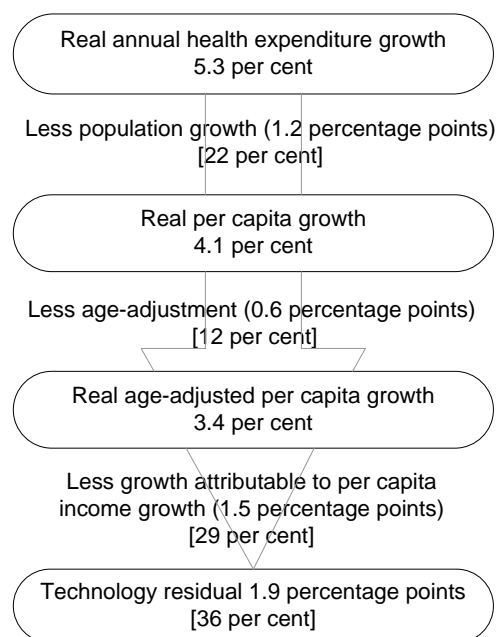
Source: PC (2005a).

The estimates presented in table 3.2 suggest that while technology has been a major driver of the annual growth in real healthcare expenditure over the period 1992-93 to 2002-03 (based on the preferred elasticity estimate of 0.6), it has by no means been the only driver. Growth in income has also been an important contributor, accounting for about 29 per cent of the average annual growth in health expenditure over this time. Population growth has also had a significant impact, accounting for over 22 per cent of growth. Population ageing accounted for 12 per cent of the average annual growth over the decade (box 3.4). However, using the alternative method to control for ageing, taking into account the cost of death (see above), the estimated contribution of population ageing shrinks to just 5 per cent of the growth in health expenditure (technical paper 1).

However, as discussed, the likely interaction between the growth rates of each of these variables, in particular ageing and technology and income growth and technology, should be kept in mind when considering their estimated contributions to growth.

Box 3.4 Derivation of the technology residual, 1992-93 to 2002-03

The average annual compound growth in real health expenditure from 1992-93 to 2002-03 is decomposed into the impacts of: population growth; ageing; and GDP growth. An income elasticity of 0.6 is assumed, consistent with the mid-range estimates in table 3.2.



Source: Commission estimates.

The estimates presented in table 3.2 and box 3.4 provide a ‘snapshot’ of the residual based on the growth in expenditure over the given ten-year time period. However, the impact of the residual varies according to the period chosen.

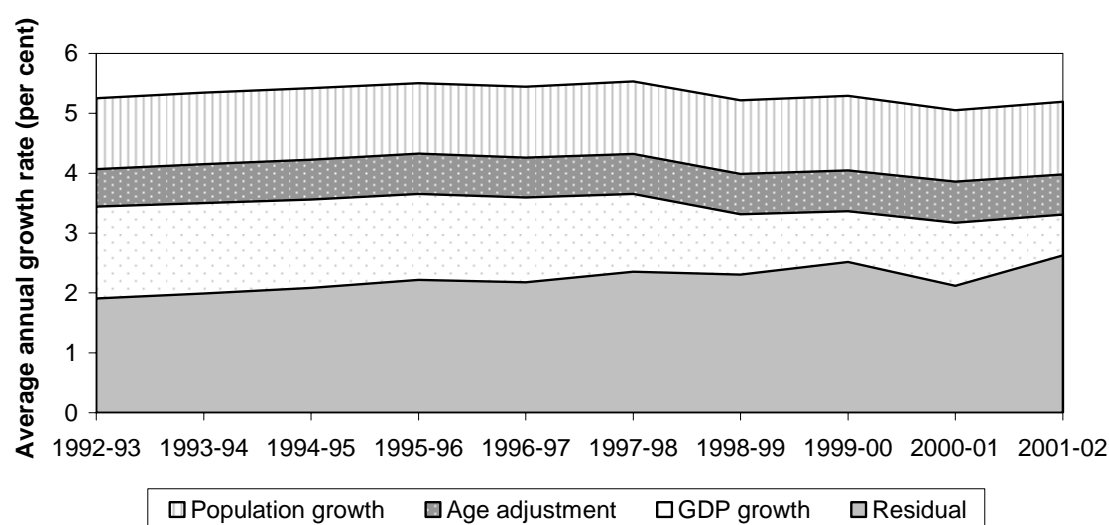
Figure 3.1 illustrates the average annual compound growth in real health expenditure and its determinants between 1992-93 to 2001-02. For each year, the average growth rate is calculated between that year and 2002-03. For example, the growth rate in real healthcare expenditure reported in the chart for 1995-96, is the average annual growth rate in real health expenditure over the seven year period 1995-96 to 2002-03.

The average annual growth in real health expenditure is reasonably stable across the ten-year period, varying between 5.0 and 5.5 per cent. However, as a proportion of this growth, the residual has increased steadily from 36 per cent over the ten-year period to 51 per cent between 2001-02 and 2002-03 (based on an income elasticity of 0.6).

Shactman et al. (2003) also found there was an increase in the contribution of technology to hospital spending growth in the United States. One explanation they offer is that some of the offsetting cost savings produced by technologies — reductions in the length of hospital stays through less invasive surgery, for example — have levelled off, as the ability of new technologies to generate these types of saving has moved toward its feasible limit (Shactman et al. 2003). However, there is no evidence that this is yet the case in Australia, with the average length of hospital stay falling each year between 1996-97 and 2002-03 (DoHA 2005b).

Further decomposition of the residual suggests that increased private health insurance coverage, rather than technological change per se, was the main driver of the higher residual growth rate in the late 1990s (technical paper 1). However, the positive relationship between health expenditure and insurance coverage can be explained to some extent by the fact that patients with private insurance have higher use of newer, more expensive technologies (chapter 2).

Figure 3.1 The residual over time^{a,b}



^a For each year displayed on the axis, the average annual growth rate is calculated between that year and 2002-03. ^b The growth rate presented for 2001-02, is based on a single year of growth (2001-02 to 2002-03), and hence is more subject to statistical fluctuations than the growth rates calculated by averaging over longer periods.

Data source: Commission estimates.

3.3 The direct approach

The direct approach to quantifying the impact of technology on health expenditure is based on specifying a proxy for technological change. The obvious drawback of this approach is that it is the impact of the proxy (rather than technology itself) on health expenditure that is being quantified. The results can only be generalised to the extent that a ‘good’ proxy is chosen.

Previous studies

A number of studies have used econometric techniques to quantify the impact of determinants of health expenditure (not necessarily including technology). Early papers (for example, Getzen (1992)), regress health expenditure against its hypothesised determinants across countries and time. However, Hansen and King (1996, p. 130) argue that the results obtained in these studies ‘may be misleading, or even completely spurious’ because most of the variables included in the models are non-stationary, thus violating one of the key assumptions of ordinary least squares regression.

More recent papers have applied modern time series techniques — in particular, unit root testing, cointegration and error correction models — to health expenditure data (for example, Gerdtham 1992; Gerdtham and Löthgren 2000; Murthy and Ukpolo 1994; and Roberts 1998). The determinants of healthcare expenditure considered in these models include: GDP; the relative price of healthcare; the percentage of public financing of healthcare; the number of practising physicians per head of population; and the fraction of aged in the population. Technology, often cited as a major driver of expenditure, is conspicuously absent from these models. This has been rectified to some extent by recent papers by Blomqvist and Carter (1997), Di Matteo (2005), Dreger and Reimers (2005) and Okunade and Murthy (2002).

Okunade and Murthy (2002) use total US research and development (R&D) and US health sector R&D expenditure as proxies for technological change. They find evidence of a stable long run (cointegrating) relationship between real US health expenditure per capita, real GDP per capita and technological change in the United States between 1960 and 1997.

Dreger and Reimers (2005) adopt a similar approach, using three proxies for medical progress: life expectancy; infant mortality; and the percentage of the population older than 65. They find a cointegrating relationship between real health expenditure per capita, real GDP per capita and each of the technological change proxies across 21 OECD countries.

Di Matteo (2005) uses non-linear modelling of time effects as a partial proxy for technological change. Regressing real per capita health expenditures in the United States and Canada on age distribution, income, province/region specific indicators and time, he finds that, once technological change is accounted for, ageing and income explain a relatively small proportion of expenditure variation. Similarly, Blomqvist and Carter (1997) adopt a linear time trend to account, at least in part, for the impact of technological change on health expenditure. Using annual data across a cross section of OECD countries, they find that technological change (as proxied by the time trend) accounts for 2 percentage points of the annual growth in real health expenditure.

The Commission's modelling

The Commission has estimated the impact of technology on Australian health expenditure using US health R&D spending as a proxy for technological change. The Commission's econometric methodology largely follows the approach of Okunade and Murthy (2002). A comprehensive discussion of the data and methodology is presented in technical paper 1.

R&D spending is a popular proxy for technological change because of the long time series available (OECD 2001). Some have criticised the use of R&D as an innovation indicator on the basis that R&D is an input to the commercialisation process and thus does not reflect the introduction of new products or services (Centre for Health Economics Research and Evaluation, sub. 9; Kleinknecht et al. 2002; MIAA sub. PR54). However, providing the average efficiency of firms in transforming R&D expenditures into commercialised new products or processes remains stable over time, this criticism does not invalidate the use of R&D as an innovation indicator. (However, if this efficiency has deteriorated over time — due to regulatory barriers, for example — then the impact of technology will be understated by our analysis.¹) Further, Kleinknecht et al. (2002) demonstrate a reasonable correlation between absolute values of R&D indicators and other common innovation indicators such as patent applications and expenditure on innovation.

The Commission has chosen to use US health R&D expenditure because the United States accounts for just under half of the world's health R&D activities (Global Forum for Health Research 2004). In the absence of time series data on global

¹ The Commission's analysis assumes that the relationship between US Health R&D and health expenditure over the last decade is the same as the average relationship between these variables over the 32-year estimation period.

health R&D, US health R&D represents the best measure of spending on health-related technological innovation over time.

Other possible proxies, such as specific medical equipment measures or patents for a particular set of technologies,² do not provide a sufficiently comprehensive measure of technological change, given the broad definition of technology adopted in this study (chapter 1). A more comprehensive measure — Therapeutic Goods Administration approvals — was investigated by the Commission, but could not be used because of a lack of time series data. Also, such a measure would still exclude important technological innovations, such as new procedures.

Finally, outcome-based proxies, such as life expectancy and the proportion of the population greater than 65 (used in Dreger and Reimers 2005), are not considered good proxies in this context for two reasons. First, these series reflect demography and population health more broadly, and thus observed changes over time may be driven by a myriad of factors other than advances in medical technology. Second, these series would be expected to be related to health expenditure for other reasons. For example, the proportion of the population over 65 will be positively related to health expenditure because older people use more health services. So any estimated relationship between the proxy and health expenditure can not be attributed only to the impact of technology.

Methodology

For the econometric approach, just as for the residual approach, the determinants of expenditure controlled for have a large bearing on the estimated impact of technology.

The Commission has chosen to focus on the following key determinants of real per capita healthcare expenditure:

- GDP growth;
- the proportion of the population older than 65;
- health sector inflation in excess of economy-wide inflation;

² MIAA (sub. PR54) suggests that the number of patents might be a more appropriate measure of innovation than R&D expenditure for the medical devices industry. However, this suffers a similar limitation to the R&D proxy in that it requires the assumption that the number of patents filed to those commercialised is constant over time. Nonetheless, the Commission investigated using US medical technology patents as the technological change proxy. However, the only easily accessible database that provides this type of information, the National Bureau of Industry Economics database (Hall et al. 2001), only reports data for patents granted prior to 1999.

-
- the proportion of the population with private insurance; and
 - technological change (US health R&D).

These are similar to the determinants controlled for in the residual approach (section 3.2; technical paper 1). The key differences are that under the direct approach:

- population growth is not controlled for because the starting point is real *per capita* health expenditure;
- the impact of technology is quantified directly through the R&D proxy; and
- ageing is measured by the proportion of the population older than 65, whereas in the residual approach it is controlled for using more complex adjustments based on assumptions about the age and gender expenditure profile (technical paper 1).

Prior to testing for relationships between health expenditure and its hypothesised determinants, the Commission used various tests (unit root and structural break tests) to establish the time series properties of each series. Cointegration tests were used to test for stable, long-term relationships between the variables. Details about the unit root, structural break and cointegration tests can be found in technical paper 1.

The impact of technology

Stable long-term relationships are found between health expenditure, GDP, private health insurance coverage and technology. The proportion of the population older than 65 is not found to be a significant factor in the growth in real per capita health expenditure. This finding is consistent with a number of other econometric studies of the determinants of health expenditure including Gerdtham et al. (1992), Hitiris and Posnett (1992), Richardson and Robertson (1999) and Moise and Jacobzone (2003). Similarly, the Commission's ageing report (PC 2005a) found that ageing had played a limited role in *historical* health expenditure growth.

One explanation is that the historical expenditure impact of an ageing population has been offset to some degree by a decline in the cost of dying, driven by the fall in the death rate over the last 35 years. For example, if hospital costs associated with the end of life are controlled for in the residual analysis, ageing is estimated to account for just 5 per cent of the average annual growth in health expenditure over the decade (technical paper 1). It should be noted that demographic change can be expected to have a much more significant impact on health expenditure in the future as both the degree of ageing and the death rate are projected to increase (technical paper 1).

Other explanations of why ageing may not show up in this type of analysis — institutional rationing, for example — are explored in the Commission's ageing report (PC 2005a). Estimates from the model with ageing included are presented in technical paper 1. Excess health inflation is not included in the final model because of concerns about its measurement (section 3.2) and because the series was found to have a structural break.

The elasticity of real health expenditure per capita with respect to technological change is estimated to be 0.25. This implies that a 1 per cent increase in expenditure on health R&D translates to a 0.25 per cent increase in real per capita health expenditure. Okunade and Murthy (2002) estimate an elasticity of 0.32 of US per capita health expenditure with respect to technological change (using the same proxy).

The model implies that technological change has contributed 1.9 percentage points to the annual growth in real healthcare expenditure of 5.3 per cent over the last decade (1992-93 to 2002-03) or 36 per cent of the annual growth in real healthcare expenditure during this period. Coincidentally, this is the same as the mid-range residual estimate. This estimate of the contribution of technological change to health expenditure falls within a wide range of statistically plausible values, from 0.4 percentage points at the lower bound to 3.4 percentage points at the upper bound.³ This range is similar (although slightly wider) than the range estimated for the contribution of technology using the residual approach.

FINDING 3.1

The Commission's modelling provides support for the proposition that advances in medical technology have been a major driver of the growth in real healthcare expenditure over the past ten years. Advances in technology are estimated to have contributed about one-third of the average annual growth in real health expenditure over the period. Other important contributors to the increase in health expenditure include population and income growth and, to a lesser extent, past ageing of the population and rising private health insurance coverage.

³ Calculated based on the 95 per cent confidence interval for the coefficient on the R&D variable.

4 Individual technology expenditure impacts

This chapter assesses the impact of some individual technologies on Australian healthcare expenditure over the last decade. The ‘bottom up’ analysis presented in this chapter complements the aggregate level ‘top down’ analysis in chapter 3. These chapters together form the Commission’s response to the terms of reference (b) which requires it to consider the net impact of advances in medical technology on healthcare expenditure over the past ten years.

While this chapter focuses on identifying the impact of new technologies on observed changes in spending on particular health interventions, it should be kept in mind that other factors, such as income, population growth and, to a lesser extent population ageing, will have also played a role in the changes in expenditure (chapter 3). Further, this chapter makes no attempt to canvass the benefits from advances in medical technology. These are detailed in chapter 5.

The impacts of advances in technology on two key drivers of health expenditure, namely pharmaceuticals and inpatient care, are discussed in section 4.1. The expenditure impacts of some individual innovations are discussed in section 4.2. For some of the technologies used as case studies, the Commission has attempted a quantitative analysis of their expenditure impacts. Further details about the assumptions and methodology used to estimate these impacts are provided in technical paper 2.

Section 4.3 addresses terms of reference (e), which requires the Commission to consider the impact of advances in technology on the distribution of costs and financial incentives across different parts of the health system. In particular, this section considers how the cost burden of new technologies has affected their diffusion.

4.1 Which technologies have driven the increase in healthcare expenditure?

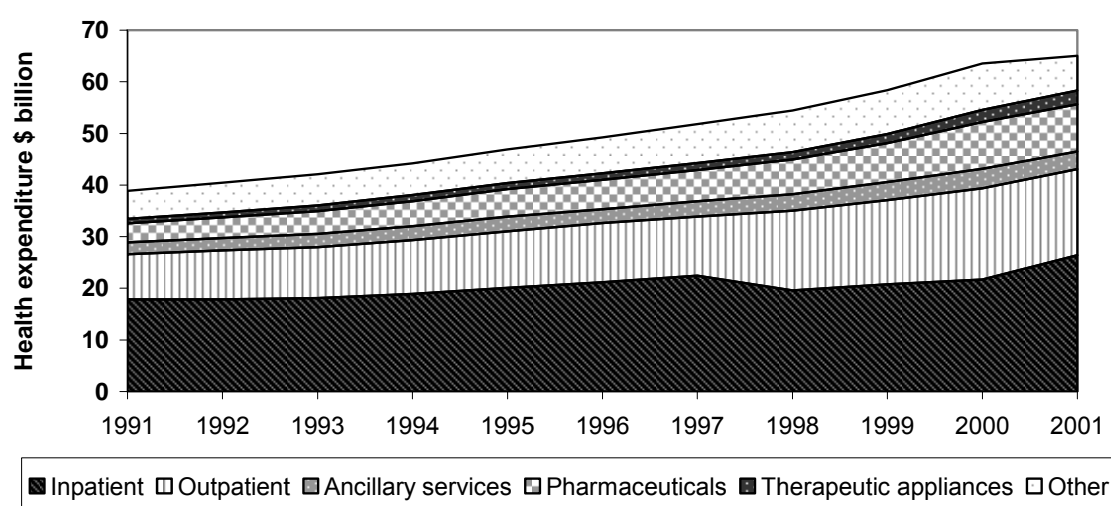
Disaggregating health expenditure data by area of expenditure can provide some insight into the types of technologies that have been major contributors to the

growth in expenditure over the last decade. The key advances in this respect are those which:

- were adopted in areas of the health system accounting for a large share of total health expenditure; or
- produced strong expenditure growth in significant areas of health expenditure.

Figure 4.1 shows real total health expenditure in Australia between 1991 and 2001 by area of expenditure.¹

Figure 4.1 Real healthcare expenditure by area of expenditure, 1991 to 2001^a
2000-01 prices



^a 'Inpatient' reflects total inpatient expenditure on curative and rehabilitative and long-term nursing care. 'Outpatient' includes physician, dental and other outpatient expenditure. 'Pharmaceuticals' and 'therapeutic appliances' refer to expenditure on these services by outpatients only. Spending on these services within the hospital system is captured under the inpatient category.

Data source: OECD (2005d).

Real expenditure on each area of the health system increased over the period 1991 to 2001 (figure 4.1). Total health expenditure increased by 67 per cent (an average of 5.2 per cent per year) over this time. Inpatient care (curative, rehabilitative and long-term) was the largest category of expenditure, accounting for over 40 per cent of total expenditure in 2001. Thus, advances in technology that

¹ More recent health expenditure data disaggregated by area of expenditure are available in Australian Institute of Health and Welfare (AIHW 2004d) (see overview). Organisation for Economic Cooperation and Development (OECD 2005d) data are presented in this chapter because an expenditure breakdown by inpatient and outpatient categories is required.

have had a significant impact on increasing expenditure in this area are likely to have played an important role in the growth in overall health expenditure.

The two fastest growing categories of expenditure were pharmaceuticals and therapeutic appliances, which increased by 147 per cent and 204 per cent respectively. However, therapeutic appliances — medical durables such as glasses, hearing aids and orthopaedics and other prostheses external to the user — account for such a small proportion of total health expenditure (4.1 per cent in 2001), that advances in technology in this area could not have had much impact on total health expenditure. Technological advances responsible for the growth in pharmaceutical expenditure (14 per cent of total health expenditure in 2001), on the other hand, are likely to have played a more important role in aggregate health expenditure growth.

The impact of technological advances on two of the areas identified as key drivers of the growth in health expenditure — pharmaceuticals and inpatient care — are discussed in more detail below.

Pharmaceuticals

The Pharmaceutical Benefits Scheme (PBS) accounted for around 50 per cent of pharmaceutical expenditure in Australia in 2002-03 (in terms of both government and patient contributions) (DoHA 2004a; table 8.5). The real cost of pharmaceuticals funded by the PBS increased by an average of 9.1 per cent annually between 1993-94 and 2003-04. Rising expenditure on pharmaceuticals can be attributed to both increases in volume and cost. Table 4.1 shows the number of scripts and the average government payment per script under the PBS over the decade. The number of scripts increased by an average of 4.1 per cent annually over the ten-year period, while the average payment per script, in real terms, increased by 5.1 per cent per year.

Table 4.1 Real cost to government of subsidised PBS prescriptions, 1993-94 to 2003-04

2002-03 prices

<i>Year</i>	<i>Number of scripts</i>	<i>Average PBS payment^a</i>	<i>Total cost</i>
	million	\$	\$ million
1993-94	120	17.94	2159
1994-95	124	19.21	2377
1995-96	131	20.78	2719
1996-97	133	21.89	2906
1997-98	134	23.16	3114
1998-99	139	24.65	3426
1999-00	149	25.73	3844
2000-01	160	27.45	4402
2001-02	168	28.14	4740
2002-03	174	29.17	5063
2003-04	181	29.79	5381

^a Average PBS payment is the average government payment per script in each year.

Source: HIC (2005b).

Improvements in pharmaceutical technologies have played a role in increasing both the volume of scripts and the average cost per script. New pharmaceuticals have increased the volume of scripts by:

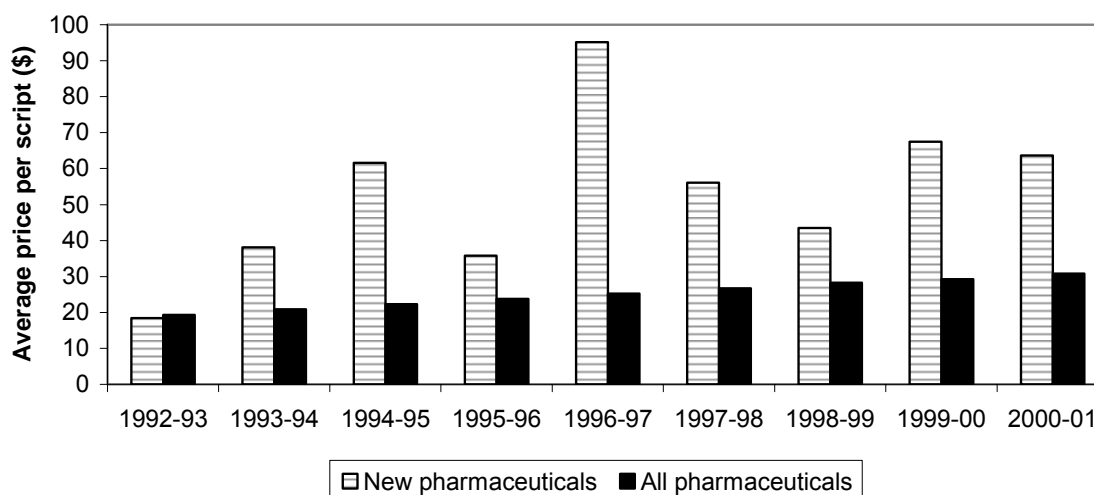
- offering treatment for conditions that previously required surgery or were untreatable — HIV/AIDS, for example; and
- offering safer or more effective treatment, and thus lowering the treatment threshold (DoHA, sub. 34).

For example, the number of prescriptions for statins — which are more tolerable and effective than the previous drugs for treating high cholesterol (bile acid sequestrants, fibrates and nicotinic acid) — increased by more than 600 per cent over the period 1993-94 to 2003-04 (appendix F).

Obviously though, other factors such as the ageing of the population and the associated rise in the prevalence of chronic conditions, have also played an important role in increasing pharmaceutical consumption.

The listing of new, more expensive pharmaceuticals is a key reason for the increase in the real average price per script over time (Medicines Australia, sub. 30). Sweeny (2002a) shows that the average price of new drugs has been about twice the price of all drugs over the period (figure 4.2).

Figure 4.2 **Average price per script of PBS drugs^a**
2000-01 prices



^a The average price of a prescription is based on the government approved dispensed price, including the price paid by government to the pharmacy and the patient co-payment (appendix F).

Data source: Sweeny (2002a).

Medicines Australia (sub. 30) pointed out that of the four most costly PBS products and the three generating the most prescriptions all, except statins, are more expensive than the previous technology they have replaced. Further, the Productivity Commission (PC 2001a) finds that while manufacturer prices for the top-selling pharmaceuticals across all drug categories are much lower in Australia than in a number of other countries, the discount for innovative pharmaceuticals is smaller than for other drug categories (generic and ‘me too’).

Where newer drugs are more expensive than their comparators, the higher prices have to be justified through the economic evaluation processes of the Pharmaceutical Benefits Advisory Committee (PBAC) (chapter 9). Thus, where they have been approved for listing, these higher-priced drugs must offer net benefits relative to their predecessors.

Another driver of part of the increase in the average price per script is supply chain costs (fees to pharmaceutical wholesalers and community pharmacists). In addition to the flat dispensing fee paid to community pharmacists, both they and wholesalers receive a mark up linked to the price of the products dispensed. This arrangement exacerbates the cost to the PBS of new, more expensive pharmaceuticals. Davies (2004) claims that supply chain costs account for about one-third of PBS spending.

Inpatient care

The total cost of treating patients in public and private hospitals increased by 11 per cent in real terms over the period 1996-97 to 2002-03. This growth in expenditure can mainly be attributed to increases in the average cost per treatment. Table 4.2 shows the number of separations and the average cost per separation for the Australian hospital system from 1996-97 to 2002-03.

Total separations across all hospitals remained reasonably stable over the same period. However, this overall stability masks a 15 per cent increase in private separations at the expense of public hospital separations (down 2.3 per cent over this period). In part this reflects government measures to encourage the uptake of private health insurance. Moreover, while total separations have remained stable, the fall in the average length of stay from 3.65 to 3.05 days, has seen a 14 per cent decrease in total hospital bed days over this period.

Increases in the total cost of hospital care have been driven mainly by the 8.5 per cent increase in the real average cost of a separation over the period, despite the fall in the average length of stay. The average cost per separation in public hospitals grew much more strongly than in private hospitals over the period (13 per cent compared to 1.7 per cent).² Decomposing the average cost into its direct and overhead components shows that direct costs have driven the increase in average cost over the period, increasing by 17 per cent, while overhead costs have fallen by 10 per cent.

² The stronger growth in public hospital costs may reflect changes in the casemix of public and private hospitals. Private hospitals may be doing more simple, elective procedures since government measures to increase the uptake of private insurance were introduced, leaving public hospitals with a higher proportion of costly, complex procedures. This is consistent with the larger decrease in the average length of stay in private hospitals (18 per cent) compared with public hospitals (15 per cent) over the period. MIAA (sub. PR54) claimed that the slower cost growth in private hospitals may be due to greater efficiency gains in the private sector.

Table 4.2 Hospital costs, 1996-97 to 2002-03 ^a
2001-02 prices

<i>Year</i>	<i>Total separations</i>	<i>Average cost^b</i>	<i>Total cost^c</i>
	'000	\$	\$ million
Public hospitals			
1996-97	4051	2536	10 275
1997-98	3550	2651	9411
1998-99	3597	2731	9823
1999-00	3628	2742	9945
2000-01	3615	2774	10 026
2001-02	3767	2847	10 725
2002-03	3957	2877	11 386
Private hospitals			
1996-97	1651	2297	3793
1997-98	1508	2055	3098
1998-99	1548	2121	3282
1999-00	1543	2251	3474
2000-01	1766	2250	3974
2001-02	1918	2264	4341
2002-03	1904	2335	4446
All hospitals			
1996-97	5703	2510	14 316
1997-98	5058	2549	12 894
1998-99	5145	2655	13 659
1999-00	5171	2652	13 713
2000-01	5381	2660	14 315
2001-02	5685	2701	15 356
2002-03	5861	2723	15 960

^a The information in the table includes data from both public and private hospitals collected by the Department of Health and Ageing's National Hospital Costs Data Collection (DoHA 2005b). ^b Average cost per separation is calculated as a weighted average of the costs in participating private and public hospitals. ^c Total cost is calculated by multiplying average cost per separation in participating hospitals by total separations (in all hospitals). Separations in participating hospitals were 74 per cent of total separations in 2002-03.

Source: DoHA (2005b).

The adoption of newer, more costly technologies — devices, some procedures and pharmaceuticals, for example — is likely to have played a key role in the observed increase in the direct cost of treating patients. However, other factors such as increases in medical wages above the rate of inflation can also explain some of the increase.³

³ There are very few salaried medical officers in the private sector (unless there is an intensive care or emergency department where a full-time medical practitioner is required) and, thus, remuneration for most medical practitioners are not captured in the cost data for private hospitals (DoHA 2005b).

The hypothesis that the adoption of new technologies has played an important role in increasing average hospital costs is supported by examination of the areas of direct expenditure that have experienced the largest increase in costs over the period (1996-97 to 2002-03). Emergency departments and critical care have experienced strong growth in direct costs (both with increases over 57 per cent over the period (DoHA 2005b). Expenditure in these areas is also likely to have been influenced by recent technological advances — for example, improvements in devices to monitor patient physiological variables (cardiovascular performance, oxygen and carbon dioxide levels) (Australian Society of Anaesthetists, sub. 8).

Direct hospital spending on pharmaceutical and operating rooms — also areas in which there have been considerable advances in technology — increased by about 20 per cent. Similarly, spending on prostheses grew very strongly in both public and private hospitals (increasing by 104 per cent and 227 per cent respectively). This growth was most likely driven by the availability of more sophisticated and expensive prostheses — cementless joint prostheses, for example — which have increased unit costs and also facilitated treatment of younger and older age groups.

In contrast, expenditure on ward medical and ward nursing staff in public hospitals increased by only 14.2 and 7.2 per cent respectively. This comparatively slow growth in expenditure on nursing staff in particular may reflect the fact that hospitals have adopted new technologies that reduce hospital stays — laparoscopic surgical techniques, for example. This possibility is discussed in more detail in section 4.3.

While total separations have remained stable over the period, this is not to say that individual technological advances have had no impact on the volume of certain treatments. As is discussed in section 4.2, some new technologies — intraocular lenses (IOLs) for cataract surgery, for example — have strongly increased the number of separations for particular conditions.

For other conditions, new technologies (particularly pharmaceuticals), have decreased separations. For example, public hospital separations for asthma and bronchitis-related conditions and HIV and related infections, fell by 42 per cent and 12 per cent respectively over the period 1996-97 to 2002-03. In both cases, there have been improvements in the drugs available for treatment of these conditions, reducing the need for hospitalisation (box 4.1). (Potential cost savings generated by these improved drugs are discussed in box 4.3.)

Box 4.1 **Improvements in HIV/AIDS and asthma medications**

Recent advances in pharmaceuticals for the treatment of asthma and HIV are likely to have contributed to the fall in hospital separations for these diseases.

Asthma

Medications for relieving the short-term symptoms of acute asthma attacks (short-acting beta-2 agonists, such as *salbutamol* (Ventolin)) have been available for several decades. More recently, medications for the long-term management of the symptoms of asthma have become available.

Prophylactic anti-asthma drugs (preventers), such as corticosteroids, are used to decrease airway obstruction for patients with moderate to severe asthma. While these drugs have been available for more than a decade, a more potent product, *fluticasone*, became available through the PBS in 1997-98 (National Asthma Council Australia 2002).

Long-acting beta-2 agonists such as *salmeterol* have been available through the PBS since 1994-95. These are used in conjunction with short-acting beta-2 agonists and inhaled corticosteroids to control asthma symptoms.

HIV/AIDS

New potent antiretrovirals, including *lamivudine* and protease inhibitors, became available in Australia in 1995. Combination antiretroviral treatments (involving combinations of reverse transcriptase inhibitors and protease inhibitors) have been widely utilised since 1996. A number of these treatments are available through the Highly Specialised Drugs Program of the PBS.

FINDING 4.1

Technological advances have played an important role in increasing expenditure on pharmaceuticals and inpatient care:

- *For pharmaceuticals, direct expenditure has increased due to the higher unit cost of new drugs and increases in the number of patients treated.*
- *For inpatient care, expenditure growth has been driven by increases in the average cost of treatment fuelled in part by the adoption of expensive new technologies.*
- *New technologies have had offsetting effects on hospital separations:*
 - *for some diseases, improved pharmaceuticals have reduced the need for hospitalisation; and*
 - *less invasive and more effective procedures and improved anaesthetics have led to increased separations for some conditions, but have also reduced the length of hospital stays.*

The relationship between new technologies and the cost and volume of treatments is explored in more detail in section 4.2.

4.2 Expenditure impacts of individual technologies

Individual technologies may have a range of different impacts on health expenditure depending on the net cost of treating an individual patient and the number of people treated. Thus, it is useful to distinguish between cost and volume effects when assessing the impact of a technology on expenditure. For example, while some technologies may reduce the cost per patient of treating a given disease, if the treatment can be provided to a wider group of patients, total expenditure may rise.

Further, even if a new technology reduces the cost of treating a particular disease, if it leads to more effective treatment of that condition, increased longevity and associated degenerative diseases may increase total health expenditure over time. Finally, if a new technology allows treatment of a previously untreatable disease, then it is likely to increase health expenditure.

New technologies and per patient healthcare costs

The vast majority of new technologies are introduced to diagnose or treat diseases for which other methods of diagnosis or treatment already exist. The net cost of treating a given patient using a new technology will depend on the:

- unit cost of treatment using the new technology relative to existing technologies;
- extent to which the technology complements or substitutes for, or adds on to, existing technologies;
- impact of the technology on costs elsewhere in the health system; and
- impact of the technology on the stream of healthcare costs over time.

Technology and the unit cost of treatment

The unit cost of treatment for a disease is defined as the per patient cost of providing an episode of treatment (that is, the treatment cost at a point in time). The impact of a new technology on the unit cost of treatment can be difficult to assess. For example, in a hospital setting it is necessary to consider the effect of the technology on: labour costs (through surgery time, for example); length of patient stays; the probability of post-operative complications; indirect costs, such as imaging and pathology; as well as the cost of the technology itself, including upfront and ongoing costs.

Nevertheless, some technologies unambiguously decrease unit costs. Advances in anaesthetic agents, for example, may have produced unit cost savings, through faster patient recovery (and shorter length of stay) as well as reduced probability of adverse events. Further, advances in practice methods, such as pre-anaesthetic consultation prior to admission to hospital, have also contributed to unit cost savings through reduced length of stay (Australian Society of Anaesthetists, sub. 8).

On the other hand, some technologies have increased unit costs (at least in the short term). The introduction of drug eluting stents (DES), in place of bare metal stents (BMS) as an adjunct to coronary angioplasty is one such example.⁴ The cost of carrying out a coronary angioplasty with DES is higher than the cost of the same procedure with BMS, primarily due to the cost of DES — about \$3600 compared to \$1500 for BMS (appendix H). There do not appear to be any immediate offsetting unit cost savings in terms of shorter operating times or faster patient recovery from using DES, although there may be cost savings over time (see below).

Another factor that needs to be taken into account when comparing costs of new procedures with older technologies, is the possibility for learning to decrease costs over time. A new technology may initially increase labour costs if staff are required to develop new skills to use the technology. However, the initial labour costs will tend to fall over time as these skills are refined. For example, the longer operating times using surgical robotic systems (compared to conventional open or laparoscopic surgery) can be partially attributed to ‘learning curve’ issues. The Australian Safety and Efficacy Register of New Interventional Procedures — Surgical (ASERNIP-S 2004) noted that as experience with robotic systems increased, operating times and complications tended to fall.

Unit cost comparisons for pharmaceuticals tend to be simpler than for devices or procedures and, in general, are based on comparing the cost of a daily dose. For example, the average price of a prescription for statins is approximately the same as the price of a prescription for bile acid sequestrants (Medicines Australia, sub. 30). Thus, the introduction of statins has not significantly changed the unit cost of treating a patient with high cholesterol. On the other hand, selective serotonin reuptake inhibitors (SSRIs) tend to be more expensive per therapeutic daily dose than the tricyclic antidepressants (TCAs) which were the most commonly prescribed antidepressant prior to the introduction of SSRIs (Hegarty et al. 2003) (appendix G). The impact of statins and SSRIs on whole-of-health system costs is explored in more detail below.

⁴ By holding open the artery, stenting is designed to reduce the need for further interventions after angioplasty.

Technologies as substitutes, complements or 'add ons'

Another important determinant of the impact of a new technology on expenditure is the degree to which it substitutes for, or complements, existing technologies in the treatment or diagnosis of a disease. New technologies introduced to complement an existing course of treatment inevitably increase the unit cost of treatment. However, their overall expenditure impact may be offset to some degree by cost savings produced elsewhere in the health system.

Coronary stenting as an adjunct to coronary angioplasty is an example of a technology introduced to complement an existing procedure. Stenting increases the cost of an angioplasty procedure, both because of the cost of stenting — about \$1500 for BMS (appendix H) — and because of additional time taken to insert the stent. In 2002-03, the average cost of coronary angioplasty with stent was \$6805, while the cost of angioplasty without stent was \$4983 (DoHA 2005b). In 2003-04, stents were inserted in 93 per cent of patients undergoing coronary angioplasty, an increase from 12 per cent in 1994-95 (AIHW and NHF 2004).

Diagnostic imaging technologies offer another example of technological advances that have complemented existing treatments. These technologies offer improved diagnosis of various diseases, from cancers to neurological conditions. For example, increased access to mammography screening (through the introduction of BreastScreen Australia), is one of the factors believed to be responsible for the 8.5 per cent rise in the average annual number of cases of breast cancer diagnosed in the period 1996 to 2003 compared with 1993 to 1997 (SCRGSP 2005). Digital mammography has the potential to increase further diagnosis rates (BreastScreen Victoria, sub. 22). Similarly, in the five years following the introduction of the prostate specific antigen (PSA) test in Australia, the reported incidence of prostate cancer doubled (appendix J).

By increasing the number of cases of disease diagnosed, diagnostic imaging technologies increase healthcare expenditure, both through the cost of these imaging technologies themselves, and in the treatment of patients who would otherwise have remained undiagnosed. On the other hand, these technologies may prove expenditure-reducing over time because early detection and treatment may negate the need for more intrusive (and expensive) treatments once the disease has progressed.

When new technologies substitute for those previously used, their expenditure impact depends on the unit cost of the new technology relative to existing ones (discussed above), and the degree to which they substitute for the existing technology.

In many cases when new improved treatments become available, old technologies are superseded. For example, the phacoemulsification (phaco) technique for cataract extraction, combined with implantation of a foldable IOL, has virtually replaced the previous, more invasive, intracapsular cataract extraction technique (appendix M).

In other cases, potential cost savings from the introduction of new technologies are not realised because the predicted substitution for existing technologies does not occur and the technology instead becomes an ‘add on’. ACT Health noted that there is a:

... strong tendency to fail to realise potential cost benefits of new technologies because redundant and more expensive technologies are not being withdrawn. (sub. 11, p. 3)

NSW Health commented that:

... in health care, there is general agreement that technology comes at a cost which tends to be additive rather than substitutive ... (sub. 20, p. 3)

And further noted:

Newer technologies rarely ‘replace’ an existing technology but have an additive effect as applications widen ... (sub. 20, p. 8)

Diagnostic imaging provides an example of the tendency for some new technologies to add to, rather than replace, existing ones. As improved but more expensive diagnostic technologies have become available, there has been a tendency for patients with some conditions to face an escalation of diagnostic effort. In these cases, patients are tested with simpler and cheaper technologies such as X-ray or ultrasound initially, before progressing to computed tomography (CT) and/or magnetic resonance imaging (MRI) and/or positron emission tomography (PET) if the diagnosis remains uncertain. Baker et al. (2003) find empirical evidence that CT and MRI technologies have been used additively in the US health system.

For conditions that can usually be detected by X-ray or ultrasound — spinal cord injuries in trauma victims, for example (Hendley et al. 2002) — a progressive escalation through imaging modalities is likely to produce the lowest overall imaging expenditure. However, in other cases, it may be more appropriate for patients to be imaged with CT or MRI at the outset. For some conditions, particularly cardiac and abdominal conditions, the evidence suggests that MRI should be used as a complement to other imaging modalities (ultrasound or CT) (Goh et al. 1999; Nikolaou 2003).

Technologies and costs across the health system

As noted in section 4.1, technologies that increase costs in one area of the health system may decrease costs in another. The possible savings generated by some new pharmaceuticals in the other areas of the health system are well documented (box 4.2). However, it is very difficult to offer conclusive evidence of cost savings for any particular technology because of the myriad of other factors that are captured in the data — changes in disease prevalence, for example.

Box 4.2 Cost savings generated by new pharmaceuticals

A number of studies have estimated the magnitude of cost savings generated by the introduction of new pharmaceuticals.

Lichtenberg (1996) analyses the relationship between hospital expenditure and drug prescriptions by disease in the United States. He finds that hospital bed days declined most rapidly for the diseases which had the greatest increase in drug prescriptions and the most innovative drugs. He estimates that for every US\$1 increase in pharmaceutical expenditure, hospital expenditure fell by US\$3.65.

Lichtenberg (2002b) finds that a reduction in the age of drugs prescribed (that is, a shift to newer, improved technologies) reduces non-drug (hospital, physician consultations and home healthcare) expenditure over seven times as much as it increases drug expenditure. About two-thirds of these cost savings result from reduced hospital costs.

While there have been no studies of aggregate hospital cost savings from new drugs in Australia, there have been claims that a number of the newer drugs available have led to substantial cost savings elsewhere in the health system. These include:

- statins for high cholesterol (reducing the need for hospital treatment for heart attacks and strokes);
- *omeprazole* (reducing the need for surgery on stomach ulcers);
- corticosteroids and long-acting beta-2 agonists (reducing asthma hospitalisations) (box 4.1; Medicines Australia, sub. 30);
- combination antiretroviral treatment for HIV/AIDS (box 4.1);
- SSRIs (reducing doctor visits and the length of hospital stay following overdose).

Some evidence for these claims in relation to HIV/AIDS and asthma drugs is presented in box 4.3. For SSRIs and statins, more details, including estimates of these cost savings, can be found in technical paper 2. The question of whether cost savings in other parts of the health system are adequately taken into account in PBS processes is discussed in chapter 9.

Pharmaceuticals are not the only technologies that have the potential to generate cost savings elsewhere in the health system. Technologies that enable people with diseases or disabilities to be self-sufficient may provide offsetting savings in the areas of community and residential care. For example, hip and knee replacements may contribute to cost savings in the hospital and nursing home sectors through improved patient functioning and mobility (box 4.3).

Box 4.3 Offsetting cost savings from selected new technologies

There is some evidence that recent increases in expenditure on some technologies have been offset to some degree by savings elsewhere in the health system. However, it is difficult to be conclusive about cost savings from any particular technology because of difficulties in establishing causality, with a range of other factors also at work.

Asthma medications

Studies have shown that treatment of asthma with inhaled corticosteroids reduces the likelihood of hospitalisation for asthma-related conditions (ACAM 2003). Since the introduction of improved inhaled corticosteroids in Australia (and other new asthma medications such as the long-acting beta-2 agonists), there have been large declines in hospitalisations for asthma-related conditions (section 4.1).

International studies suggest that these new medications have produced substantial cost savings. The Williamsburg Institute (1997) cited in AstraZeneca (sub. 23) found that for every \$3 spent on asthma medication, \$17 was saved due to reduced emergency room visits.

Antiretrovirals

Combination antiretroviral therapy may produce offsetting cost savings in the hospital system both by reducing the incidence of AIDS (by stopping the progression of HIV to AIDS) and by inhibiting opportunistic infections associated with HIV.

There has been a decline in the incidence of AIDS in Australia since the introduction of combination antiretroviral treatments (Correll et al. 1998; Law et al. 2000). Law et al. (2000) estimate that between 1995 and 1998 there were 33 per cent fewer AIDS diagnoses than there would have been if the new antiretroviral treatments had not reduced the rate of progression of the disease.

International evidence suggests that potent antiretrovirals may be cost reducing overall. Petersen (1999) cites a study that found that for every 10 per cent increase in protease inhibitor use in regions of the United States, per patient oral medication costs increased by US\$86 while overall healthcare costs decreased by US\$135, mainly

(Continued next page)

Box 4.3 (continued)

through lower hospital treatment costs for opportunistic infections. Similarly, Bozzette et al. (2001) find a decline in the average monthly treatment costs for HIV-infected patients (from US\$1792 to \$US1359) after the introduction of highly active antiretroviral therapy. They conclude that the fall in treatment costs was driven by reductions in hospital costs which more than offset the increases in pharmaceutical expenditure for patients receiving this treatment.

Joint replacements

A US study (cited by MIAA sub. 17) found that total knee replacements save an average of US\$50 000 in hospital costs and US\$40 000 in nursing home costs per patient. It is claimed that improved prosthetic technologies such as those which enable minimally invasive surgery have the potential to provide even greater offsetting savings. MIAA (sub. 17) claimed that minimally invasive surgery reduces the average length of a hospital stay following joint replacement from 4 to 1.5 days.

MIAA (sub. 17) also stated that computer assisted surgery — which has improved accuracy relative to traditional joint surgery — has the potential to reduce hospital stays as well as patients' requirements for physiotherapy, home care and pain medication following surgery. However, the US National Institute of Health (2004) cautioned that computer assisted surgery is expensive, increases operating room time, and that the benefits are as yet unclear (appendix E).

Technologies and costs over time

The discussion above focuses on the impact of new technologies on per patient treatment costs at a given point in time. However, to assess the expenditure impact of a new technology comprehensively, it is necessary to consider its impact on the net cost of treating a patient over time. Differences exist between the 'point in time' and lifetime impact on expenditure because of differences in the effectiveness of technologies — their impact on longevity and the need for repeat interventions, for example.

Some technologies are unit cost increasing in the short term but may generate cost savings over time by reducing the need for repeat procedures. For example, unit prostheses costs for hip and knee replacements increased by 10 per cent in the public sector and 11 per cent in the private sector between 1998-99 and 2002-03, driven partly by improvements in technology. However, these new technologies may save costs for treating a given patient over time because they are purported to have lower failure rates and thus require less revision surgery (KPMG Consulting 2001) (appendix E).

In other cases, a new procedure may simply delay a more invasive procedure and thus increase costs over time. For example, in some cases, individuals receiving coronary stenting will later need to undergo bypass surgery (NSW Health, sub. 20). In cases where there is a greater risk of restenosis or additional complications, there is a higher probability that repeat procedures will be required after stenting (although the probability of a repeat procedure may be lower if DES are used instead of BMS (appendix H)). In these cases, it may be more cost effective for patients to undergo coronary artery bypass surgery at the outset (Hill et al. 2004).

Advances in technology over the last decade have improved life expectancy associated with a number of diseases, including heart failure, renal failure and cancer (NSW Health, sub. 20). Although clearly generating large benefits, improvements in longevity increase health expenditure per patient over time because surviving patients continue to use health services. In fact, these patients may be particularly intensive users of services because of ongoing treatment costs or disabilities associated with their disease. Ultimately, many of them will contract other chronic diseases with high ongoing treatment costs. Meltzer (1997) argues that healthcare costs incurred in the additional years of life need to be taken into account when comparing the cost effectiveness of interventions. The benefits of improved longevity, and the way they are incorporated into cost effectiveness measures, are discussed in chapters 5 and 7 respectively.

Technologies that have allowed treatment of a broader population

New technologies that offer more effective, safer or less invasive interventions can allow treatment of a much broader group of patients. As Fuchs (1998, p. 2) observes ‘advances in medical technology have made it feasible and desirable to do more for each patient and to intervene with more patients’. Therefore, even a technology that reduces the net unit cost of treating a patient may be expenditure increasing if it increases the number of patients eligible or willing to receive treatment.

In studies of the most costly medical conditions in the United States, Thorpe et al. (2004; 2005) find that for many of these conditions, rising prevalence of treatment — rather than changes in cost per case — account for most of the growth in spending (box 4.4). Similarly, DoHA noted that in Australia, technology-driven changes in the volume of treatment are an important factor behind increases in health expenditure:

Growth in demand for services, which is partially driven by availability of new and better technologies, has historically outstripped unit cost savings brought about by new technologies. This is expected to continue. (sub. 34, p. 2)

Box 4.4 Per patient costs vs treatment prevalence: some empirical studies

Thorpe et al. (2004) analyse expenditure growth in the fifteen most expensive medical conditions in the United States between 1987 and 2000. They decompose the percentage change in nominal healthcare expenditure on each condition into: the increased cost per treated case; the rise in treated prevalence; and the increased population.

They find that for several of the medical conditions considered, the rise in treated prevalence is the key driver of expenditure growth. These include: mental disorders (treated prevalence accounts for 59 per cent of expenditure growth), diabetes (50 per cent), and pulmonary conditions (42 per cent). They do not unravel the extent to which the rises in treated prevalence represent an increase in epidemiological prevalence as against an improved ability to diagnose and treat sufferers. However, they claim that for mental health in particular, improved diagnosis and treatment have driven the trend.

In a similar analysis, Thorpe et al. (2005) decompose the growth in US real private health insurance spending between 1987 and 2002 into spending per treated case and the rise in treated prevalence. They find that the rise in treated disease prevalence rather than increased cost per case is the primary factor responsible for the growth in private insurance spending. Again, the extent to which this reflects improved technologies for diagnosis and treatment, rather than higher epidemiological prevalence or changes in the treatment thresholds, is unclear.

Improved anaesthetic agents, combined with more sophisticated monitoring and minimally invasive surgical techniques have reduced hospital stays and post-operative complications, increasing the number of patients able to undergo surgical interventions. For example, the introduction of laparoscopic cholecystectomy has considerably reduced the length of stay for gall bladder removal (compared to open surgery techniques). Further, laparoscopic surgery reduces complication rates, mortality and post-operative morbidity relative to open surgery (Rob et al. 1998).

In New South Wales, cholecystectomy rates in the years following the introduction of laparoscopic techniques in the 1990s were, on average, 24 per cent higher than the rates in previous years (Rob et al. 1998), suggesting that the introduction of the minimally invasive technique reduced the threshold for surgical intervention. This is also consistent with international evidence. For example, Chernew et al. (1997) show that cholecystectomy rates increased by 20 to 30 per cent across states of the United States, following the introduction and diffusion of laparoscopic techniques at the beginning of the 1990s.

Improvements in pharmaceutical technology have produced drugs with fewer side effects and that are easier to administer, expanding the potential treatment population. For example, studies show that SSRIs are better tolerated than the

TCAs. Improved tolerability, along with simpler dosing regimes, has meant that patients are more likely to maintain their course of treatment on SSRIs and are consequently less likely to experience a relapse. These perceived improvements offered by SSRIs may be one of the factors behind the strong increase in antidepressant prescriptions since their introduction in 1990. Between 1990 and 2002, use of antidepressants increased by 352 per cent (appendix G).

Advances in technology that have increased the safety and efficacy of procedures have also broadened the treatment population by allowing older patients to receive interventions that previously would have been denied to them. For example, Rob et al. (1998) argue that the increase in the average age of private hospital patients in New South Wales undergoing cholecystectomy after the introduction of the laparoscopic procedure (from 50.6 to 53.4 years in the five years after laparoscopic surgery was introduced) may reflect the willingness to treat older, frailer patients using the new technique. Further, Queensland Health (sub. PR43) point out that surgical and biomedical advances, such as heart stabilising devices, have reduced surgery times and complications associated with cardiopulmonary bypass, allowing older and sicker patients, previously considered too challenging for surgery, to undergo operations.

Improvements in diagnostic technologies have also contributed to increases in the volume of treatment for certain diseases by bringing forward the stage at which these diseases can be detected and then treated. For some diseases, questions have been raised about the appropriateness and cost effectiveness of early intervention (box 4.5).

Box 4.5 Improved diagnostic technologies for prostate and breast cancers**Prostate cancer**

The PSA test, introduced in Australia in 1989, allows for prostate cancer to be detected at an earlier stage than the previous diagnostic tests. In the five years following its introduction, the reported incidence of prostate cancer almost doubled.

While screening for prostate cancer using PSA tests allows small tumours to be detected, clinicians are often unable to identify when a detected tumour will warrant intervention, and thus some men will undergo an unnecessary radical treatment. Further, some studies have indicated that PSA testing has increased the cost of treating prostate cancer because the treatment of early stage cancers tends to be more expensive.

That said, early detection is argued to improve the chance of cure, as well as providing a greater choice of treatment options because the cancer is more likely to be contained to the prostate gland (Benoit and Naslund 1997; Urological Society of Australasia 2005b) (appendix J).

Breast cancer

Improved breast cancer screening techniques in the last fifteen years have decreased the size at which growths can be detected. Gorman (2002) questions the value of identifying such small growths when it is uncertain whether such growths pose future dangers. Similarly, Olsen and Gotzsche (2001) find that screening may lead to unnecessary treatment in some cases. However, the Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32) argued that screening is responsible for the decline in breast cancer mortality rates since 1993 and that further improvements in mortality will become evident as the effect of the national breast screening program becomes measurable.

In some cases, technologies may increase the volume of treatment because they are applied to a wider range of indications than advised. For example, there is some evidence that SSRIs are being prescribed for patients with ‘chronic mild depression’, although the PBS restrictions state that SSRIs should only be prescribed for the treatment of major depressive disorders (McManus et al. 2003) (appendix G).

On the other hand, some technologies have increased total treatments because they have applications in treating diseases other than those for which the technology was originally intended. For example, a study of ‘blockbuster’ drugs in the United States found that secondary uses accounted for more than 40 per cent of total sales in 1995 (Gelijns et al. 1998 cited by AstraZeneca sub. 23).

Technologies for a previously untreatable condition

Most of the advances in medical technology over the last decade have provided ways to treat or diagnose patients more effectively or efficiently than possible under existing technologies. However, there have also been breakthroughs in treating previously untreatable conditions. In general, these breakthroughs will increase expenditure through the new costs incurred in providing the treatment. However, where the symptoms of the disease were previously costly to manage — because of high aged or palliative care costs, for example — a new technology for treating the disease may reduce expenditure over the longer term.

Gene therapy, a technique still in its infancy, has potential to offer treatment for some previously untreatable diseases. For example, trials of gene therapy to treat adenosine deaminase (ADA) deficiency — one of the causes of severe combined immunodeficiency which leaves sufferers highly susceptible to recurrent infection — have generated some promising results (Victorian Government 2005). However, a French trial has been halted twice due to reports of trial participants developing leukaemia (Centre for Genetics Education 2004b).

If eventually gene therapy is shown to be efficacious and safe, it will generate large benefits. Nonetheless, it will also be expenditure increasing because it could significantly extend life (Cooper 2004). More detail about the potential expenditure impacts of other applications of gene therapy are presented in chapter 11.

In other cases, technologies have been developed to treat entirely new diseases. These technologies are unambiguously expenditure increasing at the time they are introduced. An example is the antiretrovirals developed to treat the symptoms of HIV/AIDS after the first recognised case of the disease was reported in 1981. However, improvements in these technologies over time may then be cost reducing. For example, major advances in the treatment of HIV/AIDS in recent years — new potent antiretrovirals (box 4.1) and ‘fusion inhibitors’ (GlaxoSmithKline Australia, sub. 21) — may reduce the net costs of treating patients through offsetting savings in the hospital system (box 4.3).

Summarising the expenditure impacts of new technologies

This section brings together the net expenditure impact of some of the technologies discussed above, specifically statins, SSRIs, drug eluting stents and the phaco technique for cataract surgery. Primarily, the Commission has attempted to identify whether these technologies have been expenditure increasing or decreasing from a whole of health system perspective.

To quantify the net expenditure impact of these technologies it is necessary to specify the counterfactual, that is, how the relevant condition would be treated if the

technology in question had not become available (the no technological change scenario). It is also necessary to make further assumptions about the costs and volume of treatment under the no technological change scenario.

To simplify the analysis, all expenditure impacts are considered at a point in time. Thus, the dynamic expenditure impacts of the technologies — healthcare costs patients incur after their lives have been extended by a technology, for example — are not accounted for.

Table 4.3 summarises the point in time expenditure impacts of the technologies considered. A discussion of some of the assumptions used to produce these estimates is provided in box 4.6. The net expenditure estimates, along with a more detailed description of the assumptions and methodology, are presented in technical paper 2.

Table 4.3 Net expenditure impact of selected advances in medical technology, 2000-01

New technology	Previous technology	Per patient costs			Volume	Net expenditure impact
		Unit price	Substitute, complement or add on	Costs elsewhere		
Statins	Bile acid sequestrants, fibrates, nicotinic acid	Unchanged	Substitute	↓	↑	↑
SSRIs	TCAs	↑	Substitute	↓	↑	Severe depression ? Mild depression
Phaco technique and foldable IOLs	Intracapsular cataract extraction technique	↓	Substitute	↓	↑	↑
Long-acting agonists	Corticosteroids and short-acting agonists	na	Complement	↓	↑	↑

na Not applicable.

Source: Technical paper 2.

Box 4.6 Estimating the expenditure impacts of selected advances in technology

For each technology the net expenditure impact is estimated by comparing current treatment expenditure with the hypothesised whole-of-health system cost if the technology were not introduced and the previous drug, device or procedure remained the main treatment. This box summarises the main assumptions made in estimating the expenditure impacts as well as summarising the likely direction of the impact. A more detailed discussion is provided in technical paper 2.

Statins

It is assumed that if statins were not introduced, bile acid sequestrants, fibrates and nicotinic acid would have remained the major cholesterol-lowering drugs used in the prevention of coronary heart disease. In this case, the cost of treating a patient with high cholesterol would be largely the same because these drugs are about the same price as the statins.

As the strong growth in statin prescriptions since 1993-94 cannot be attributed to an increase in the prevalence of high cholesterol (which has remained reasonably stable over this period), it is assumed to arise from a broadening of the treatment population because of the relative efficacy and tolerability of the statins.

The Australian Long-Term Intervention with Pravastatin in Ischaemic Disease study suggests that the offsetting cost savings from statins (decreased hospital and long-term medical costs associated with coronary heart disease and stroke), are approximately \$290 per patient per year (Medicines Australia, sub. 30). Despite these offsetting cost savings, the analysis suggests that the introduction of statins increased health expenditure because of their large impact on the volume of treatment.

SSRIs

It is assumed that if SSRIs had not been introduced, TCAs would have remained the most commonly-used antidepressants. In this case, the cost of treating a patient with depression would be significantly lower (\$5 for a TCA prescription compared with \$31 for a SSRI prescription).

The growth in SSRI use *above* the growth in the prevalence of depression is attributed to a broadening of the treatment population because of the improved tolerability and lower toxicity of the SSRIs. In particular, there is some evidence of 'leakage' of the SSRIs to treat patients with chronic mild depression, rather than major depressive disorders (McManus et al. 2003).

Taking into account the offsetting cost savings associated with SSRIs compared to TCAs (fewer physician visits and shorter hospital stays) as estimated in Skaer et al. (1995), the analysis suggests that SSRIs may have been expenditure reducing, to the extent that they have diffused to those with major depressive disorders. For patients with chronic mild depression, on the other hand, the expenditure impact is unclear because the offsetting hospital cost savings are likely to be considerably lower.

(Continued next page)

Box 4.6 (continued)

Phaco technique for cataract surgery

It is assumed that if improved techniques for cataract surgery (the phaco technique combined with the implantation of a foldable IOL) had not been introduced, cataract operations would have continued to be performed using the more intrusive intracapsular cataract extraction technique. In this case, the average cost of cataract operations would be higher, more than \$4500 compared with just over \$3750 using the phaco technique. These cost differences mainly reflect the longer operating and length of hospital stay associated with intracapsular extraction.

It is assumed that the volume of cataract surgeries would have grown by about 30 per cent under this alternative scenario because of population growth and the ageing of the population. However, the additional 27 000 surgeries *above* this amount in 2000-01 are attributed to the lower intervention threshold, and the improved productivity, brought about by the introduction of the phaco technique.

For the additional patients undergoing surgery, there are some offsetting cost savings in the aged care and hospital sectors, from a reduction in the risk of falls. However, these are estimated to be insufficient to offset the growth in spending on cataract surgeries due to the new technique.

Long-acting beta-2 agonists

It is assumed that the long-acting beta-2 agonists to control the symptoms of asthma have been adopted as a complement to existing medications, namely, short-acting beta-2 agonists to relieve acute asthma symptoms, and corticosteroids for longer-term symptom control.

To the extent that the long-acting agonists improve symptom control in patients with moderate to severe asthma, these patients are less likely to attend hospital emergency departments or be admitted to hospital with exacerbations of asthma. In the absence of specific studies on the likely expenditure impact, all of the \$18 million reduction in hospital expenditure on asthma conditions since the introduction of these drugs is attributed to their impact. Even using this generous estimate of the offsetting cost savings, these drugs are still estimated to be expenditure increasing overall.

Three of the advances in medical technology examined are estimated to have increased health expenditure over the last decade, even after accounting for possible offsetting cost savings. SSRIs, on the other hand, are estimated to have reduced expenditure for certain patient groups. Although some of the expenditure-increasing technologies were about the same or lower unit cost than the treatment they superseded (statins and phacoemulsification), the consequent broadening of the treatment population led to an increase in overall health expenditure.

The estimates are dependent on the assumptions made about the impact of the new technology on the unit cost, volume and offsetting cost savings from treatment, and

thus they provide only a broad indication of the overall expenditure impact of the technology. Importantly, these technologies are also likely to have delivered significant benefits, which have not been evaluated in this expenditure analysis.

FINDING 4.2

Analysis of the expenditure impacts of some of the major advances in medical technology over the past decade suggests that most have increased net health expenditure:

- *For some, the expenditure impact has been unambiguous because they have higher unit costs; complement or add to the existing mix of technologies; or treat an entirely new disease.*
- *Others have reduced unit treatment costs or have generated offsetting savings elsewhere in the health system, but have often facilitated significant increases in the volume of treatment.*

4.3 Funding responsibilities and expenditure on technology

This section addresses terms of reference (e) which requires the Commission to consider the impact of advances in medical technology on the distribution of costs and financial incentives across different parts of the health system. The question of who pays for a new technology has important implications for both the use and the cost of the technology, and for ensuing impacts on overall health expenditure (chapter 2). In particular, the cost burden of a new technology may affect its uptake because of certain characteristics of the Australian health system which include:

- budget caps;
- cost spillovers; and
- cost shifting.

Further, legislation governing the provision of prostheses by private health insurers may have also affected the diffusion of new technologies.

This section analyses how the division of funding responsibilities among the Australian Government, private insurers and the State and Territory Governments, has affected total expenditure on new technologies. The effect of out-of-pocket payments by consumers on demand for technology is discussed in chapter 2.

Budget caps

Capped funding arrangements in the public sector constrain the adoption and/or use of new technologies. Under a capped budget, new technologies must compete with other types of expenditure for the available funding (NSW Health, sub. 20). Thus, the impact of advances in technology on healthcare expenditure would have been greater over the last decade in the absence of these mechanisms. For example, commenting on the 7 per cent annual growth in pharmaceutical expenditure in NSW public hospitals (which operate largely under capped budgets) compared with the 12.6 per cent annual growth in the (notionally uncapped) PBS over the period 1998-99 to 2002-03, NSW Health stated:

One could speculate that the different growth rates reflect the different financing systems but it could also reflect tighter control over drug expenditure in major hospitals through drug committees. (sub. 20, p. 9)

Capped funding arrangements for diagnostic imaging provide another example of how these types of budget constraints can affect the diffusion of technologies. The Australian Government and relevant bodies have entered into four Memorandums of Understanding (MoUs) for Medicare-funded diagnostic imaging services (radiology, cardiac imaging and obstetric and gynaecological ultrasound) to ensure that spending on diagnostic imaging services remains within defined levels for the five-year target period (2003–2008) (DoHA, sub. PR56).

While these MoUs have been effective in constraining public expenditure for diagnostic imaging services (DoHA sub. 34), it is likely that patient access to these imaging technologies has been restricted as a result. As the Victorian Department of Human Services (VDHS) commented:

While this may be an effective way of controlling costs, it is not the best way of ensuring cost-effective delivery of health care services. The College of Radiologists has argued that Australia is lagging other countries by at least 10 years in patient access to these services ... (sub. 24, p. 22)

However, DoHA (sub. PR56) argued that access to new diagnostic technologies will not be unreasonably constrained in the future because the cap can be adjusted in the event that a new technology is approved by MSAC and listed on the MBS.

Commenting on these types of arrangement more broadly, DoHA argued that budget caps promote the cost-effective use of new technologies:

We disagree with the Commission's contention that a patient's access to technology is necessarily limited under a capped funding arrangement. Treatments will be available where their effectiveness, compared to other treatments, is in proportion with the higher costs. (sub. PR56, p. 4)

However, this does not guarantee that the range of technologies will be used in a cost-effective manner. As the Centre for Health Economics, Monash University noted:

... although caps on expenditure will reduce the risk of budget excesses, they do not explicitly assist in limiting use of technologies to circumstances where the technology has been found to be acceptably cost effective. (sub. 2, p. 16)

Further, in a cost-constrained environment, not all cost-effective technologies will necessarily be adopted.

Capped budgets may also create a bias toward adopting particular types of technology. The focus on cost containment will tend to favour the adoption of technologies that reduce costs in the short term, even if they may be cost increasing over the longer term or generate additional costs in other areas of the health system (see below). For example, there is some evidence of a bias toward adopting cost-reducing technologies in the public hospital sector over the last few years, with separations increasing in those diagnostic related groups (DRGs) with a decreasing average length of stay but remaining stable for those with an increased or unchanged length of stay (box 4.7). It is possible that casemix funding arrangements have provided incentives for hospitals to adopt technologies that improve their productivity.

Budget caps may also create a disincentive to invest in high cost or ‘lumpy’ technology, even where it may be cost effective over the long term. For example, upgrading information technology systems can have high upfront costs but may generate significant efficiencies and offer patient benefits over time. The VDHS claimed that its ability to purchase expensive medical equipment for public hospitals is constrained by its funding arrangements, regardless of potential cost–benefit improvements:

... in an environment where the acquisition of major equipment items can be governed more by budget constraints than by cost–benefit tests, simply replacing equipment at the end of its useful life, much less acquiring equipment incorporating the latest technological advances, is a challenge. (sub. 24, p. 50)

Box 4.7 **Growth patterns in public hospital separations**

Between 1998-99 and 2002-03, public hospital separations increased by 10 per cent and the average length of hospital stay decreased by almost 7 per cent.⁵

By examining the trends in separations and average length of stay for each of the 660 DRGs between 1998-99 and 2002-03 it can be observed that:

- separations for the DRGs that have exhibited a decrease in the average length of stay have on average increased by 11 per cent;
- separations for the DRGs that have exhibited an increase (or no change) in the average length of stay have on average been unchanged.

Presumably, technology has provided benefits in terms of improved treatment outcomes for both sets of DRGs. However, overall expansion in separations has only occurred for those DRGs that have experienced a decrease in the length of stay. One reason for this may be that capped hospital budgets, in combination with casemix funding arrangements, encourage adoption of technologies that improve hospital productivity through reductions in the length of stay. This may or may not coincide with the provision of the most cost-effective technologies from a broader community perspective.

Source: DoHA (2005b).

NSW Health pointed out that a benefit of capped budgets for public hospitals may be reduced duplication of technology and cost shifting:

... the combination of largely public financing and capped budgets for public hospitals with a salaried doctor workforce avoids the inflationary consequences normally associated with fee-based health systems where expensive technology is duplicated across hospitals and cost-shifting occurs amongst multiple private payers driving up costs. (sub. 20. p. 9)

Cost spillovers

As outlined in section 4.2, adopting cost-increasing technologies in one area of the health system may save costs in another. These spillovers can occur across different parts of the health system with different budgets and funding sources — such as from State and Territory Governments to Australian Government funded areas and vice versa. As the Australian Healthcare Association (AHA) noted:

The net impact of the costs and benefits of new technologies very often crosses jurisdictional or sector boundaries, such as Commonwealth-state or acute-residential. In

⁵ The time period here differs from that in section 4.1 because a breakdown by DRG was required for this analysis. The choice of time period has a bearing on the observed trends in separations and average length of stay.

other words, many cost-increasing technologies in one sector are also cost-decreasing in another ... These situations create significant difficulties for rational forward planning and decision making at senior levels of management. (sub. 25, p. 6)

Where these offsetting cost savings are not taken into account by decision makers, they may manifest in lower use of new technologies than would be desirable. As the Australian Diagnostic Imaging Association commented:

An unhelpful 'funding silos' mentality and compartmentalised responsibilities within and across jurisdictions including within and across Commonwealth, State and Territory jurisdictions continue to preclude effective evaluations of health care services and costs. (sub. 12, p. 4)

It is difficult to know the extent to which spillovers have led to sub-optimal use of new technologies. The availability of new pharmaceuticals through the PBS is one example of how spillovers may affect the adoption of new technologies. To receive Australian Government funding for new medicines through the PBS, companies must demonstrate the cost effectiveness of their product to the PBAC (chapters 8 and 9). It has been claimed that cost savings generated elsewhere in the health system are not adequately taken into account as part of this process. For example, Medicines Australia noted:

Unfortunately, broader Government policy does not seem to recognise the impact that new, innovative medicines can have by reducing cost pressures in other parts of the health system. (sub. 30, p. 65)

Further, others have argued that the lack of emphasis on these types of cost saving in the evaluation process has led to inefficient outcomes. In a recent report prepared for GlaxoSmithKline Australia, the Allen Consulting Group claimed:

Recent discussions about the impact of advances in pharmaceuticals tend to take a fairly narrow approach to the assessment of their costs and benefits. Considering the expenditure on pharmaceuticals separately instead of as part of overall resource use ... has been criticised as reflecting a 'silo mentality'. ... One disadvantage of such a narrow approach to the assessment of the costs of pharmaceuticals is that it could result in inefficiency because pressure to reduce the consumption of pharmaceuticals could lead to increased consumption of other healthcare resources. (sub. 21, p. 13)

The issue of whether cost savings in other parts of the health system are adequately addressed in PBS processes is discussed in more detail in chapter 9.

Cost shifting

Cost shifting between different parts of the health system will also tend to dampen the expenditure impact of new technologies. In general, cost shifting will result in lower use and later adoption of new technologies, as each part of the health system

attempts to avoid responsibility for providing the technology. Several participants in this study commented on the issue of cost shifting between the Australian, State and Territory Governments (box 4.8)

Box 4.8 Participants' comments on cost shifting in the Australian healthcare system

The Australian Nursing Federation commented:

The current divide of State and Federal responsibilities for health care delivery has resulted in chronic cost shifting activities, duplication of services and lack of continuity and communication between services and across sectors. A piecemeal approach to health care provision generally does not lend itself to effective planning and utilization of technological advancements. (sub. 26, p. 3)

The AHA noted:

AHA believes that the current health funding system has a number of problems, including the following:

- Inefficiencies, due to cost-shifting and funding duplication
- Lack of accountability for health funding
- Gaps in service provision due to cost-shifting and lack of integration across jurisdictions ... (sub. 25, p. 2)

ACT Health observed:

... there are structural constraints to ensuring the introduction and uptake of new technologies in ways that increase the chances of attaining their potential health and economic benefits. These included:

- the current division of Commonwealth/State responsibilities for health services, which may create opportunities for cost shifting. Group members also stated that these divisions led to considerable duplication of effort in the introduction of new technologies with inconsistent uptake across the country and between sectors ... (sub. 11, p. 2)

The funding of MRI provides an illustration of cost-shifting behaviour between the Australian and State and Territory Governments. The AHA claimed that the States have not funded MRI because it is perceived to be a responsibility of the Australian Government:

The legacy of poor Commonwealth-State relations has an impact on costs of technology. For example, increased provision of MRI facilities in public hospitals would be cost reducing, alleviating expensive transportation of patients between hospitals and delays in assessing correct treatment regimes for patients. But the States will not fund MRI because its provision is perceived to come within the Commonwealth's responsibility for ambulatory care. (sub. 25, p. 3)

On the other hand, it has been claimed that there may have been some indirect shifting of responsibility onto the States from the Australian Government. If PBAC or MSAC recommends that the Australian Government should not fund a

technology, there may be an expectation that State Governments will become the residual providers. One example of this may be genetic testing. The Australian Government funds only a small number of the available genetic tests, while several of the non-listed tests are funded by the State Governments (box 4.9).

Box 4.9 Funding arrangements for genetic testing

While there are approximately 220 genetic tests available in Australia, only six tests are covered by the MBS. State health departments provide funds for genetic testing for some non-MBS items (Cancer Council Australia and Clinical Oncological Society of Australia, sub. 32).

Some participants observed a need for an expansion of government funding of genetic testing. The Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32, p.18) affirmed that there was a 'powerful case' for expanding MBS coverage of genetic testing, while the Royal College of Pathologists of Australasia commented that:

... it must be recognised that until the approach to funding of genetic testing in Australia is addressed, it is unlikely that the community will benefit significantly from further technological advances in this area. (sub. PR52, p.1)

The Australian Health Ministers Advisory Council Advisory Group on Human Gene Patents and Genetic Testing is currently examining potential expenditure issues for genetic technologies. DoHA anticipates that the Australian Government's funding arrangements will be able to be determined through the existing health technology assessment processes (DoHA, sub. PR56).

If the costs of being a residual technology provider become a burden on state government finances, it will become increasingly necessary for State Governments to adopt their own health technology assessment (HTA) processes (AHA, sub. 25). The cost of duplicating HTA processes at the state level has questionable efficiency consequences (chapters 8, 9 and 10).

Governments may also shift costs to patients by increasing co-payments for prescription medicines or gap payments for medical services. Increasing patient contributions is likely to reduce both government expenditure on health services and the total quantity of these services demanded in the short term (chapter 2). However, for some conditions, the resulting reduction in medication use or deferral of medical services may manifest in health problems requiring more costly interventions in the longer term, if these broader impacts are not taken into account.

Prostheses funding arrangements

The use and cost of some new prostheses may differ between the private and public sectors because of legislation governing the provision of these technologies to health fund members. From 2001 until 2005, private health insurers were required to fund (with no gap) any prosthesis listed on the Prosthesis Schedule (Schedule 5 of the *National Health Act 1953* (Cwlth)) (chapter 10). The *National Health Amendment (Prostheses) Act 2005* (Cwlth) was passed in March 2005 to allow private health insurers to offer a ‘no gap’ and ‘gap permitted’ range of prostheses (chapter 10).

Under the no gap system, new devices and prostheses diffused quickly to private patients. For example, Steketee (2005) reports estimates from BUPA Australia that 90 per cent of patients in private hospitals undergoing stenting received DES, compared with 30 per cent of public patients (appendix H). However, once new technologies have diffused to the private sector, there is significant pressure to adopt them in the public sector.

Expenditure on new prostheses in the private sector has also been higher because of apparently higher unit prices charged to private health funds compared with public hospitals for similar items. For example, the VDHS (sub. 24) suggested that the unit costs for joint replacements are between 12 and 30 per cent higher in the private sector. Similarly, BUPA Australia noted that it pays significantly more for some prostheses than public hospitals — for example, it pays about 50 per cent more for a Boston Scientific DES (\$3600 compared with \$2400) and over 60 per cent more for a Medtronic Pacemaker (almost \$9900 compared with \$6040) (sub. 28).

It has been argued that the higher unit prices faced by private insurers were a by-product of the no gap requirement. For example, BUPA Australia claimed:

These prices are fuelled by the legislative restrictions which prohibit health funds from effectively negotiating prostheses prices on behalf of their members. Health funds, as payers of prostheses, have no market power in this area. This is brought about by the current inequitable system that mandates that health funds must pay the full price of prostheses charges, and that there can be no out-of-pocket cost for consumers. This allows prostheses suppliers an easy path to put significant upward pressure on their prices. Whilst the current system is meant to have a negotiation process, in actual fact, this does not exist. (sub. 28, p. 4)

However, MIAA (sub. PR54) commented that these price differentials may persist for a number of other reasons, including volume discounts for the public sector. That said, some of the price differentials quoted by BUPA Australia appear large.

The proportion of the population with private health insurance has affected total spending on new technology because of the higher use and, in some cases, prices

for these technologies in the private sector. It is too early to assess the extent to which the recent legislative changes will alter these trends.

As noted above, to the extent that the previous no gap requirement for prostheses increased demand for new technology in the private sector, there is likely to have been increased pressure to use these technologies in the public sector. In the case of laparoscopic cholecystectomy, for example, there is some evidence of convergence in the use of this technology in the public and private sectors over time. When the technology was first introduced in the mid-1990s, it diffused more rapidly to private hospitals. For example, in New South Wales in 1995, 92 per cent of cholecystectomy patients in private hospitals had laparoscopic surgery compared with 80 per cent of patients in public hospitals (Rob et al. 1998). However, by 2003-04, 96 per cent of cholecystectomy patients in both public and private hospitals underwent laparoscopic surgery (AIHW 2005d).

NSW Health noted the pressure on the public system to adopt technologies from the private sector:

The diffusion of a technology within the private sector may also increase clinician and community expectations. This exerts pressure for the expansion of the technology to the public sector, irrespective of the effectiveness and cost effectiveness of the technology or previous service planning. Once a technology diffuses into the private sector, and has attracted significant attention, it is often too late to undertake a formal assessment and will put further pressure on the public system. (sub. 20, pp. 14–15)

In particular, this pressure may come from peer influence and from medical staff working in both sectors (chapter 2).

FINDING 4.3

The division of funding responsibilities in the health sector influences expenditure on new technologies:

- *The technology choices of individual public agencies and institutions are often constrained by short-term budget caps. Hence, they have little incentive or ability to take into account the impacts of their treatment choices on either their own future spending or on consequent expenditure in other parts of the health system.*
- *This creates a bias toward technologies that produce short-term cost savings in particular parts of the health system, possibly at the expense of technologies that are more cost effective but have higher upfront costs.*

FINDING 4.4

Increases in the proportion of patients using private hospitals (reflecting in part increased private health insurance coverage), combined with regulatory restrictions on gap payments for prostheses, have increased spending on medical technologies by inducing faster diffusion of more advanced and expensive technologies and apparently higher unit prices in the private sector. Diffusion in the private sector appears to place pressure on public hospitals to adopt the technology.

4.4 Summing up

The analysis in this chapter provides support for the finding in chapter 3 that technology, on average, has increased net health expenditure over the last decade. However, it makes little sense to consider the increase in expenditure generated by new technologies in isolation from the benefits they provide. These benefits are examined in chapter 5.

Considering two areas of the health system that have driven health expenditure growth over this period — pharmaceuticals and inpatient care — it is evident that technology has played a key role in the growth in expenditure in both areas. New pharmaceuticals have increased PBS expenditure by increasing the average price of drugs available and by expanding the treatment population for various diseases. Advances in technology for inpatient care have mainly affected expenditure through increases in the average cost of treating a patient. While hospital separations have remained relatively constant, the stability masks two offsetting effects of the impact of new technologies on the volume of treatment. First, less invasive and more effective procedures have increased the number of patients treated. Second, improvements in pharmaceuticals have reduced separations for other diseases.

Considering the expenditure impacts of some individual technologies, it is evident that in the majority of cases examined, these have increased net health expenditure. Even technologies that have decreased the unit costs of treatment, or produced offsetting cost savings elsewhere in the health system, have tended to generate increases in the volume of treatment and, thus, are more likely to have increased overall health expenditure.

The division of government funding responsibilities in the Australian health system, and the incentives created by these divisions, may have dampened the net up front expenditure impact of new technologies. In particular, budget caps and cost shifting behaviour arising from compartmentalised funding arrangements, create bias toward

adopting technologies that produce short-term cost savings in particular areas of the health system.

An increase in the proportion of the population with private health insurance, on the other hand, has magnified the impact of new technologies on expenditure, particularly in combination with arrangements that have required private insurers to offer reimbursement for the latest prostheses to private patients, regardless of price.

It is improbable that these different incentives and the distribution of responsibilities for costs combine to produce the most cost-effective or efficient outcome for the community overall.

5 Benefits of advances in medical technology

The terms of reference (f) require the Commission to investigate the net impact of advances in overall and individual health technologies on economic, social and health outcomes, including an examination of which demographic groups are benefiting from these advances.

The previous two chapters examined the expenditure impacts of advances in medical technology, both in the aggregate (chapter 3), and in relation to specific technologies or categories of technologies (chapter 4).

Although a number of factors drive the use of, and therefore expenditure on, medical technology (chapter 2), underlying all these is a desire to capture the benefits it can provide, such as improved patient care or saving lives. Medical technology may also have effects beyond its primary intended purpose.

Most formal studies, however, have focused on the expenditure impacts of medical technology, partly because costs are more easily identified and quantified than are benefits. According to the Australian Nursing Federation, ‘research on the benefits of technological advances in health care is still in its infancy’ (sub. 26, p. 5).

To the extent allowed by the available information, this chapter examines the benefits of advances in medical technology. It begins with a discussion of how outcomes can be measured and issues that arise in their measurement (section 5.1), before outlining what some health outcomes have been for Australia (section 5.2). Section 5.3 discusses the relationship between the use of advances in medical technology and health outcomes over the past decade. Section 5.4 summarises the analysis of the previous sections.

Offsetting cost savings, although obviously a benefit, are not considered in this chapter. These cost savings were incorporated in the analyses of chapters 3 and 4, as contributing to the net expenditure impacts of advances in medical technology. The distribution of benefits across various groups in society is discussed in chapter 6, and the overall impact of medical technology on cost effectiveness of healthcare delivery is discussed in chapter 7.

5.1 Measuring outcomes

The classification of outcomes provided by the terms of reference for this study — economic, social and health — is one of many ways that outcomes can be categorised. Medicines Australia (sub. 30) provided an alternative interpretation, comprising clinical, humanistic and economic categories.

These broad distinctions can be arbitrary, and interactions among different types of outcomes need to be accounted for. Moreover, a thorough ‘economic’ analysis should in theory incorporate all of these outcomes — individual and social, tangible and intangible — not just what can be readily measured in financial terms or physical output (appendix B). In practice, measuring outcomes — however they are categorised — is fraught with difficulty. Pragmatic decisions often need to be made in light of available information and the ultimate purpose of the analysis. Some of these issues are outlined in this section, using the three broad groups of outcomes identified in the terms of reference as a framework for discussion. More detailed discussion is contained in appendix B.

Measuring health outcomes

Health outcomes are those outcomes that relate to physical, social and mental wellbeing. This broad perspective is consistent with the World Health Organization definition of health, and incorporates a range of considerations involving the non-material aspects of quality of life (QoL). This includes, but is not confined to, life expectancy and the absence of illness or disability.

Such a broad conception of health makes it difficult to identify appropriate measures of benefits. Indeed, the UK Department for International Development Health Systems Resource Centre (DFID 2000, p. 2) noted that ‘the search for an agreed and accurate measure of health benefits has proven elusive’, with many specific indicators used (box 5.1). These include general single-dimension and summary indicators, incorporating so-called QoL instruments, that are discussed below. Because each offers a different perspective and requires different information, the choice of which to use depends largely on circumstances.

Single-dimension measures of population health outcomes

Single-dimension outcome measures focus on a specific aspect of health. Some of the most commonly cited measures include:

- mortality rates — the number of deaths in a specified period as a proportion of the population (generally quoted in terms of deaths per thousand people);

- life expectancy — estimated using mortality data, this indicates how long a person can be expected to live, measured at a particular age (often birth);
- disease incidence — the number of new cases of a condition that are diagnosed in the population during a specified time period; and
- disease prevalence — the number of cases of a condition in the population at a particular point in time (appendix B).

Box 5.1 Health outcome indicators — an overview

Many specific indicators of health and health outcomes have developed over the years relating to, for example, years of life saved, number of deaths averted, and improvements in emotional, physical or social functioning.

- They can be single-dimensional, relating to a particular aspect of health such as life expectancy, or multi-dimensional ‘summary’ measures, incorporating several aspects of health such as mortality and morbidity.
- Some are specific to patients, conditions or contexts, while others are more generic and relate to outcomes at the population or systemwide levels.
 - Patient-, condition- or context-specific measures can relate closely to actual patient outcomes and experience, and can provide useful complementary information for broader measures, but do not provide a common measurement unit to allow comparisons for cost-effectiveness analysis or resource allocation.
- They can involve final (ultimate) outcomes or intermediate (surrogate) outcomes, which are linked causally to an ultimate outcome, such as risk factors for, or detection of, disease. A possible ultimate outcome is, for example, the prevention of death or suffering due to stroke, with reduced blood pressure the related surrogate outcome.
 - Intermediate outcomes tend to be used when it is infeasible to measure final outcomes, as can be the case in clinical trials. Nonetheless, the Department of Health and Ageing (DoHA) prefers final outcomes, such as deaths prevented, life years gained or quality-adjusted life-years, to be used in submissions to the Pharmaceutical Benefits Advisory Committee (PBAC).

Sources: Cairns (1996); DoHA (2002b); Peacock et al. (2001).

On their own, these measures provide a relatively narrow, although potentially useful and easy to understand, perspective of outcomes. For example, although average length of life and mortality data provide some indication of the wellbeing of a population, they do not provide a picture of the state of health or quality of the years lived. Yet QoL becomes more important as the population lives longer and the potential for further gains in longevity becomes more limited (Australian Nursing Federation, sub. 26; Dolan 2000).

When used in conjunction with other measures, such as in the calculation of summary measures, single-dimension measures can contribute to a broader picture of health status. They can also be a basis for calculating other single-dimension measures used in clinical trials, such as years of life saved (YOLS), which are calculated as the difference between life expectancy with a specific treatment and life expectancy with another (or no) treatment. The usefulness of the information these measures provide is of course highly dependent on the quality of the data on which they are based (appendix B).

Summary measures of health outcomes

As noted by Gold et al. (2002):

Although mortality-based rates are useful in a cursory way, they provide insufficient information to make any but the most basic judgments about the health of a population or the comparative impact of an intervention. The contribution of chronic disease, injury and disability to population health goes unrecorded. (pp. 115–16)

Summary measures of population health aim to fill this gap by combining information on mortality and non-fatal health outcomes to represent population health in a single number (Mathers et al. 1999; appendix B). They have been developed for various purposes (box 5.2), including the need to compare outcomes across conditions and/or interventions in light of rapidly expanding healthcare expenditure, and the inadequacies of single-dimension statistics for this task.

Box 5.2 Potential uses of summary health outcome measures

- Comparing health conditions or overall health status between two populations or the same population over time.
- Quantifying health inequalities.
- Ensuring that non-fatal health outcomes receive appropriate policy attention.
- Measuring the extent of different health problems using a common metric.
- Analysing the benefits of health interventions for use in cost-effectiveness studies.
- Providing information to assist in setting priorities for health planning, public health programs, research and development, and professional training.

Sources: Mathers et al. (1999); Murray et al. (2002).

The measures most commonly referred to are the:

- quality-adjusted life-year (QALY), the most widely used measure of health-related utility — which combines QoL and survival into a single index number

by weighting the time spent in each health state by an associated quality/utility weight between 0 (death) and 1 (full health) (health states deemed worse than death can have negative values); and

- disability-adjusted life-year (DALY) — which is calculated as the sum of years of life lost due to premature mortality and years lost due to disability, and is said to provide a measure of the burden of disease (box 5.3; appendix B).

Box 5.3 **Burden of disease**

The ‘burden of disease’ is the overall impact of a disease — incorporating impairments to quality of life, disability and premature mortality — due to its presence in a population. It therefore measures the *health burden* that particular diseases, conditions or risk factors place on society.

Estimates of the health burden of disease can be used to estimate the *economic burden* of specific diseases — by, for example, multiplying the DALYs attributed to a disease by the estimated value of a DALY. This provides an estimate of the burden (in dollar terms) that can be attributed to the projected disability arising from new cases of, and from premature mortality due to, a condition. This value reflects factors such as the impact on the ability of those who have the condition to participate in work, social activities, and other activities or roles. It does not include the influence on families and carers, however, so may not provide a complete picture of the burden.

Burden of disease estimates cannot be directly related to healthcare expenditure, which is a measure that only examines the financial cost (burden) of treating the disease. To the extent that expenditure on prevention and treatment reduces disease burden, expenditure estimates relate to the burden averted by the health system, whereas measures such as DALYs relate to the current incident burden not averted.

Sources: ACAM (2005b); appendix B; Mathers et al. (1999).

Both QALYs and DALYs involve describing health (as a health state or condition), developing values or weights for the state or condition, and combining values for different states or conditions with estimates of life expectancy (Gold et al. 2002). They differ, however, in the aspects of health that they value, populations from which values are derived, the way life expectancy is handled, weights used and underlying assumptions (Gold et al. 2002; appendix B). One QALY can be thought of as a year of healthy life, while one DALY can be thought of as a lost year of healthy life. Various technical, conceptual and practical issues confront the calculation and use of QALYs (box 5.4), as well as of DALYs, so caution is needed in using and interpreting them (appendix B).

Box 5.4 **Potential problems using QALYs in economic evaluation**

- Restrictive underlying assumptions that may not reflect reality.
- Lack of sensitivity when comparing the efficacy of similar drugs, and the treatment of less severe health problems.
- Difficulty accommodating chronic diseases, where QoL is more important than survival (disease-specific measures tend to be used in such cases).
- Difficulties quantifying the impact of preventative measures, where health impacts may not occur for many years, because the importance attached to each dimension depends significantly on age, and life context and responsibilities.
- Inadequate weight attached to emotional and mental health problems.
- Lack of consideration of QoL of carers and other associates.
- The assignment of lower value to life extensions for the chronically ill/people with disabilities than for otherwise healthy people.

Sources: Nord et al. (2003); Phillips and Thompson (2001).

Measuring social outcomes

The benefits of advances in medical technology may not accrue exclusively to the technology's direct users — patients or service providers, for example. Others also may be affected indirectly. Social outcomes refer to these 'external' outcomes that are non-pecuniary. They are also often intangible and, consequently, can be difficult to quantify. Moreover, they may not be clearly 'positive' or 'negative', so can give rise to debates about ethics and the nature of society and its values. When concrete indicators of outcomes cannot be devised, more qualitative and anecdotal indicators need to be used.

Various possible social outcomes can result from advances in medical technology.

- *Health-related spillovers.* Vaccinations against infectious disease protect those who are vaccinated and may also reduce the likelihood of infection of unvaccinated people. Improved diagnostic techniques may reduce contagion risks.
- *Changes to community expectations* about, for example, the extent and type of treatment that should be expected for people of certain age groups or with particular conditions.
- *Changes to the age structure of society* due to, for example, changes in fertility and/or mortality rates.

-
- *Quality of life of associates and carers.* Improvements in a person's health may improve the QoL of family and friends.
 - *Contributions to general culture and knowledge.* Advances in medical technology, such as imaging, can be applied, and hence enhance knowledge, in non-medical areas such as archaeology.
 - *Environmental spillovers* can arise in the production and/or use of new technologies — if, for example, required inputs have associated risks (such as in nuclear medicine), or involve expensive or special disposal methods.

Measuring economic outcomes

As noted above, a thorough economic analysis incorporates tangible and intangible outcomes at both the individual and societal levels. Thus, in theory, it incorporates the value placed by individuals, on their life and wellbeing — even if this is not (easily) quantifiable in monetary terms. This includes the quantity and quality of leisure time, not just the 'value' of their productive capacity to the broader community (appendix B). In general, then, economic analysis can be seen to incorporate a range of outcomes, which can be considered in terms of broad categories representing the main areas of interest. In the present context, this means that 'economic outcomes' are one part of an economic analysis, along with the health and social outcome categories identified in the terms of reference. Bearing this in mind, in this report, economic outcomes are defined to involve material and production-related aspects of life and the economy. They can be measured at several levels and with various indicators (box 5.5).

Medical technology can affect economic outcomes both directly and indirectly. Direct outcomes are the immediate consequence of using a technology in a specific application (the administrative and efficiency impact of adopting appropriate information and communications technology (ICT), for example). The indirect outcomes are flow-on effects such as improved health leading to increased labour supply and, through this, increased GDP per capita (Bloom et al. 2004; Lichtenberg 2002a).

As with most indicators, measuring economic outcomes involves numerous difficulties, including: conceptual and methodological issues surrounding measurement of the 'quantity' aspect of the indicator; attribution of the health condition to (changes in) the outcome; and valuation, including valuing productivity in paid work, unpaid work and regular activities (appendix B).

Box 5.5 **Some economic impacts of advances in medical technology**

Technological change can have impacts at various economic levels, including on:

- **individuals**, whose health status can affect their labour force participation, hours in paid and unpaid work, earnings, number of days at work and/or school, and (quality of) leisure time;
- **associates of the individual**, as reflected in, for example, the time spent by carers in paid and unpaid work, and leisure, and their productivity in these pursuits;
- **healthcare sector organisations**, with possible effects on the overall use of resources — such as emergency departments, beds, labour, and time spent undertaking particular tasks — and productivity;
- **firms and industries** in general, in relation to the age structure of their workforce, and workplace productivity, which can be affected by levels of absenteeism, productivity levels while at work, and the retirement age of individuals whose health is affected; and
- **the economy as a whole**, including possible effects on productivity, labour force participation rates, the age structure of the workforce, and GDP.

There is particular (and unresolved) debate about whether, and how, indirect economic outcomes (specifically health-related impacts on workplace productivity), should be included in an assessment of technology impacts. The Commission notes that measurement of indirect outcomes does require caution — the approach adopted should be consistent and avoid double-counting. Hence, to the extent that QALYs and other QoL measures incorporate an individual's work-related functionality/productivity, these productivity impacts should not be measured as an additional indirect economic benefit. On the other hand, if the work of colleagues is also affected and this is not captured by the QALY measure, then these indirect effects could be considered (appendix B).

General measurement issues

In addition to the indicator-specific measurement issues alluded to above, other general issues are involved in measuring outcomes.

- *Discounting.* Discount rates, reflecting the different value placed on what occurs now and in the future, can be used to consistently measure expenditure or benefits that occur at different times. The need to discount costs is accepted but there is debate about whether health benefits should also be discounted and the appropriate level of the discount rate, including whether it should differ from that used to discount costs (appendix B).

-
- Discounting effectively gives less weight to changes in health that endure for a long time or occur in childhood, and conditions with high levels of mortality at younger ages, compared with those that last for shorter periods.
 - *Marginal or average outcomes?* Average outcomes — the way in which most health outcome information is reported — refer to the total impact of a technology expressed as a proportion of the total affected population. Marginal analysis, on the other hand, examines the additional or incremental impact of the technology, that is the impact on the last relevant unit (patient treated, for example) to which it is applied. Marginal and average values are unlikely to be identical in the healthcare context, where the net benefits of technology vary substantially across the patients or organisations that use them.
 - Marginal analysis generally is preferred for cost-effectiveness analysis and resource allocation decisions although some have argued that it may not always be sufficient for assessing health-related outcomes (appendix B).
 - *Valuing outcomes.* There are several approaches for valuing mortality and morbidity outcomes in healthcare, all involving the measurement of the value of a ‘statistical life’. Value-of-life estimates can then be used to value QALYs and DALYs (appendix B). Such valuation involves various ‘conceptual, ethical and practical problems’ (McIntosh et al. 1999, p. 358) that are avoided by both cost-effectiveness and cost–utility analysis, and many of the estimates seem very high (appendix B). However, expressing both costs and benefits in monetary terms allows comparison of the net benefits of health and non-health expenditure.

5.2 Health outcomes in Australia

In 2003 (the most recent year for which data are available), Australians on average could expect to live longer and healthier lives than they could expect a decade earlier. There were differences in the level of, and changes in, health status across groups and regions, however.

The 132 300 deaths in Australia in 2003 represented an age-standardised mortality rate of 6.4 per 1000 population, compared with 8 per 1000 population in 1993, a decline of 20 per cent (ABS 2004d). In that time, mortality rates for females fell 18.8 per cent, from 6.4 to 5.2 per 1000 population, while those for males fell 22.5 per cent from 10.2 to 7.9 per 1000 population (ABS 2004d). Although mortality rates fell in all jurisdictions, they were much higher in the Northern Territory than elsewhere (9 per 1000 population) and lowest in the Australian Capital Territory (5.8 per 1000 population).

The Victorian Department of Human Services (VDHS, sub. 24) commented that overall mortality improvements equated to 640 000 extra years of life already lived over the past decade.

Life expectancy at birth for Australians in 2003 was about 80.4 years, compared with about 77.7 years a decade earlier, an improvement of 2.7 years.

In that time, life expectancy for females increased 2.3 per cent, from 80.9 to 82.8 years, and that for males rose 4.5 per cent, from 74.5 to 77.9 years (ABS 2004d). Life expectancies were lower: in the Northern Territory than for other jurisdictions; in rural and remote populations; and for Indigenous Australians.

5.3 Linking outcomes to advances in medical technology

That advances in medical technology have delivered various, sometimes significant benefits, is undeniable. Increases in expenditure and numbers of patients treated often reflect (at least in part) the perceived benefits of advances that have resulted in, for example, less invasive and more effective procedures (chapter 4).

However, any attempt to quantify the influence of advances in medical technology on health, social and economic outcomes confronts many difficulties.

- *Isolating the impact of medical technology.* Many factors other than medical technology, both within and external to the healthcare sector, influence health outcomes. These include socioeconomic and demographic characteristics, infrastructure, diet and the environment (SCRGSP 2005). For the most part, studies of specific technologies are better suited to estimating the contribution of advances than are studies of technology at an aggregate level.
- *Lags between cause and effect.* At both patient and population levels, the full impact of an intervention may not be felt immediately. Preventative interventions and vaccinations, for example, target populations before the onset of a condition, which may not otherwise have occurred until many years in the future (if at all). Even treatment of acute conditions can have uncertain lifetime impacts beyond the treated episode.
- *Identifying and measuring the appropriate indicator of outcomes,* as discussed in section 5.1.
- *Data and information availability.* The information required for accurate measurement of the impacts of medical technology are often unavailable, incomplete or inconsistent. Thus, any conclusions based on these must be treated with some caution.

-
- *Applicability of trial results to the real world.* In many cases, the available data have been generated in a trial setting. The extent to which this translates into outcomes in the real world is affected by factors such as the design and length of the trial (especially where lags or long-term side effects are an issue), and the characteristics of the participating groups relative to future real-world patients.
 - *Benefits can change over time.* The Medical Industry Association of Australia (MIAA, sub. PR54, p. 4), for example, commented that ‘it is highly unlikely that the benefits of today’s pacemakers will be the same as the pacemakers available in 10 years’. Likewise, the benefits of some surgical procedures may increase as practitioners become more experienced in performing them.
 - *Methodological issues.* Formal studies of the benefits of technological advances have been conducted, with some applying econometric techniques and using health outcome measures such as QALYs and DALYs as inputs. These tend to be limited in scope (many focus on pharmaceuticals), and there are issues about the appropriateness of the models used and underlying assumptions, as well as data quality.
 - *Valuing outcomes.* The methods used to estimate the value of life, productivity gains and so on, are subject to controversy (appendix B).

Additional complications exist for analysing benefits in this study.

- *Lack of local studies.* Of the available studies, most have not been undertaken for Australia. Although international studies can be useful and broadly indicative of impacts, any inferences drawn for Australia must be mindful of differences in the broader health, social and economic environment across countries.
- *Timeframe of analysis.* The period of analysis in many studies does not coincide with that required for this report, that is, the past ten years.
- *The focus on advances in medical technology.* Several studies use measures of the cost of technology (such as total health or pharmaceuticals expenditure) that include all vintages of the technology in question, rather than just the ‘new’ component (that is, the expenditure that reflects advances).

These issues necessarily constrain the present analysis. Nonetheless, several observations can be made about the impact over the past decade of advances in medical technology — in the aggregate, by broad category (pharmaceuticals), and by specific technologies.

The impact of medical technology in aggregate

The evidence on the impact of advances in medical technology in aggregate is relatively limited, with most research focusing on specific technologies (especially pharmaceuticals, as discussed below).

Estimates of the impact of healthcare expenditure on health outcomes, and the returns to health-related research and development (R&D) can provide an indirect way to assess the aggregate impact of technology. Studies of this type tend to use longevity or mortality as the health outcome of interest. Lichtenberg (2003a, p. 3) noted that, until recently, it had generally been thought that the contribution of medical care to increasing longevity has been ‘quite modest’. Other factors, such as education, lifestyle, nutrition and the environment, have been suggested as more important influences. Recent research has, however, found that some medical technologies have played a greater role than previously thought.

Impact of healthcare expenditure on health outcomes

A recent Australian study, using 1996 population data, found that medical expenditures were health-improving (in terms of reducing mortality), and that their benefits relative to their costs were still increasing (Connelly and Doessel 2004). To the extent that some of this expenditure was incurred on ‘new’ technologies, it suggests that technological advances may have had a positive impact on longevity in Australia.

A study in the United States (MEDTAP International 2004) suggested that improvements in health and the associated expenditure between 1980 and 2000 resulted in 470 000 fewer deaths, 2.3 million fewer people with disabilities and 206 million fewer days spent in hospital than would otherwise have been the case. The study only examined impacts on longevity, but assumed that all improvements in health outcomes were due to increased expenditure on health services (other contributing factors were assumed not to have changed in net terms in that time).

Impact of medical research on health outcomes, and returns to research

Both ‘formal’ research (basic laboratory studies and applied research such as randomised clinical trials) and ‘informal’ research (improvements in knowledge generated outside the context of basic research and clinical trials, such as through clinical practice) have improved population health outcomes (Heidenreich and McClellan 2003). Heidenreich and McClellan (2003), investigating changes in treatment of acute myocardial infarction (AMI), for example, noted the benefits that derived from formal research, but also that the health benefits of the informal

development of medical practices ‘far outweighed their costs’ (p.192). They commented further that:

... informal, incremental developments in clinical ‘know-how’ that occur beyond the setting of formal biomedical research studies are major contributors to growth in the biomedical knowledge base and to the resulting improvements in population health. (Heidenreich and McClellan 2003, p. 192)

US studies that have attempted to quantify the returns to medical research, have found the gains in terms of lives saved to be substantial. Murphy and Topel (2003), for example, estimated that, the net value (total value of the gains less the increase in health expenditure) of increased longevity was eight times greater than research expenditure over the 1970–98 period (even if only 10 per cent of that value was due to increases in medical knowledge). The greatest returns were in the first decade of the period. Reduced mortality from cardiovascular disease (CVD) has been the main contributor to increased longevity (Cutler and Kadiyala 1999; Rosenberg 2002). Cutler and Kadiyala (2003) commented that the average 45 year old American now lives 4.5 years longer than in 1950, simply due to the reductions in CVD mortality.

Cutler and Kadiyala (2003) investigated the link between medical research and CVD mortality. Examining the effects of research on both treatments and behavioural change, they suggested that around one-third of the improvement in CVD mortality was due to each of high-technology invasive treatments, low-technology pharmaceutical innovation and behavioural change. The subsequent estimated rate of return to medical technology innovation was around 4 to 1, with the return to new knowledge about 30 to 1. Access Economics (2003c) estimated that annual rates of return to Australian medical R&D were between one and five times expenditure. In the 1999 base case, the figure was 2.4 times (1.3 due to improved longevity and 1.1 due to improved wellness).

Impact of health status on other outcomes

A number of studies at the aggregate level examine the impact of improved health status on other, generally economic, outcomes. The contribution of medical technology to these other outcomes would need to be assessed indirectly — by estimating the impact of technology on health (which, as already noted, only tends to have been quantified in relation to specific technologies). These studies have found improved health increases:

- GDP per capita, which a recent cross-country study estimated increased by around 4 per cent for each extra year of life expectancy (Bloom et al. 2004); and
- workforce participation among older workers. Cai and Kalb (2005), for example,

found that over 81 per cent of older working-age Australian men who reported poor health were not in the labour force, compared with only 15 per cent of those who reported very good health. Another Australian study (Walker 2004), found that, although government incentives and improved job availability significantly influenced participation, improved health in 1998 would also have led to an additional 500 000 people aged 65 to 70 years remaining in the workforce (increasing their earnings and reducing government expenditure on pensions).

Recent US research shows that poor health can also have significant effects on productivity (measured as the percentage of time that a worker is working at full potential), mostly due to lost productive hours rather than absence (Gross 2003). Therefore, to the extent that advances in medical technology have played a role in improving health, they would have indirectly contributed to increased worker participation, productivity and GDP per capita.

The value of improved health outcomes

Many studies, including some of those cited above, have attempted to place a value on improved health outcomes. Nordhaus (2003), for example, estimated the value of improvements in living standards due to decreased mortality to be equivalent to as much as 40 per cent of US consumption over the period 1975–95, or between about 1.6 and 2 per cent of consumption per year. He suggested that including morbidity improvements might add another 5 per cent or more to the estimated value of health improvements.

MEDTAP International (2004) estimated that the value of the reduced deaths in the United States between 1980 and 1998 was US\$1.9 trillion (assuming a value of life of US\$4 million), with the two-year increase in life expectancy estimated to be worth US\$1.5 trillion (assuming a net present value of a life year of US\$100 000, undiscounted).

Murphy and Topel (2003) estimated the value of increased longevity in the United States between 1970 and 1998 to be US\$2.6 trillion per year (in 1996 US dollars), equal to about 45 per cent of average measured GDP over that period. The gains peaked at about \$350 000 for men at age 50, and at about \$180 000 for women at age 45. The 1970–80 period accounted for more than half of the overall value of the gains (US\$37 trillion), with gains lowest (though still high) between 1990 and 1998 (US\$16.7 trillion).

The value of increased longevity in Australia likewise may be considerable.

- Access Economics (2003c) valued improved health in Australia between 1960 and 1999 at \$5.4 trillion (\$2.9 trillion due to longevity and \$2.5 trillion to

morbidity improvements). The longevity component accounted for 46 per cent of Australian consumption expenditure over the period, and was worth \$142 billion per year by 1999. Cardiovascular improvements accounted for about one-third of the gains.

- In a less formal approach, the VDHS (sub. 24) estimated the value of lower mortality rates alone in Australia over the past decade, would be \$110 billion, when considering the years to be lived in the future. This figure would double if the same gains were realised in relation to morbidity. These figures are based on the assumptions that two-thirds of the years gained are healthy, half are due to healthcare (including public health programs and education campaigns, as well as medical technology) and the value of a healthy year of life is \$100 000.

The economic gains of increased longevity have been found to rise over time, and increase with a larger population, higher average lifetime incomes, and better existing health levels, and the closer the ages of the population are to the onset of disease (Murphy and Topel 2003). Murphy and Topel (2003) suggested that economic growth and population ageing alone would increase the economic return to improved treatment of many diseases by almost 50 per cent between 1990 and 2030.

The impact of broad categories of technologies

Most quantitative research relating to the impact of broad categories of technology has focused on pharmaceuticals, in part reflecting the greater availability of data relative to other technologies (Lichtenberg 2003a).

Participants in this study commented on the variety of benefits that pharmaceuticals can provide including saving and prolonging lives, improving QoL (by, for example, decreasing recovery times, allowing people to lead more active and productive lives, and reducing their pain), preventing and curing disease, reducing the need for admission to hospitals and institutions, and improving safety and/or reducing side effects (GlaxoSmithKline Australia, sub. 21; Medicines Australia, sub. 30; MIAA, sub. 17; Pharmacy Guild of Australia, sub. 13).

Medicines Australia commented on the range of conditions for which pharmaceuticals have improved outcomes in the recent past:

For the main chronic illness areas such as diabetes, asthma, cardiovascular disease, musculoskeletal disease and mental health, medicines are central to improved outcomes in the past 10–20 years. The introduction of statin medications for elevated cholesterol, improved oral hypoglycaemic medications for type 2 diabetes, inhaled corticosteroids for asthma and SSRI [selective serotonin reuptake inhibitors] antidepressants for depression have all had significant impact on disease burden. (sub. 30, p. 60)

A number of studies, mostly conducted overseas, have tried to quantify these benefits. The quality of the results is affected by factors such as sample size, and the extent to which they control for the severity of illness and define appropriate lags between drug launch and effect.

Crémieux et al. (2005) found a ‘strong statistical relationship’ between pharmaceutical expenditure and health outcomes in Canada between 1981 and 1998, particularly in relation to infant mortality and life expectancy at age 65, and for private rather than public spending. They estimated that 15 000 lives had been saved due to the increase in pharmaceutical expenditure since 1981, noting that outcomes would have been better (an average of 584 fewer deaths each year, or up to 10 509 fewer deaths in the first year of life, and several-month increases in life expectancy) had expenditure in all provinces equalled that of the two highest-spenders. Pharmaceutical expenditure generally had a more significant impact on life expectancy (except infant mortality) than did other medical expenditure.

Lichtenberg (2003b) examined the relationship in the United States across diseases between the reduction in life years lost before age 75 and the relative use of new pharmaceutical products over the period 1970–91. Overall, he estimated that each new drug approved during that period saved 18 800 life years in 1991. Over 45 per cent of the variation in the reduction in mortality across diseases was explained by new-drug share — the reduction in life years lost was five times greater for the 19 diseases with the highest relative use of new drugs than it was for the 19 diseases with the lowest relative use. The impact was ‘much greater’ between 1970 and 1980 than it was for the 1980–91 period, but the significance of the impact was larger over the entire 21-year period than either subperiod, reflecting the long-run effects of new drugs. Only the highest third of the age distribution benefited between 1980 and 1991. He tentatively estimated the social rate of return to pharmaceutical innovation over the period to be 68 per cent.

Lichtenberg (2003a) found that, after controlling for education, income, nutrition, the environment and ‘lifestyle’, the launch of new chemical entities (NCEs) had a strong positive impact on the probability of survival — accounting for 40 per cent (1.96 years) of the long-run increase in longevity in the sample as a whole between 1986 and 2000. Many older non-NCE drugs had no impact. The maximum impact was felt with a three to five-year lag, reflecting gradual diffusion.

Using Puerto Rican data, Lichtenberg (2004a) found that drug vintage had a significant effect on a patient’s three-year probability of survival (between 2000 and 2002) — estimated mortality rates strictly declining with drug vintage. He estimated that new drugs introduced from 1970 to 2000 reduced the mortality rate by about 0.58 per cent per year. The actual mortality rate was about 16 per cent lower than it would have been if all drugs consumed were of pre-1970 vintage.

Using 1997 US data, Lichtenberg and Virabhak (2002) examined the impact of new drugs on various indicators of health — survival, perceived health status, and presence of physical or cognitive limitations. They found that those taking newer drugs had better post-treatment health than those using older drugs for the same condition. The effect was greater for those with lower initial health, suggesting that ‘pharmaceutical-embodied technical progress has a tendency to reduce inequality as well as promote economic growth’ (p. 28).

Frech and Miller (2004) also examined the impact of pharmaceuticals, both on life expectancy and disability-adjusted life-expectancy (DALE) (appendix B) in OECD countries. They found that pharmaceutical consumption had a greater impact on DALE than on life expectancy, suggesting ‘much of the benefit of modern healthcare is on quality of life’ (Frech and Miller 2004, p. 35). Non-pharmaceutical expenditure did not appear to have an impact (although they noted this could have been due to statistical anomalies).

In terms of economic outcomes, Gross (2003) noted that pharmaceuticals are able to target many of the chronic illnesses that affect productivity. Lichtenberg (2001, p. 247) found that those consuming new drugs were ‘significantly [in a statistical sense] less likely to experience work-loss days than persons consuming older drugs were’, although the effect was not very large. (The age of drugs did not affect school days and only marginally affected bed days, but did affect the number of hospital stays.)

Lichtenberg (2002a) also found that newer vintages of pharmaceuticals decreased the probability that people experienced activity limitations, reducing the number of days where their activity was restricted. Accordingly, he concluded that newer drugs contribute to increased labour supply and, therefore, GDP per capita. Lichtenberg (2005) estimated that the growth in the lagged stock of pharmaceuticals (used to treat 47 chronic conditions) between 1982 and 1996 reduced:

- the probability of being unable to work by 1.8 per cent per year, and of being limited in work by 2.0 per cent per year; and
- the number of ‘work days lost’ by 1.0 per cent per year, and ‘restricted activity days’ by 1.5 per cent per year.

He estimated further that the benefits of new drugs, measured as the value of the increase in workforce participation, was eight times greater than the estimated cost of the new drugs. Assuming only 28 per cent of the effect of new drug approvals was attributable to the drugs (the remainder attributable to other medical innovations), benefits were still more than double the expenditure on them.

The beneficial impact of pharmaceuticals has been shown to be enhanced by disease management programs and education, as noted by AstraZeneca:

A major US health plan enrolled over 2000 patients in a disease management program which focused on education about the disease, and the importance of following treatment regimens including medicines such as angiotensin-converting enzyme (ACE) inhibitors ... Patient outcomes were also improved — mortality rates were 15 per cent lower than the expected rates, and patient's ability to perform their normal activities increased by 15 per cent. (sub. 23, p. 4)

The impact of individual technologies

The impacts of specific pharmaceuticals, medical devices and other technologies on health, social and economic outcomes are discussed in this section.

Impact of specific pharmaceuticals

Various Australian and international studies have illustrated the impact of specific pharmaceuticals (box 5.6).

Box 5.6 Impacts of specific pharmaceutical advances

Health outcomes

- *Stomach ulcer medication* — the number of operations to treat stomach ulcers fell from 97 000 to fewer than 19 000 in the ten years following the introduction of stomach-acid-blocking H2 antagonist drugs (Canada).
- *New cancer drugs* have reduced some of the adverse effects of chemotherapy — preventing nausea, restoring lost energy, and stimulating weakened immune systems. They also accounted for 50 to 60 per cent of the gain in US cancer survival rates (which have risen from 50 to 62.7 per cent) since the 1970s, contributing to 10.7 per cent of the increase in US life expectancy at birth.
- *Adjuvant chemotherapy* increased breast cancer survival rates by 33 per cent. In the adjuvant setting, *non-steroidal aromatase inhibitors* increased quality of life and reduced toxicity for metastatic patients, as well as increasing disease-free survival.
- *Herceptin* has been shown to prolong survival of women who have advanced metastatic breast cancer with a specific genetic alteration. Adding Herceptin to standard chemotherapy has been found to control the cancer for longer and increase survival compared with chemotherapy alone. Patients on Herceptin have also been found to be in less pain and suffer less shortness of breath. There may also be benefits for women in the earlier stages of the disease.

(Continued next page)

Box 5.6 (continued)

- *Statins* are considered a key contributor to the large decline in deaths from coronary heart disease, reducing risk factors and overall mortality, although they are generally more effective in secondary than in primary prevention (depending on risk factors).
- Changes in pharmaceutical treatment for AMI — including aspirin, beta-blockers, thrombolytics and ACE inhibitors — in the United States between 1975 and 1995 accounted for about 70 per cent of the change in mortality outcomes for AMI. This included reduced use of older treatments that had proven harmful in some cases.
- *New asthma medication* resulted in a 28 per cent decline in mortality from the condition over ten years during the 1990s (Australia).
- *Selective serotonin reuptake inhibitors (SSRIs)* for depression may have contributed to a reduction in suicide rates for some age groups, and have fewer side effects compared with older antidepressants (enhancing patient compliance).
- Patients treated with *recombinant thrombolytic drugs (rt-PA)*, developed in the 1990s, are at least 30 per cent more likely to have ‘minimal or no disability’ three months after having an ischaemic stroke than those who are untreated immediately following the stroke. Glycoprotein inhibitors are also reported to have improved outcomes for stroke patients in the United States.

Social outcomes

- *Medications for mental illness* have contributed to improved social attitudes to mental illness, and reduced the treatment burden on patients and family members.

Economic outcomes — productivity

- *Influenza vaccines* — vaccinated individuals in a US sample lost 18 to 43 per cent fewer work days, with 18 per cent fewer days of reduced effectiveness, than those receiving a placebo.
- *Migraine medications* reduced productivity loss by 49 per cent per headache during the workday in one US study, while another US study found that more than 50 per cent of workers who received a triptan drug injection for an attack returned to work within two hours, compared with 9 per cent of those who received a placebo.
- *New diabetes medications* resulted in 19 fewer lost work days (5 compared with 24) per 500 days, for those taking the medication compared with the placebo group (United States). Patients with type 2 diabetes who undergo ‘well-managed’ drug therapy are also more likely to be employed and be more productive.
- A new *atypical antipsychotic medication* led to a doubling of employment rates of people with schizophrenia in a US study.
- *New (non-sedating) antihistamines* — a US study reported a 2 per cent increase in daily work output in the three days after receiving the medication, compared with a 7.8 per cent reduction in work output for those receiving sedating antihistamines.

Sources: Appendixes F, G, I; GlaxoSmithKline Australia, sub. 21; Heidenreich and McClellan (2003); Lichtenberg (2004b); Medicines Australia, sub. 30; MEDTAP International (2004).

The impacts documented by these studies include:

- improved health outcomes, such as:
 - increased survival rates, decreased mortality rates and increased longevity due, for example, to asthma medication, statins, and anti-cancer drugs;
 - reduced need for surgery due to stomach ulcer medication, for example; and
 - reduced side effects, for example, due to new cancer drugs and antidepressants;
- improved social outcomes, including improved attitudes to mental illness; and
- improved economic outcomes, such as increased productivity, due to influenza vaccines, non-sedating antihistamines, and new medications for migraines and diabetes; and higher employment rates of patients taking antipsychotic medication.

Impact of specific medical devices

Although published studies have not quantified the impacts of advances in medical devices to the same extent as they have for individual pharmaceuticals, several specific impacts (covering various conditions) have been noted, at least qualitatively. At a broad level, advances in medical devices have reduced disease risk factors, long-term complications of related chronic diseases, and the need for drugs. They have also improved mobility and day-to-day functioning, and reduced hospital admissions, length of stay and the indirect costs of caring for patients.

How medical devices have delivered these benefits can be illustrated with specific examples.

- *Blood pressure monitoring devices* have helped to reduce risk factors for heart disease (MIAA, sub. 17).
- *Diagnostic devices* for heart disease and stroke have helped to monitor symptoms and diseases (MIAA, sub. 17).
- *Home monitoring kits* have improved (made more accurate) self-monitoring of blood glucose levels for diabetes (MEDTAP International 2004).
- *Ambulatory heart monitors* have accelerated rehabilitation, allowing people to lead normal lives or improving their QoL (MIAA, sub. 17).
- *Prostheses* (knee and hip replacements, for example) have alleviated pain and improved physical function in most patients who have not responded to non-surgical therapies. They have also improved most aspects of patients' health-related quality of life, although hip replacements may have delivered a greater return to patients than knee replacements, and primary surgery may have offered

greater improvement than revision surgery (appendix E). Hip replacements have also reduced the need for older people to live in nursing homes (MIAA, sub. 17; MTG 2003).

- *Intraocular lenses* have improved outcomes of cataract operations, restoring vision soon after surgery, with vision restoration helping to prevent premature death due to visual impairment, and reducing the need for older people to live in nursing homes (appendix M).
- *Colonic stents* allow an obstruction to be eased when people are too ill to have an operation or when the cancer is too advanced to be removed by an operation, improving patient QoL (MTG 2003).
- *Implantable cardioverter defibrillators (ICDs)* have been found to significantly reduce mortality from sudden cardiac death (MEDTAP International 2004).
- *Cardiac resynchronisation therapy (CRT)*, which involves inserting a device similar to conventional pacemakers, combined with drug therapy for heart failure patients has been found to reduce complications and mortality relative to traditional drug therapy alone. A recent European study estimated that CRT alone resulted in a 36 per cent reduction in mortality. A US study found that a new version of ICDs, the CRT-D, which combines a defibrillator with a biventricular pacemaker, reduces all-cause mortality and hospitalisation. Overall, both CRT and CRT-D appear to improve patients' functional capacity, exercise tolerance and QoL (MIAA, sub. PR54).
- *Microcoil devices* help prevent stroke and provide effective minimally invasive treatment for brain aneurysms (MEDTAP International 2004).
- *Insulin pumps for diabetics* have improved patient QoL, by providing more control over their condition and increasing flexibility of lifestyle in terms of eating and exercising. They have also improved clinical outcomes (better blood glucose control, resulting in fewer episodes where patients need help from others, and reduced diabetes-related complications). Consequently, they have reduced mortality rates — improved control of glucose levels can prolong life by an average of five years. (MTG 2003)
- *Drug eluting stents* provide some, possibly small, QoL benefits relative to bare metal stents by reducing the rate of restenosis following coronary angioplasty. However, as yet no difference has been found in their impact on major events associated with coronary heart disease (appendix H).

Some positive impacts of other advances in medical technology

Advances in imaging technologies have resulted in less invasive, better quality images and more sophisticated and accurate measurements, that can be delivered faster. This has reduced the need for exploratory surgeries, and broadened the range of treatment and management options (Australian Diagnostic Imaging Association, sub. 12; MTG 2003; SA Government, sub. 35). Advances in ultrasound and cardiac catheterisation, for example, have improved treatment planning and outcomes for heart attacks by providing information on heart functioning and performance (MEDTAP International 2004). Improvements in brain and vascular imaging have also allowed much faster diagnosis of stroke and its possible cause, allowing treatment to begin earlier, thereby improving health outcomes (MEDTAP International 2004).

Although the merits of positron emission tomography (PET) imaging in some uses has been controversial, the Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32) commented on the benefits this can provide in the treatment of cancer. They cited a study of patients with four types of cancer (non-Hodgkins lymphoma; lung; head and neck; and bowel cancers), which found that PET imaging:

- facilitated an increase in cancer survival rates by five to six months on average;
- allowed patients to receive better targeted care based on information about metastatic disease; and
- avoided ‘futile and costly’ surgery or radiotherapy (with consequent QoL improvements and possible productivity gains) (p. 23).

Other benefits delivered by specific technologies include:

- faster recovery from eye surgery and other procedures, due to lasers (MTG 2003);
- reduced hospital stays and recuperation times, due to minimally invasive surgery (MTG 2003) and improved anaesthetics (Australian Society of Anaesthetists Inc, sub. 8);
- an ability to perform procedures on younger, sicker and older patients, and to perform riskier procedures, due to advances in anaesthesia;
- the possibility of earlier treatment of some diseases, with subsequent improvements in mortality, morbidity and length of hospital stays, due to improved turnaround times and accuracy of many pathology tests (Royal College of Pathologists of Australasia, sub. PR52);

-
- better management of people with diabetes, due to the development and widespread availability of the haemoglobin Alc laboratory test, and easier management of the condition due to the development of non-invasive tests that do not require skin puncturing (MEDTAP International 2004); and
 - fewer medical errors, improved efficiency and effectiveness of healthcare, and improved access for rural and remote communities, due to ICT (appendix K).

But advances in technology do not guarantee the ‘best’ outcomes

There is often a presumption that a newer technology must be better simply by virtue of its being an ‘update’ of an existing solution or of its being seemingly more sophisticated. If this presumption does not reflect reality, inappropriate and/or excessive use of the technology can result.

The extent of benefits depends on how technology is used

Advances in some types of technology may only deliver significant additional benefits in a particular setting or for a particular subgroup of patients. At a broad level, benefits can depend on:

- whether the technology is used in primary prevention (that is, to prevent a first episode of a condition) or in secondary prevention (that is, after a person has already had an episode) — as noted in box 5.6 and appendix F, for example, statins have been found to be more effective in secondary prevention than in primary prevention, where the benefits are less clear;
- the age of patients — some interventions, such as some asthma medications, have different effects on younger than on older patients;
- the extent to which patients comply with use instructions; and
- comorbidities — the presence of which can, for example, result in an otherwise beneficial intervention having less beneficial (or even detrimental) impacts or interacting negatively with treatments for the other conditions.
 - In the case of diabetes, for example, the reduction in cholesterol due to statin therapy was found to lower the risk of coronary events (MEDTAP International 2004). More recent research found, however, that statins had no significant effect on ‘severely ill’ diabetics who require haemodialysis, but that their relative risk of fatal stroke doubled (Wanner et al. 2005).

The uptake of technologies in practice has not, however, always reflected these differential outcomes. In part, this is due to the fact that clinical trial design does not always allow these differences to be detected. It also partly reflects the difficulty

practitioners have denying access to available medical advances even if the benefit to a specific patient may be marginal at best (Callahan 2003). That patients do not bear the full cost of interventions reinforces the tendency to use newer technologies.

Low technology solutions are sometimes at least as effective

Interventions, medical and non-medical, that do not rely on ‘high technology’ solutions can be effective and appropriate in some cases. Asthma management plans, for example, have been shown to be effective in managing the disease — helping many to control their asthma and reducing the need for hospitalisation — even though the use of these plans has been falling since 1995 (ACAM 2005b). Preventative measures, including lifestyle changes, can also be effective ways to either prevent the onset of, or manage, illnesses such as CVD and type 2 diabetes.

Yet the emphasis has often been on using new ‘high technology’ medical interventions. This has led to claims by participants to this study, as well as in the broader literature, that some conditions have been ‘medicalised’, and some technologies overused.

- Already the most commonly performed surgical procedure in Australia, the use of caesarean sections to deliver babies is increasing (accounting for about 30 per cent of births), even when medically unnecessary. This is despite the availability of less-technologically intensive yet effective alternatives, and the risk of complications (to the mother and/or baby) associated with the procedure (Darby 2005; Professor Lesley Barclay and Dr Robyn Thompson, sub. PR48). Suggested drivers of this trend include convenience to the mother and the specialist, the demand for women to choose their own means of birth, increased numbers of older mothers, rising obesity rates, and a desire by women to ‘maintain pelvic shape’ (Darby 2005).
- Overprescribing of medication, including for mental illness and attention deficit and hyperactivity disorder (ADHD), has also generated debate.
 - SSRIs have proven very effective for a number of people with depression, and their use (for an increasing number of indications) is growing (box 5.6; appendix G). Questions are mounting, however, about whether the ‘right’ people are receiving the treatment, particularly as the severity of potential side effects (such as increased risk of suicide and symptoms of psychiatric disease) is coming to light. SSRIs are not recommended for younger people, for example, even though they are being prescribed antidepressants, while counselling has been suggested as a more appropriate alternative for milder cases (Dr Yolande Lucire, sub. PR47; Bell 2005; Macken 2005). The efficacy of cognitive behaviour therapy (face-to-face and over the internet) and other talk therapies, for instance, has been demonstrated in trials, although such

psychological treatments face resistance among many psychiatrists (Richards 2004; Skatssoon 2004).

- The number of diagnoses of, and prescriptions for, ADHD has risen dramatically in the past decade or so (Allen 2005; Cameron 2005; Cummings 2005). Some in the medical profession believe this growth is in part the result of misdiagnosis — the symptoms of ADHD being almost identical to those resulting from other causes, such as trauma (Cummings 2005). They suggest that identifying and addressing these underlying causes can be more effective than automatically treating the symptoms with medication (Cummings 2005; Dunlevy 2005). Psychological or other low-technology therapies (such as physical exercises to stimulate the lower part of the brain) can sometimes be more appropriate, and would avoid the adverse effects that can result from drug treatment (Cameron 2005). On the other hand, some have suggested that only a small proportion of those exhibiting symptoms of ADHD are using medication to control it, indicating ‘cautious’ prescribing practices (Dunlevy 2005).

Various factors have contributed to these problems. Some have arisen due to what Callahan (2003, p. S345) describes as ‘a supposed imperative to use available technologies’, regardless of what evidence-based medicine might suggest is appropriate. This imperative and a shortage of doctors are also allegedly leading hospitals to overuse expensive medical equipment in a bid to attract to their hospitals (insured) private patients (who do not directly bear the costs of the equipment), as well as doctors (Stafford 2005c). In the case of hip replacements, the head of orthopaedic surgery at the Queensland University of Technology suggested that ‘every patient wants a titanium implant because they’ve read that it’s such a good light metal and fancy pushbikes are made of it’ (cited in Burstyn 2004).

Staff shortages and the nature of government funding have been suggested as contributing to the overprescribing of some medications. In terms of depression, one doctor has commented that, given the relative costs of counselling (which attracts no Medicare rebate) and medication (which is on the Pharmaceutical Benefits Scheme (PBS)), ‘it’s clear that more people will have access to medication rather than counselling’ (Macken 2005). In the case of ADHD, ‘handing out pills’ is seen as relatively quick and easy, but ‘bringing in experts such as education specialists, speech therapists, child psychologists and behavioural therapists is far harder and more expensive’ (Cameron 2005). Inequality of access to psychological therapies exacerbates the problem in rural areas.

... and technology can be a two-edged sword

Some advances in technology, while delivering sometimes significant benefits in one area, have also given rise to problems. This has been evident, for example, in the case of ICT applications in healthcare. The use by general practitioners of electronic prescribing packages, for example, offers potentially substantial benefits in terms of efficiency and health outcomes (by decreasing medication errors). On the other hand, advertising that appears with some of these packages has been blamed for the overprescribing of ‘expensive’ medications and increased PBS costs (appendix K). Advances in ICT, and specifically the internet, have also increased consumer access to health information, with a potential to improve health outcomes. However, there are issues about the quality of this information, the extent to which consumers can interpret it, and the dangers of self-diagnosis (appendix K). Genetic testing, too, can provide valuable information and potentially contribute to disease prevention, but may also cause anxiety and distress during testing and among those undergoing prophylactic therapy (appendix L).

In terms of medicine-specific advances, problems can to some extent be attributed indirectly to the benefits they provide, and have resulted from such factors as:

- unrealistic expectations and inadequate understanding about the true nature of the benefits delivered by the technology (such as assisted reproductive technology (ART));
- the seeming imperative to use a technology because it is available, even:
 - if its benefits in a specific case are unclear or marginal at best (such as with some diagnostic technologies); or
 - where knowledge about side effects is uncertain (such as with SSRIs and ADHD drugs, and some Cox-2 inhibitors, a class of non-steroidal anti-inflammatory drug (NSAID) used in the treatment of arthritis);
- the inability of other aspects of healthcare to keep pace with the outcomes of the technological advance (such as improved treatments and survival rates for chronic paediatric conditions); and
- the use of technology to try to prolong life, but possibly severely comprising the quality of that life (such as in critical care settings).

ART has given many otherwise infertile couples the opportunity to have children. As well as being the subject of ethical debates (discussed below), Andrea Hayward (sub. 7) pointed to the possible impact ART has had on women’s decisions on when to have children. She suggested that one factor influencing the trend for women to have their first child later in life is the ‘unrealistic expectations that reproductive technology will be able to guarantee them a baby if they delay their childbearing’

(sub. 7, p. 1) and are unable to conceive naturally. She commented further that ‘the higher the level of technology, the higher the aspirations about its potential and ability’ (sub. 7, p. 9) but that ‘some ... will remain childless as they are unable to achieve a pregnancy, or maintain a pregnancy due to age related complications’ that they mistakenly believe are avoided by ART (sub. 7, p. 1).

As noted above, advances in diagnostic imaging have provided a range of benefits. A recent advance — multidetector computed tomography (CT) scans of the heart — offers the potential for further benefits. Scans are performed in just a few seconds, require no recuperation period and may largely replace invasive diagnostic angiograms, with particular benefits in emergency situations. However, because the new technology is so sensitive, it can detect previously undetectable narrowed arteries and lung spots that may pose no health problems or risks. This has led to concerns that doctors and patients may want to ‘fix’ perceived problems with procedures that carry their own risks. (Kolata 2004)

Cox-2 inhibitors came onto the market in the late 1990s promising significant benefits over traditional NSAIDs. As well as their effectiveness in reducing the symptoms of arthritis, another particular benefit was their apparent gastrointestinal safety relative to traditional NSAIDs (Dieppe et al. 2004; Murray 2004). In the case of *rofecoxib* (Vioxx), however, potential side effects relating to cardiovascular toxicity (increased risk of heart attack and stroke for patients taking the drug for more than 18 months) were initially ignored (Dieppe et al. 2004; Murray 2004; Pountney 2004). Concerns about these side effects eventually led to its withdrawal from sale in October 2004. As well as affecting confidence in other Cox-2 inhibitors, the withdrawal increased pain and uncertainty, at least in the short term, for those forced to change what had been an effective treatment. One patient commented:

... I went off Vioxx on a Friday night and I woke up really sore and miserable on Saturday ... It can take many years to find the right medication, and it can change the quality of life depending on whether you are on the right medication or not (cited in Murray 2004, p. C32).

A number of advances in medical technology and early intervention in the past two decades have significantly increased survival rates of, but not cured, a range of paediatric illnesses. As a result, people can now live with these chronic conditions long into adulthood. This has, however, created other problems in terms of the transition from the paediatric to adult hospital systems once patients turn eighteen (Maley 2005). This transition can be daunting, leading some patients to drop out of the health system altogether to the detriment of their treatment. According to one patient (cited in Maley 2005), ‘you feel so isolated, and you don’t really want to have to go through all those tests again and explain yourself over and over to new

doctors'. A transition care program has been established in Sydney to help deal with these issues.

In the critical care setting, the focus is on saving patient lives, a task that has been significantly helped by advances in medical technology. According to Callahan (2003, p. S346), however:

The main benefit of technology in the most serious cases is that it may save a patient's life. The main hazard of technology in those same cases is that it may increase the pain and suffering of a patient who cannot be saved, making the end of life more miserable than it need be.

He suggests that the desire to use technology in seemingly hopeless cases arises because of a tendency to 'confuse the use of technology with the sanctity of life', that is:

...it has become all too easy to think that if one respects the value of life and technology has the power to extend life, then failure to use it is a failure to respect that value. (p. S345)

This is indicative of the type of ethical dilemmas that have accompanied some advances in medical technology, more of which are outlined below.

... as well as lead to ethical and other concerns and debates

Advances in scientific knowledge have led medical technology into previously unimaginable territory — increasing its ability not only to save and prolong life but also to create life — meaning that decisions need to be made about issues that once were not a consideration.

- As already noted, issues have arisen about when it is appropriate to use available technology to keep a critically ill person alive (Callahan 2003).
- Advances in technology are also allowing premature babies to be kept alive at increasingly earlier stages. For many very premature babies, long-term survival prospects are poor, while those who do survive may have serious health problems for the rest of their lives. This has led to debates about the extent to which life-prolonging treatment should be administered to babies born early in pregnancy (Dunn 2005).
- Rapid advances in ART have seen technical possibilities often move ahead of society's ability to accept them. Debates have surrounded, for example, the extent to which the technology should be used to allow gender selection of babies, the identification and non-implantation of embryos with certain undesirable characteristics or genetic diseases (Miles 2005), and whether it is appropriate to implant a woman with her dead husband's sperm (*The Age* 2005).

-
- The expense of in-vitro fertilisation (IVF) treatment has also led to debates about the extent to which the Government should subsidise access to treatment for women above a certain age, who are perceived as having made a ‘lifestyle choice’ to delay childbearing until a stage in life when their fertility is low (*The Canberra Times* 2005; Fynes-Clinton 2005).

Materials used in the development of other recent advances have generated debates centred around environmental considerations. The Australian Nuclear Science and Technology Organisation has estimated, for example, that every Australian on average will have a reactor-based nuclear medical procedure in their lifetime (Grose 2005). Whether this requires production of isotopes in Australia, and where the resultant nuclear waste will go have become significant issues of contention (Grose 2005; Noonan 2004; Wong 2004). The use of the bark from 100-year old Pacific yew trees for a drug (Taxol) to treat several types of cancer also generated controversy in the United States in the 1990s (Viscusi 1996). Issues surrounded the number of trees that were required (at least six trees per patient), and whether synthetic substitutes were a possibility.

5.4 Conclusions

Identifying and measuring appropriate indicators of health, social and economic outcomes is a complex task. There are many possible specific indicators for each, and various problems confound their measurement. Additional problems are encountered when trying to link these outcomes to advances in medical technology.

Nonetheless, the available evidence suggests that advances in medical technology have delivered benefits across a range of areas — contributing, for instance, to observed increases in length and quality of life, improvements in productivity, and improved living standards in Australia.

Accurately quantifying the overall impact of new technologies has not been possible. What can be said is that a number of specific technologies have provided significant health and other benefits. For others, benefits are not so obvious and some may even have generated unintended negative consequences but, overall, it would appear that advances in medical technology have delivered substantial benefits.

How these benefits have been distributed across various groups in society is discussed in chapter 6, while the extent to which benefits of medical technologies justify their costs is examined in chapter 7.

FINDING 5.1

Although it is not possible to quantify and attribute benefits in overall terms, the available evidence suggests that specific advances in medical technology have delivered substantial benefits across a range of areas in the past decade. They appear to have contributed to improved health status, observed increases in longevity and improved wellbeing.

6 Distribution of the benefits of new medical technology

This chapter centres on the distribution of the benefits of advances in medical technology across demographic groups, in accordance with the terms of reference (f).

The aim is to examine whether different demographic groups have different rates of use of various medical technologies, and whether diffusion patterns differ across demographic groups over time. The demographic characteristics analysed include socioeconomic status, remoteness of patients from health services, age, gender and, where possible, patient funding status (private or public) and Indigenous status. Patterns of use of various types of medical technology are reviewed, including some recent advances such as the breast cancer drug Herceptin and genetic testing for breast and ovarian cancer, as well as some technologies that are now pervasive, such as phacoemulsification surgery combined with insertion of foldable intraocular lenses (IOLs) for cataract, selective serotonin reuptake inhibitors (SSRIs), hip and knee replacements and a number of heart procedures.

After reviewing patterns of use, possible reasons explaining differences in utilisation rates across demographic groups are presented. Conclusions are drawn at the end of the chapter.

6.1 Defining appropriate access

Government policy statements regarding access to health services emphasise affordability, universal access according to clinical need, timeliness, equity across regions, and in some cases, cost effectiveness (box 6.1).

To be available for use in Australia, new medicines and medical devices require approval from the Therapeutic Goods Administration (see chapters 8, 9 and 10), which assesses their quality, safety and efficacy. To be listed on the Pharmaceutical Benefits Scheme (PBS) or the Medicare Benefits Schedule (MBS), a new drug or service must first be assessed for cost effectiveness by the Pharmaceutical Benefits Advisory Committee (PBAC) or the Medical Services Advisory Committee respectively. These two committees may also impose restrictions on the use of these

medicines or services in order to target treatment to patients with particular conditions for which it is more cost effective. Thus, a basic prerequisite for subsidised access to many new pharmaceuticals and medical services is clinical appropriateness and cost effectiveness. Clinical appropriateness is a necessary (but not sufficient) condition for cost effectiveness.

Box 6.1 Selected government policy statements relating to access to the health system

Medicare

The Council of Australian Governments included universal coverage, bulk billing and free access to public hospital care in a list of the principles of Medicare (COAG 1996).

The 2003-04 Australian Government Budget included changes to Medicare that:

... will ensure that all Australians have access to affordable, quality health care, no matter where they live or how much they earn. (Patterson 2003c, p. 5)

National Medicines Policy

The central objectives of the National Medicines Policy include:

... timely access to the medicines that Australians need, at a cost individuals and the community can afford ... (DoHA 1999, p. 1)

Australian Health Care Agreement between the Commonwealth of Australia and the State of New South Wales, 2003–2008:

6(b) Access to such services by public patients free of charge is to be on the basis of clinical need and within a clinically appropriate period; and

6(c) Arrangements are to be in place to ensure equitable access to such services for all eligible persons, regardless of their geographic location.

Achieving access to new medical technology that is cost effective is important in ensuring that those who need care and would benefit from assistance are able to obtain it. According to DoHA (sub. 34), research in the United Kingdom and Australia has shown that up to 50 per cent of patients with established heart disease are not being targeted with technology that could benefit them. In addition, the Cancer Council Australia and Clinical Oncological Society of Australia noted that:

Existing technologies, if better targeted or more accessible could prevent up to half the cancers currently diagnosed in Australia or detect cases early enough to be treated successfully and at significantly lower cost. (sub. 32, p. 2)

An inappropriate distribution of care may unnecessarily add to health system costs. Wyeth Australia Pty Limited commented:

A patient's inability to access clinically-required treatments may lead to less appropriate treatments being used and adversely increase long-term healthcare expenditure. (sub. 37, p. 14)

6.2 Measurement issues

Utilisation rates for selected medical technologies are presented below as an indicator of which demographic groups obtain access to the latest advances in medicine. Compared with other indicators, such as health status, or potentially preventable health conditions or potentially avoidable hospitalisations, rates of use of particular technologies can be more closely linked with specific medical advances. Isolating the impact of one medical advance is a challenge when new technologies are introduced continually. In addition, a myriad of factors determine health outcomes.

Utilisation rates need to be interpreted with care.

- Without some benchmark for determining an *appropriate* utilisation rate for a particular health intervention, it is not possible to conclude whether differences in utilisation rates across demographic groups imply under- or over-servicing. Yardsticks exist for some types of services, an obvious one being population screening. For example, evidence suggests that it is cost effective to use mammograms for population screening of women for breast cancer who are aged between 50 and 69 years. However, for other technologies, it is difficult to estimate appropriate rates of use at a population level without examining a large number of individual patient records. Health outcomes (such as mortality rates) across different demographic groups are referenced below as a broad gauge of the need for care amongst various groups in the community.
- New interventions may be modified over time with practitioner experience and new information. This may affect cost-effectiveness measures, so the benchmark for appropriate intervention rates is likely to change as the technology develops.
- Utilisation rates cannot provide information about the quality of care received, which also affects cost effectiveness and health outcomes.

There are a number of difficulties associated with examining who has access to new medical technology.

- It takes time for technology to diffuse sufficiently to have a measurable population impact (Robertson and Richardson 2000).

-
- The most detailed longitudinal data available relate to hospital care. Other data sets are substantially less detailed and time series may not be available. It is therefore more difficult to examine advances in non-acute care such as preventive medicine (for example) and substitutability between this and acute care.
 - National hospitals' data are compiled relatively slowly and are only available after a time lag, hampering study of the most recent advances in medicine.
 - There is a dearth of longitudinal data hampering study of the diffusion of technology and assessment of whether differences in intervention rates across demographic groups are associated with better or worse health outcomes. In addition, there is a paucity of linked data hindering an examination of the treatments and associated health outcomes for a given patient. A notable exception is the linked health data sets in Western Australia.
 - Few data collections incorporate patient characteristics other than age, sex and post code, limiting research on the distribution of access to care. For example, the Health Insurance Commission (HIC) commenced collection of patient post code and Indigenous status in 2002 (when pharmacists were required to check Medicare cards). Prior to that only patient age and sex were available. Similarly, the national elective surgery waiting times data collection does not include patient characteristics.

Identifying selected demographic groups

The methods used to classify patients into different demographic categories and data collection systems are not perfect. This section outlines some of the problems associated with the methods used in this chapter to identify the socioeconomic status of patients, their Indigenous status, and how easily patients are able to access health services based on their residential location.

Identifying differences in socioeconomic status

Indicators of disadvantage are generally based on an assessment of a set of individual characteristics including employment, education and income. In Australia, most studies use the index of relative socioeconomic disadvantage (IRSD). The IRSD is also used in this chapter. It is a composite measure based on the characteristics of individuals in a certain region, including income, educational attainment, public sector housing, unemployment and occupational skill levels. The IRSD measures the average disadvantage of all people living in a statistical local

area¹ and will generally understate the range of inequality at the individual level (AIHW 2004e).

There are alternative approaches.

- Some studies referred to in this chapter isolate the individual components of the IRSD and examine them alone (for example, income or education). However, partial analysis could be biased because characteristics such as education and income are likely to be related. In addition, as noted earlier, it is difficult to find data for an extensive range of patient characteristics.
- Another approach to measuring socioeconomic status in Australia was developed by the National Centre for Social and Economic Modelling (Thurect et al. 2004) and is based on the distribution of equivalent family income (EFI) in an Australian Bureau of Statistics (ABS) Census Collection District.

The type of classification system used can affect the result (box 6.2).

Identifying Indigenous status

Data on Indigenous people are generally limited because sample sizes may be too small, and the extent to which the Indigenous population is able to be identified is not consistent over time, or across geographic regions and is generally incomplete.

Remoteness

This chapter uses the Australian Standard Geographic Classification (ASGC) system to analyse the impact of living in remote locations on the use of health services. The ASGC groups geographic regions with similar remoteness characteristics (based on the road distance to a given cluster of goods and services). There are five major categories: major cities (where services are most accessible), inner regional, outer regional, remote and very remote (where services are least accessible).

The data need to be interpreted with care as, in some cases, patients' postal addresses do not reflect their residential address, and patients may move closer to where they can obtain treatment. The Commission is not aware of estimates of the materiality of these scenarios.

¹ A Statistical Local Area (SLA) is part of the Australian Standard Geographic Classification system used by the Australian Bureau of Statistics to divide Australia into smaller regions. SLAs may be made up of one or more Census Collection Districts.

Box 6.2 The impact of using different systems for classifying socioeconomic status — hospital admissions

The IRSD and EFI approaches provide different answers to whether more advantaged socioeconomic groups are more likely to be admitted to hospital than more disadvantaged socioeconomic groups.

Thurect et al. (2004) analysed use of hospitals by socioeconomic status of patients in New South Wales by imputing the EFI for each patient based on the distribution of EFI in each ABS Census Collection District. They found that after standardising actual hospital usage for differences in age and sex, patients in more advantaged socioeconomic groups had marginally higher rates of hospital use. They noted that, given previous studies have suggested that patients in less well-off socioeconomic groups tend to have poorer health even after taking account of age differentials, this may suggest that better-off patients are able to more effectively access medical and hospital services.

The Australian Institute of Health and Welfare (AIHW), on the other hand, used the IRSD to classify hospital admissions by socioeconomic status. They compared those in each socioeconomic quintile with the whole Australian population and found that those in the two most disadvantaged quintiles were more likely to be admitted to hospital, and were more likely to have an overnight stay in hospital than the Australian average (AIHW 2005b).

6.3 Who has access to new medical technology

At any point in time, disparities in health status between different demographic groups signal differences in the need for healthcare. Poorer health outcomes amongst more disadvantaged socioeconomic groups or Indigenous people, for example, would imply a potential for these communities to improve their health status given the current set of medical technologies available. Health outcomes such as mortality rates and incidence and prevalence of disease are discussed below as a broad gauge of whether health service utilisation rates are appropriate. Possible reasons for apparent under- or over-use of new medical technologies amongst certain groups in the community are discussed in section 6.4 and include both demand and supply factors.

Disparities in health status

Australian and international research shows that, in general, health status is worse amongst the more socioeconomically disadvantaged and those living in more remote areas. However, this does not apply for all groups for every disease, for

example, breast cancer (see appendix I on Herceptin). Examples of disparities in health status at the aggregate level include:

- The most recent national burden of disease data (for 1996) show that the mortality burden for those living in the most socioeconomically disadvantaged regions was at least 41 per cent higher for males and at least 26 per cent higher for females than the burden for males and females in the least disadvantaged regions (Mathers et al. 1999).
- For the period 1998–2000, life expectancy at birth and at ages 15, 25 and 65 was highest in the least socioeconomically disadvantaged areas and lowest in the most disadvantaged areas (Draper et al. 2004).
- Like other disadvantaged groups in Australia, the health status of Indigenous Australians is poor compared with the rest of the population (ABS 2004d; ABS and AIHW 2003; SCRGSP 2003; SCRGSP 2005; Zhao et al. 2004).
- According to Draper et al. (2004) for both males and females in each age group in the period 1998–2000, death rates for residents in remote and very remote areas were significantly higher than for those in regions with better access to healthcare facilities.

Australian studies finding links between socioeconomic advantage and better health outcomes include: AIHW (2004e), Draper et al. (2004), Glover et al. (2004), Population Health Division (2004) and Walker (2001). Australian health disparities have also been documented by income, occupation and geographic region (AIHW 2003a and 2004e; Draper et al. 2004; Walker 2001). Some international studies showing links between poorer health status and socioeconomic disadvantage were noted in Alter et al. (1999) and Morrison et al. (1997).

While, in general, absolute mortality rates have declined in Australia, there is some evidence that declines in mortality rates have been faster among those in socioeconomically advantaged groups, leading to increases in relative disparities across the socioeconomic spectrum (Draper et al. 2004 and Population Health Division 2004). According to Draper et al. (2004), relative inequalities between the most and least disadvantaged males rose between 1985–87 and 1998–2000, but fell or remained stable for females in some age groups (table 6.1).

Table 6.1 **Changes in inequality in death rates over time, 1985–87 to 1998–2000^{a,b}**

		Relative inequality		Absolute inequality	
Age group	Gender	1985–87	1998–2000	1985–87	1998–2000
		Per cent difference in rate ratio		Difference in absolute death rates ^c	
0–14 years	Males	50 ^d	78 ^d	42 ^d	32 ^d
	Females	66	61	39	22
15–24 years	Males	49	90	49	57
	Females	55	57	22	16
25–64 years	Males	68	75	230	163
	Females	50	51	95	70
65+ years	Males	14	17	8	7
	Females	11	11	4	3

^a Socioeconomic status measured using IRSD. ^b All differences are between the most and least disadvantaged groups. ^c Difference in absolute death rates is per 100 000 for ages 0 to 64 and per 1000 for ages 65 or over. ^d For example, in 1985–87, death rates in the most disadvantaged areas were approximately 50 per cent higher than in the least disadvantaged, and in 1998–2000, the corresponding difference was 78 per cent. In terms of absolute death rates, in 1985–87, the difference between the most and least disadvantaged was 42 deaths per 100 000, and in 1998–2000, the corresponding difference was 32 per 100 000.

Source: Draper et al. (2004).

Use of health services

Studies of the use of health services across different demographic groups are outlined in various sections of this chapter. Those in less advantaged, less affluent, less educated groups, and those in more remote areas (with some exceptions) often have lower rates of service use relative to their apparent need. Similarly, while there may be differences in the types of disease suffered by Indigenous people compared with other Australians and, therefore, the types of intervention and technology that are appropriate, there is evidence that Indigenous people are less likely to undergo treatment for their illnesses. Studies include: heart procedures (Coory and Walsh 2005), lung cancer surgery (Hall et al. 2004), renal transplant and waitlisting for renal transplant (Cass et al. 2003), cervical cancer screening (Coory et al. 2002) and most diagnostic and therapeutic procedures in public hospitals except infectious/parasitic, and injury (Cunningham 2002).

International evidence suggests that new technologies spread to different demographic groups at different rates and that this contributes to existing health disparities. The most advantaged groups gain access to the latest technologies first, initially increasing inequities in health status, but technologies gradually diffuse to less advantaged groups over time (Crystal et al. 1995; Sambamoorthi et al. 2003;

Victora et al. 2000). This is a dynamic process — as new technologies are continually introduced, delays in access by the least advantaged groups lead to a continuation of health disparities over time.

Australian studies centering on the dynamic process of diffusion of new technologies across patients are limited, although some research is underway at the Australian National University. There is Australian evidence that some types of new treatment reach those in younger age groups first and diffuse to older Australians only after a lag (AIHW 2004e; McClellan and Kessler 2002; Rob et al. 1998).

The Commission has obtained data on utilisation rates for selected advances in medicine (discussed below), including treatments for heart disease, breast cancer, cataract, anxiety and depression, and joint replacement. These examples were chosen because they represented a significant step forward at the time they were introduced, facilitating an examination of utilisation rates over time, even though some are now considered mainstream treatments. Selection was also based on availability of data for different demographic groups.

Coronary heart disease

Coronary heart disease (CHD) includes heart attack (myocardial infarction) and angina. Risk factors are smoking, high blood pressure, high cholesterol, insufficient physical activity, overweight and obesity, and diabetes. Males, older Australians, Indigenous Australians and people living in more disadvantaged areas are at higher risk of CHD.

In 2001-02, men aged 40–90 years were twice as likely to develop CHD than women in the same age range and men were more likely to be admitted to hospital with the disease than women (AIHW and NHF 2004). In 2003, 85 359 potential years of life were lost amongst males due to ischaemic heart disease compared with 24 467 amongst females (ABS 2003b). The incidence of CHD, death rates and hospitalisation for the disease also increase markedly with age (AIHW and NHF 2004). Differences in death rates by age and sex are shown in table 6.2.

Between 2000 and 2002, age standardised death rates from CHD were highest in remote areas and lowest in major cities (AIHW and NHF 2004). Based on the IRSD, in 2000–02, age standardised death rates from CHD were 29 per cent higher amongst Australians living in the most disadvantaged areas compared with those in the least disadvantaged areas.

Table 6.2 Rates of death from ischaemic heart disease, 2003^a

<i>Age group</i>	<i>Males</i>	<i>Females</i>	<i>Persons</i>
45–54 years	54.3	12.2	33.1
55–64 years	142.2	39.0	91.1
65–74 years	417.1	160.6	285.3
75–84 years	1238.6	758.4	963.3
85+ years	3852.5	3145.3	3368.6

^a Deaths per 100 000 people.

Source: ABS (2003b).

Indigenous death rates from CHD were 2.6 times higher than those of the rest of the population between 2000 and 2002. Indigenous people were also nearly twice as likely to be admitted to hospital for CHD than other Australians in 2001–02 (AIHW and NHF 2004). In the Northern Territory, Indigenous people had a higher proportion of healthy years of life lost due to cardiovascular disease than non-Indigenous people (Zhao et al. 2004).

Despite the greater prevalence of heart disease amongst Australians living in the most disadvantaged areas — including Indigenous people — there is some evidence that these groups are less likely to receive treatment (box 6.3). These findings are consistent with a large number of international studies that find that more disadvantaged socioeconomic groups are less likely to have cardiac procedures (in particular, angiography), and may also wait longer for surgery (Alter et al. 1999, Alter et al. 2003, and Pilote et al. 2003 in Canada; Hetemaa et al. 2003 in Finland; Payne and Saul 1997, Britton et al. 2004 and Parkes et al. 2005 in the United Kingdom; Pell et al. 2000 in Scotland; and Holmes et al. 2005 in the United States).

The Commission analysed unpublished Australian data from the AIHW on the characteristics of hospital patients who received various types of heart procedures over the 10-year period 1993–94 to 2003–04 with the aim of comparing utilisation rates with need. Diagnostic procedures (catheterisation and angiography) and revascularisation procedures (coronary artery bypass graft (CABG) and angioplasty with or without the insertion of stents — see appendix H on drug eluting stents) were examined, along with the implantation of cardioverter defibrillators. The latter deliver electric shocks to the heart if it is beating arrhythmically. (Abnormal heart rhythms can lead to cardiac arrest.) The term ‘procedure rates’ is used for simplicity in the text of this chapter to refer to separation rates for which a procedure was reported.²

² The term ‘procedure rate’ here refers to separation rates for which a procedure was reported. A ‘separation’ is the end of an episode of admitted hospital care — through discharge, transfer to another health service, or death. A separation may include more than one procedure, so the term ‘procedure rates’ is used here relatively loosely.

Box 6.3 Socioeconomic status and interventions for heart disease

Queensland residents admitted to a Queensland public hospital in 1998 with an acute myocardial infarction (AMI) were more likely to undergo angiography and angioplasty if they lived in a middle or high socioeconomic area compared with residents of low socioeconomic areas. There was no such socioeconomic effect for patients in private hospitals (Coory et al. 2002) (although this could reflect that most people with private insurance are in less disadvantaged groups — box 6.7). Rates of bypass surgery in both public and private hospitals were similar across socioeconomic groups. These patterns persisted after adjusting for age, sex, hospital characteristics, rurality and comorbidities. Private patients were more than twice as likely as public patients to undergo angiography, angioplasty and CABG.

Indigenous patients were less likely than others to receive percutaneous coronary interventions (PCI) either immediately after AMI or subsequently. However, rates of bypass surgery after AMI were about the same for both Indigenous and non-Indigenous people (Coory and Walsh 2005).

Australian males living in the highly advantaged socioeconomic areas were found to have higher rates of statin prescribing relative to their cardiovascular risk compared with other men (Stocks et al. 2004) (appendix F).

The results below need to be interpreted with care. Differences in procedure rates across demographic groups reflect both demand and supply side factors (see section 6.4 below). In particular, the data do not reflect differences across patients in diagnosis, disease severity, or the existence of comorbidities, although they are adjusted for differences in population age profiles where stated.

Age

Age-specific procedure rates between 1993-94 and 2003-04 are presented in table 6.3. Excluding CABG and defibrillators, the age group at which procedure rates peaked shifted from 60–69 years to 70–79 years in around 1997-98. Elderly people are now much more likely to receive heart procedures than in the past. For all procedures, annual growth rates between 1993-94 and 2003-04 were markedly higher for those aged 80 years or over (table 6.3).

Table 6.3 **Age-specific CHD separation rates and annual growth^a**

	Age group								
	<20	20–29	30–39	40–49	50–59	60–69	70–79	80–84	85+
Catheterisation									
Rate 1993-94	35.1	16.0	97.1	547.0	1599.9	2711.2	2299.1	648.8	140.5
Rate 2003-04	28.0	24.0	131.4	596.4	1702.0	3216.5	4472.5	3609.5	1301.4
Growth per year	-2%	4%	3%	1%	1%	2%	7%	19%	25%
Angiography									
Rate 1993-94	7.3	6.6	43.2	241.3	700.1	1189.3	985.6	275.9	57.0
Rate 2003-04	5.8	11.1	64.4	294.4	840.9	1593.8	2215.6	1788.9	645.7
Growth per year	-2%	5%	4%	2%	2%	3%	8%	21%	27%
Angioplasty without stent									
Rate 1993-94	0.1	0.4	8.0	56.8	150.2	232.7	167.1	43.3	10.0
Rate 2003-04	0.2	0.1	1.4	5.9	18.0	35.8	49.4	45.8	22.8
Growth per year	15%	-9%	-16%	-20%	-19%	-17%	-11%	1%	9%
Angioplasty with stent^b									
Rate 1994-95	0.0	0.0	1.4	7.2	20.2	31.1	24.8	4.4	0.5
Rate 2003-04	0.1	1.0	16.4	96.4	279.1	502.9	667.2	575.3	254.1
Growth per year	na	na	31%	33%	34%	36%	44%	72%	99%
CABG									
Rate 1993-94	0.1	0.2	5.4	51.5	207.8	452.9	458.8	119.3	22.1
Rate 2003-04	0.0	0.2	3.4	29.5	112.6	292.0	455.7	310.6	93.2
Growth per year	-17%	-2%	-5%	-5%	-6%	-4%	0%	10%	15%
Defibrillators									
Rate 1993-94	0.0	0.1	0.1	0.2	0.8	3.0	5.2	11.3	3.9
Rate 2003-04	0.0	0.8	0.9	1.9	5.4	20.4	45.0	146.7	43.9
Growth per year	na	23%	21%	26%	22%	21%	24%	29%	27%

^a Separation rates are per 100 000 people in the relevant age group. ^b Annual growth for angioplasty with stent calculated from 1994-95 because rates were zero in most age groups in 1993-94.

Source: Productivity Commission calculations based on AIHW (unpublished data).

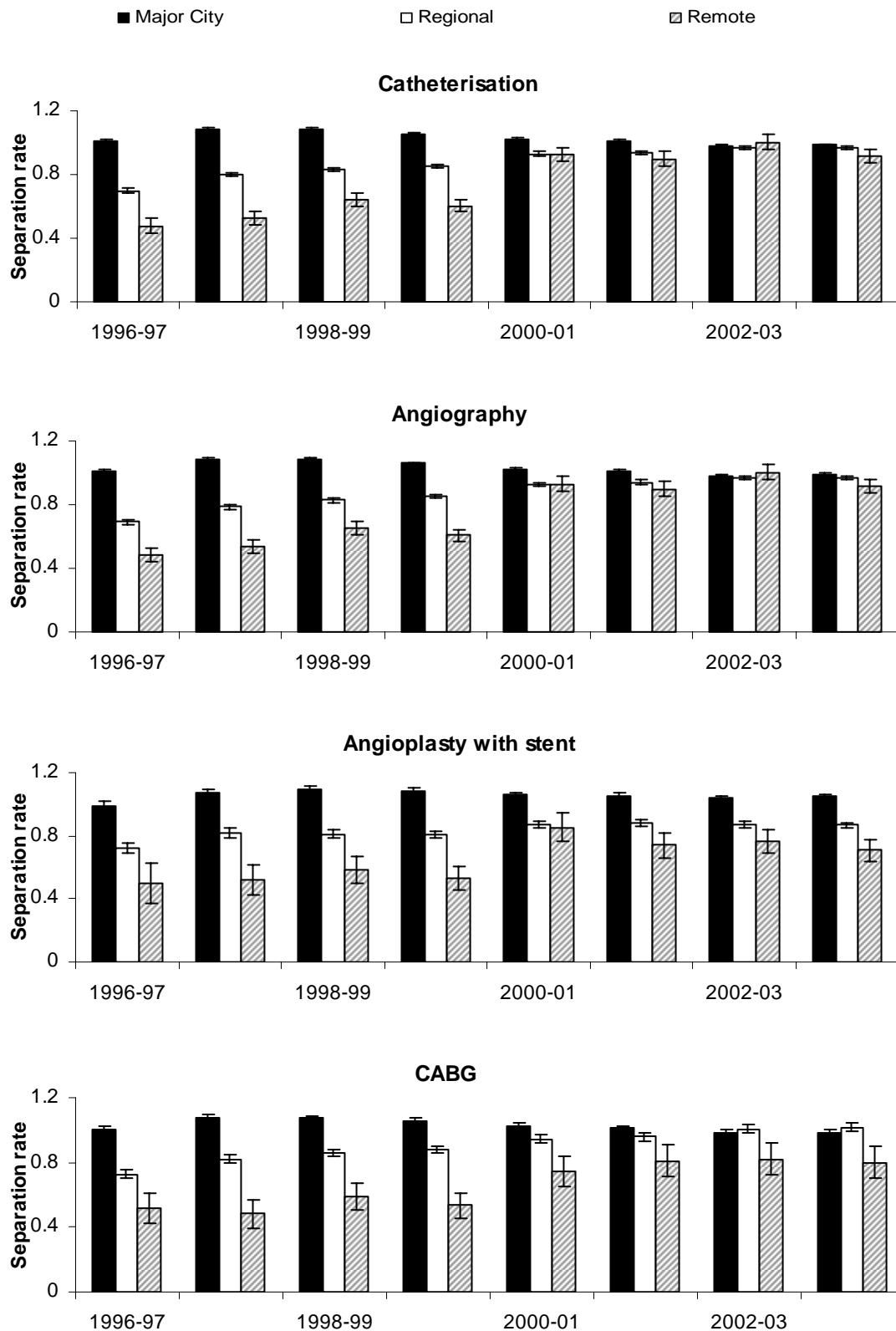
Gender

Consistent with the incidence of CHD, males were more than twice as likely as females to undergo the heart procedures examined during the period 1993-94 to 2003-04. (See data in technical paper 4.)

Remoteness area

Those living outside major cities had significantly lower age-standardised procedure rates for CHD in contrast with the pattern of death rates outlined above (figure 6.1). From 2000-01, gaps in procedure rates across regions closed markedly (except angioplasty without stent). However, age-standardised rates for those outside major cities never reflected the apparently greater need for care in these areas.

Figure 6.1 Age-standardised CHD separation rates by remoteness area^a



^a Age-standardised separation rates are per 1000 people and shown with 95 per cent confidence intervals.

Data source: AIHW (unpublished data). Data available in technical paper 4.

Socioeconomic status

Ratios of procedure rates for those in the most disadvantaged group to those in other socioeconomic groups are presented in table 6.4 for the period 1998-99 to 2003-04. Ratios that are greater than one indicate that those in less disadvantaged regions have higher procedure rates than those in more disadvantaged regions (contrary to the patterns of prevalence and incidence of CHD outlined earlier).

The evidence below is not entirely consistent with the ‘socioeconomic gradient’ commonly found in international research on heart procedures.

- In the vast majority of cases, those in the second most disadvantaged group (socioeconomic group ‘2’ in the table) were more likely to receive a procedure than those in the least disadvantaged and the most disadvantaged groups.
- The ratios for younger age groups were often less than one, suggesting a distribution of care in accordance with need. However, the ratios in older age groups were more often greater than one. In particular, Australians aged 70 years or over in the most disadvantaged regions were the least likely in their age group to receive a procedure.

Indigenous status

Procedure rates by Indigenous status in table 6.5 have been adjusted for differences in the age profile of the Indigenous and non-Indigenous populations. Between 2001-02 and 2003-04, despite the greater prevalence of CHD amongst Indigenous people, Indigenous Australians were significantly less likely to undergo heart procedures (with the exception of angioplasty without stents and CABG in 2003-04, and defibrillators in 2001-02 when the rates were not significantly different).

Patient funding status

Figure 6.2 shows that, since 1993-94, the rate of growth of procedure rates has been higher for private patients than public patients for all of the heart procedures examined here except CABG. (The data in figure 6.2 are not age standardised.) Separation rates for private patients now outweigh those for public patients for all procedures except CABG. (Angioplasty with and without stent are not included in figure 6.2 and are discussed in appendix H.)

Table 6.4 **Ratios of CHD separation rates by socioeconomic status**
1998-99 to 2003-04^{a,b}

	20–29 years	30–39 years	40–49 years	50–59 years	60–69 years	70+
	Rate ratio					
Catheterisation						
2/1	1.0	1.1	1.2	1.3	1.4	1.4
3/1	0.9	0.9	1.0	1.1	1.2	1.4
4/1	1.0	0.9	1.1	1.2	1.4	1.7
5/1	0.6	0.6	0.7	0.8	1.0	1.3
Angiography						
2/1	1.0	1.1	1.2	1.3	1.4	1.4
3/1	0.9	0.9	1.0	1.1	1.2	1.4
4/1	1.0	0.9	1.1	1.2	1.4	1.7
5/1	0.6	0.6	0.7	0.8	1.0	1.3
Angioplasty without stent						
2/1	1.0	1.0	1.1	1.3	1.4	1.5
3/1	0.4	0.9	0.9	0.9	1.1	1.1
4/1	0.7	0.7	1.0	1.1	1.4	1.8
5/1	0.3	0.5	0.6	0.8	1.1	1.4
Angioplasty with stent						
2/1	0.7	1.1	1.1	1.2	1.3	1.4
3/1	0.5	0.9	1.0	1.1	1.2	1.4
4/1	0.7	0.9	1.1	1.2	1.5	1.8
5/1	0.4	0.5	0.7	0.9	1.1	1.5
CABG						
2/1	1.3	1.0	1.0	1.1	1.2	1.3
3/1	0.9	0.7	0.8	0.9	1.1	1.3
4/1	0.7	0.7	0.8	1.0	1.2	1.5
5/1	1.0	0.4	0.5	0.6	0.8	1.1
Defibrillators						
2/1	1.2	1.8	1.2	1.3	1.4	1.4
3/1	1.0	1.0	1.0	0.9	1.2	1.5
4/1	1.6	1.3	1.4	0.9	1.2	1.7
5/1	1.2	1.0	0.8	0.9	0.9	1.2

^a A high IRSD index score (5) means the area has few families of low income and few people with little training and in unskilled occupations. A high score reflects lack of disadvantage (ABS 2001). Rate ratios reflect differences between each level of disadvantage, for example, the least disadvantaged over the most disadvantaged (age specific separation rate for group five divided by age specific separation rate for group one). ^b Separation rates are calculated for each age group and each socioeconomic region (age specific and socioeconomic status specific rates).

Source: Productivity Commission calculations based on AIHW (unpublished data) and ABS (2004 unpublished estimated resident population data).

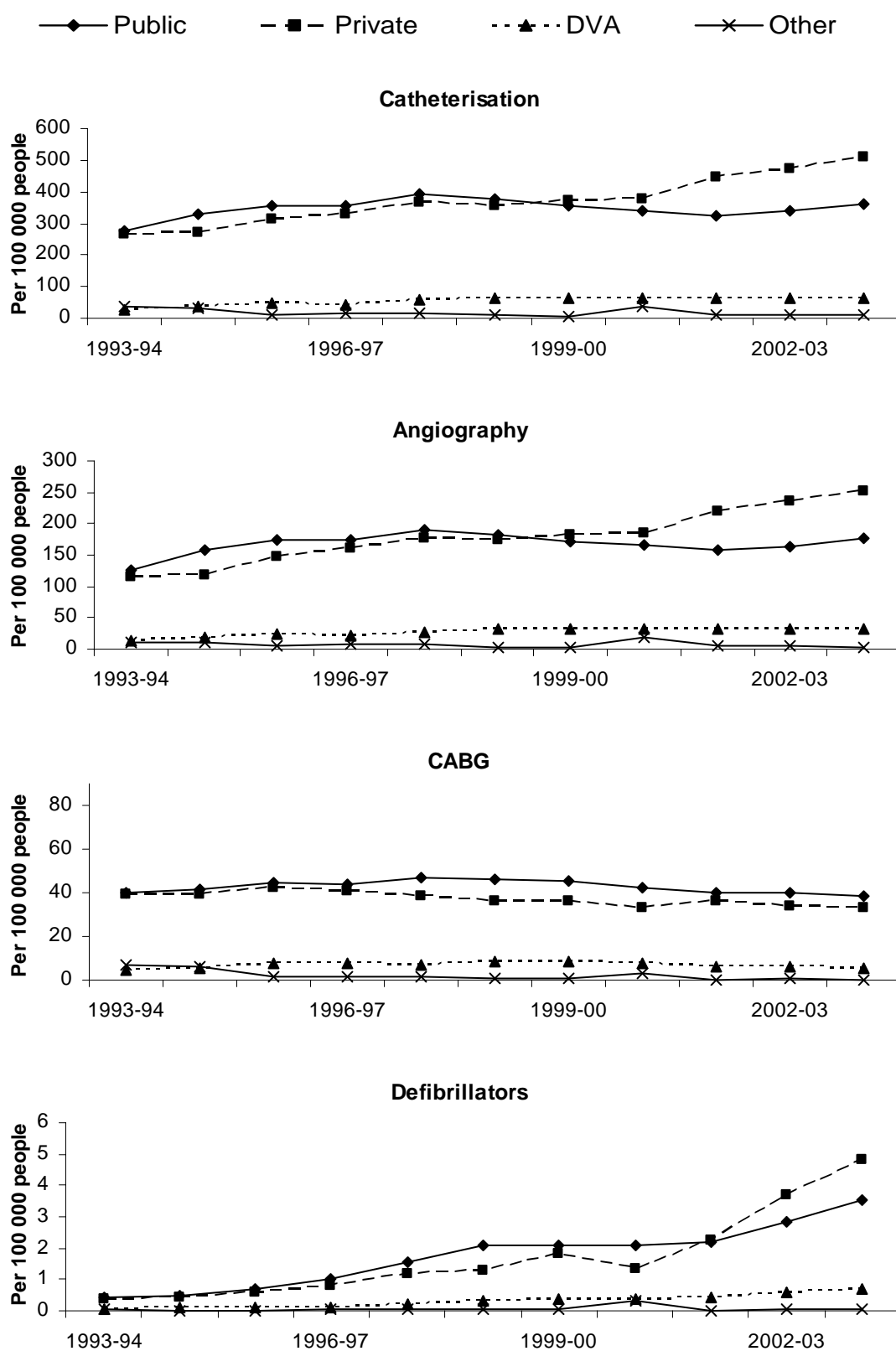
Table 6.5 **Age-standardised CHD separation rates by Indigenous status**

<i>Year</i>	<i>Indigenous status</i>	<i>LCL^a</i>	<i>Rate</i>	<i>UCL^a</i>
Catheterisation				
2001-02	Indigenous	0.56	0.60	0.64
	Non-Indigenous	1.00	1.00	1.01
2002-03	Indigenous	0.66	0.70	0.74
	Non-Indigenous	1.00	1.00	1.01
2003-04	Indigenous	0.74	0.78	0.82
	Non-Indigenous	0.99	1.00	1.01
Angiography				
2001-02	Indigenous	0.56	0.60	0.64
	Non-Indigenous	1.00	1.00	1.01
2002-03	Indigenous	0.66	0.70	0.74
	Non-Indigenous	1.00	1.00	1.01
2003-04	Indigenous	0.74	0.78	0.83
	Non-Indigenous	0.99	1.00	1.01
Angioplasty without stent				
2001-02	Indigenous	0.28	0.45	0.62
	Non-Indigenous	0.97	1.01	1.04
2002-03	Indigenous	0.30	0.51	0.71
	Non-Indigenous	0.96	1.00	1.04
2003-04	Indigenous	0.52	0.82	1.12
	Non-Indigenous	0.96	1.00	1.04
Angioplasty with stent				
2001-02	Indigenous	0.42	0.49	0.56
	Non-Indigenous	0.99	1.00	1.02
2002-03	Indigenous	0.60	0.68	0.76
	Non-Indigenous	0.99	1.00	1.01
2003-04	Indigenous	0.54	0.61	0.67
	Non-Indigenous	0.99	1.00	1.01
CABG				
2001-02	Indigenous	0.64	0.75	0.86
	Non-Indigenous	0.99	1.00	1.02
2002-03	Indigenous	0.65	0.75	0.86
	Non-Indigenous	0.98	1.00	1.02
2003-04	Indigenous	0.90	1.03	1.16
	Non-Indigenous	0.98	1.00	1.01
Defibrillators				
2001-02	Indigenous	0.39	0.83	1.26
	Non-Indigenous	0.94	1.00	1.06
2002-03	Indigenous	0.18	0.44	0.70
	Non-Indigenous	0.95	1.01	1.06
2003-04	Indigenous	0.30	0.55	0.81
	Non-Indigenous	0.96	1.00	1.05

^a Age-standardised rates are per 1000 people. LCL and UCL denote lower and upper confidence limits at 95 per cent.

Source: AIHW (unpublished data).

Figure 6.2 **CHD separation rates by funding status, 1993-94 to 2003-04**



Data source: AIHW (unpublished data). Data available in technical paper 4.

Breast cancer

Patterns of incidence and prevalence of breast cancer are outlined in the appendix on Herceptin (appendix I). Briefly, across demographic groups:

- Death rates from breast cancer increase with age.
- There were no differences in mortality rates from breast cancer between those living in the most and least disadvantaged regions in 1998–2000 (Draper et al. 2004). However, amongst women aged 25–54, manual workers (including tradespersons) were more likely to die from breast cancer than clerical workers, but both manual and clerical workers were *less* likely to die from breast cancer than managers, administrators and professionals (Draper et al. 2004).
- Evidence on the prevalence of breast cancer by remoteness area is equivocal. Studies suggest that death rates from breast cancer either do not vary with residential location, or else decline with remoteness (appendix I).

Use rates by demographic groups for three types of healthcare related to breast cancer are outlined below: surgery, Herceptin treatment for metastatic breast cancer and genetic testing for gene mutations associated with a greater risk of breast cancer. There is some evidence that types of surgery for breast cancer differ across demographic groups (box 6.4).

Box 6.4 **Surgery for breast cancer by demographic group**

Breast conservation therapy was accepted internationally in 1990 as preferable to total mastectomy for women with stage I and II operable breast cancer because it provides equivalent survival while preserving the breast (Kricker et al. 2001). There is some evidence that urban women are less likely to have mastectomy than rural women (Kricker et al. 2001) and more educated women are also less likely to have a mastectomy (after adjustment for age, stage and surgeon activity level) (Taylor et al. 1999). Across socioeconomic groups, Kricker et al. (2001) found no significant difference in the application of breast conserving therapy after adjustment for age, and size and spread of cancer at diagnosis. Hall et al. (2004) found that Indigenous women were as likely as non-Indigenous women to undergo breast conserving surgery.

Hall and Holman (2003) examined whether certain demographic groups were more likely to receive breast reconstructive surgery after surgery for breast cancer. In Western Australia, women who were more likely to receive breast reconstructive surgery were relatively young, non-Indigenous, and had less comorbidity. In addition, women were more likely to receive breast reconstructive surgery if they lived in or were treated in metropolitan areas. Private health insurance and treatment in a private hospital at the time of the primary breast cancer surgery were also positively associated with breast reconstructive surgery.

Herceptin

Herceptin is an anti-cancer agent that targets a particular type of breast cancer occurring in 20–30 per cent of cases. Herceptin was registered by the Therapeutic Goods Administration in 2000 for use in advanced metastatic breast cancer. It was not approved for listing by the PBAC, but was subsidised by the Australian Government in a separate ‘Herceptin Program’ from December 2001. Prior to that, the drug was supplied free by the manufacturer (Roche) for those on clinical trials, and was also subsidised by some State Governments through public hospitals. Detailed information about Herceptin including the future outlook for its use and cost are in appendix I.

According to NATSEM (sub. 1), the projected target population for Herceptin for the year 2001 was around 1000 patients. Prior to the establishment of the Herceptin Program, Roche supplied the drug to 50 patients (pers. comm., Roche, 4 August 2005). Data on the number of public hospital patients receiving the drug during that period are not available. From the commencement of the Herceptin Program, 544 women received Herceptin in 2002, 695 in 2003, 956 in 2004 and 867 from January to May 2005. The expected target of 1000 women was not reached until about 2004.

The distributional results in appendix I suggest that:

- Most Herceptin patients (over three quarters) were aged between 40 and 69 years.
- The rate at which women received Herceptin in New South Wales was relatively low compared with both the incidence of breast cancer in that State, and the female population aged 20 or over in New South Wales.
- The distribution of the drug by remoteness area probably reflects the different female age profile across regions.
- With the exception of the territories, those in the least disadvantaged areas received Herceptin at a higher rate than those in the most disadvantaged areas.
- More than half of the women receiving Herceptin held a health care concession card. It is not possible to compare this accurately with similar data for drugs listed on the PBS.

Genetic testing

Inherited gene mutations account for between 1 and 5 per cent of all breast and ovarian cancers and a higher proportion of early onset disease. Only a small proportion of gene mutations associated with breast cancer has been discovered.

State Governments fund testing for the BRCA1 and BRCA2 gene mutations which are associated with a 40–80 per cent lifetime risk of breast cancer, and a 10–60 per cent risk of ovarian cancer (NHMRC NBCC 2000). Testing is generally offered to those with moderate or high risk of carrying the gene — that is, those with the strongest family history of breast or ovarian cancer. More detailed information on testing arrangements for gene mutations associated with breast cancer in Australia and their cost and use is provided in appendix L.

The Commission obtained data from family cancer clinics in New South Wales, Victoria and South Australia on the age and residential post code of their clients between 1997 and 2004. The data included the characteristics of women at their first contact with the clinic (either women who were referred, self referred, or telephoned for information), women who received counselling about testing, women who underwent a test to search for the presence of a gene mutation (mutation search test), and women who had a predictive test once a gene mutation had been found in the family (predictive test). Data were not available by patient funding status. The South Australian data were census data for the State and therefore most representative at a State level. The data for the other States were from a sample of clinics and do not therefore necessarily represent the population of clients of family cancer clinics at the State level. In addition, the New South Wales and Victorian data were for clinics in capital cities. Data from regional clinics were not available. The extent of missing data on client characteristics varied across clinics, but improved over time. More detailed results are included in appendix L, but in summary, the data suggested that:

- Between 1997 and 2004, over 180 clients receiving a predictive test (around 21 per cent of those receiving a predictive test) were 60 years or over and nearly 30 women (3 per cent) were 80 years or more. Around 50 per cent of those having a predictive test were aged 49 or less.
- Those in the most disadvantaged groups were less likely to present to family cancer clinics and are therefore under-represented in testing.

Cataract

The use of the phacoemulsification technique to remove cataract-affected lenses combined with the insertion of foldable intraocular lenses were significant advances in the treatment of cataract. The use, costs and trends in cataract treatments are outlined in appendix M. In brief, the prevalence of cataract increases with age and is higher amongst women. Risk factors for the different types of age-related cataract include UV exposure, smoking and diabetes (appendix M).

There is no evidence in Australia of socioeconomic status as a predictor of cataract, including by occupation or education levels (Panchapakesan et al. 2003; Younan et al. 2002). However, in theory, since cataract rates are linked to UV exposure and smoking, those in lower socioeconomic groups or in more remote areas may be more susceptible (because they may be more likely to have occupations that lead to UV exposure). For similar reasons and because of their high rates of diabetes, Indigenous people are also likely to be at relatively high risk of cataract. Based on a study undertaken in the 1970s, Indigenous people had twice the prevalence of lens abnormalities compared with non-Indigenous people (Taylor 1997).

The Commission analysed unpublished Australian data from the AIHW on the characteristics of hospital patients who had lens insertion and or removal procedures over the 10-year period 1993-94 to 2003-04 with the aim of comparing utilisation rates with need. The term ‘lens insertion and or removal rates’ is used relatively loosely in this chapter to refer to separation rates for these procedures. A summary of the analysis of the data in appendix M is provided here.

- As expected, lens insertion and or removal rates are higher for those in older age groups.
- Age-adjusted rates of lens insertion and or removal were significantly higher for women, consistent with their higher susceptibility to cortical cataract than men.
- Prior to 2000-01, on an age adjusted basis, those living in major cities were significantly more likely to undergo lens insertion and or removal — by contrast with the expected impact of greater occupational UV exposure in regional and remote areas. However, similar to the patterns outlined earlier in the heart procedures data, in 2000-01, differences in lens insertion and removal rates across regions narrowed significantly.
- Patterns of lens insertion and/or removal across socioeconomic groups are similar to those for heart procedures.
 - There was no consistent socioeconomic gradient.
 - Those in the second most disadvantaged group were more likely to receive a procedure than those in the least disadvantaged and the most disadvantaged groups.
 - Those in less disadvantaged older age groups were somewhat more likely to be admitted to hospital for lens insertion and or removal. Notably, Australians aged 70 years or over in the most disadvantaged regions were the least likely in their age group to receive a procedure.
- Despite their relatively higher risk of cataract and documented higher prevalence of lens abnormalities, between 2001-02 and 2003-04, Indigenous Australians

were significantly less likely (on an age-adjusted basis) to be admitted to hospital for lens insertion and or removal than non-Indigenous Australians.

- Between 1993-94 and 2003-04, on average, private patients were more than twice as likely to undergo lens insertion and/or removal than public patients. However, the annual rate of growth in procedure rates during the period was highest for Veterans (10 per cent per year for patients funded by the Department of Veterans' Affairs, 9 per cent per year for privately-funded patients and 6 per cent per year for publicly-funded patients). (However, these data were not adjusted for differences in age profiles over time or across sectors.)

Anxiety and depression

Rates of use of relatively new antidepressants — selective serotonin reuptake inhibitors (SSRIs) — are discussed in appendix G. Briefly, it is difficult to ascertain which groups have the greatest need for antidepressants. Based on the 2001 ABS National Health Survey (ABS 2002a):³

- women were more likely to report psychological distress at a level commensurate with need for professional help than men;
- people in more socioeconomically disadvantaged regions were more likely to report psychological distress at a level commensurate with need for professional assistance than people in less socioeconomically disadvantaged regions;
- people in the 18–24 and 45–54 age groups were more likely to report very high levels of psychological distress compared with other age groups; and
- reported rates of very high psychological distress were similar across geographic regions.

In contrast to these 2001 survey results, data on recorded suicide death rates suggest the prevalence of depression is higher outside capital cities, and amongst men. (Although women are more likely to attempt suicide than men, men are more likely to die from suicide (ABS 2000).)

The Commission obtained data from the HIC for the period 2002 to 2004 and this is analysed in appendix G. SSRIs were distributed at higher rates to: females, persons aged 18–24 and 45–54 years, people living in capital cities and those in more disadvantaged areas. By and large, the distribution of SSRIs reflected estimates of the prevalence of anxiety and depression, although it is possible that SSRIs may be under-supplied to males.

³ These data are based on the 2001 National Health Survey, which exclude people in institutions such as hospitals and nursing homes (ABS 2002a).

As noted earlier, HIC data provide little information about the characteristics of Australians taking prescription drugs prior to 2002, so it is not possible to examine the patterns of the diffusion of antidepressants in Australia over time. However, amongst older people in the United States, SSRIs were first provided to better educated and more affluent older people, but after five years had also spread to those who were less well educated, or less affluent (Sambamoorthi et al. 2003).

Hip and knee replacements

Joint replacement surgery for hips and knees is commonly used to treat severe osteoarthritis (OA) and is discussed in detail in appendix E.

The majority of joint replacement surgery is undertaken on females, consistent with their relatively higher prevalence of self-reported OA (ABS 2002a; appendix E). In addition, the oldest age groups tend to have the highest rate of joint replacements consistent with greater self-reported OA amongst older people (ABS 2002a; appendix E).

As with heart procedures and lens insertion and removal (discussed above), Indigenous people have significantly lower age-standardised rates of joint replacement compared with non-Indigenous people. However, it is unclear how this relates to relative need in the Indigenous and non-Indigenous populations.

Rates of OA were higher outside capital cities (ABS unpublished data from the 2001 National Health Survey; appendix E). By contrast, people in remote areas had lower age-standardised rates of joint replacement than persons living in regional areas and major cities. As with heart procedures, the pattern of regional differences changed in 2000-01 and the age-standardised rate of joint replacements in remote areas increased (appendix E).

Rates of OA were highest amongst the most socioeconomically disadvantaged (ABS unpublished data from the 2001 National Health Survey; appendix E). The oldest people in the most disadvantaged regions were generally less likely to receive joint replacement surgery (similar to the pattern for heart procedures). For hip replacements, Australians aged 50 years or over in the most disadvantaged areas were least likely in their age group to receive a procedure, but the most likely to need it. A similar pattern existed for those aged 70 or over receiving knee replacements (appendix E).

International studies suggest that in the United Kingdom, women, older people and those in more deprived areas were less likely to receive joint replacements than expected based on indicators of need, and in the United States, African Americans

were less likely to receive knee replacements than white people (Dixon et al. 2004 and Yong et al. 2004).

6.4 Explaining differences in utilisation rates

Reasons underlying patterns in the use and diffusion of new medical technology across different demographic groups are complex.

The capacity of medical technology to exacerbate inequities already present in the community, through multiple mechanisms including information, access and systems issues, is an important one. (Dr Jeff Brownscombe, sub. PR55, p. 3)

There are many factors that explain access to health services more generally and these influences interact with the mechanisms for registration and listing of medical technologies to determine which demographic groups have the best and most timely access to advances in medicine. A taxonomy developed by Andersen (1995) categorises determinants of access to health services from an individual patient's perspective under three headings:

- need (family history, comorbidities);
- predisposing factors (the propensity of an individual to use healthcare services); and
- enabling factors (a person's ability to use healthcare services).

Andersen's categories are not mutually exclusive and are used only loosely to structure the discussion below.

Need and predisposing factors

Severity of disease at diagnosis, the presence of comorbidities, and individual preferences (determined by factors such as age, sex and cultural background) affect the utilisation of healthcare services generally and therefore access to new medical technology.

Greater severity of disease at diagnosis, and the presence of comorbidities may moderate intervention rates for both old and new technologies by reducing the chance that an intervention will prove successful (box 6.5). Comorbidities are related to known risk factors for disease — such as smoking, lack of exercise, obesity and diabetes — and are often more prevalent amongst those in more disadvantaged areas and Indigenous people (for example, AIHW and NHF 2004) (box 6.5).

New medical technologies such as advances in anaesthesia practices (Australian Society of Anaesthetists Inc, sub. 8), and increases in the safety of medical interventions (Dr Stan Goldstein, sub. 5) have the potential to increase the speed of diffusion of new procedures to riskier patients such as older people and those with comorbidities, or with greater severity of disease. For example:

Advances in surgical techniques ... [such as “off pump” technology and ventricular fibrillation] ... in recent years mean that the risks of cardiac surgery for all patients but especially those over 80 years, have been substantially reduced. (Alvarez 2004 p. 182)

Box 6.5 The impact of comorbidities and severity of disease on the use of medical technology

Indigenous Australians admitted to hospital for AMI were more likely to have comorbidities and complications than non-Indigenous Australians and therefore less likely to receive PCI or bypass surgery (Coory and Walsh 2005). Amongst patients admitted for AMI, Indigenous people were more than twice as likely to suffer diabetes, chronic renal failure, pneumonia and chronic rheumatic fever compared with non-Indigenous patients. Chronic bronchitis and emphysema and heart failure were at least 60 per cent more common amongst Indigenous patients. ‘If a patient had at least one comorbidity then their probability of having a coronary procedure was reduced by 40 per cent’ (Coory and Walsh 2005, p. 510).

Commenting on Hall and Holman (2003) (see box 6.4), Brown et al. (2003) suggested that Indigenous women, those living in rural or remote areas and those in lower socioeconomic groups were less likely to receive breast reconstruction surgery after surgery for breast cancer because of the advanced nature of their disease (patients from lower socioeconomic groups present with more aggressive and advanced disease), comorbidities, and risk factors such as smoking — as well as lack of access to services.

Obesity or stroke appeared to preclude some English patients from receiving knee replacement surgery (Yong et al. 2004).

Patients’ preferences affect the nature of their access to health services and the types of treatment they receive and, hence, their access to new medical technology. Amongst other things, preferences may reflect age, sex and cultural background. For example, men and women use health services differently, affecting their relative access to new medical technology. Stocks et al. (2004) cite evidence that men do not visit GPs as frequently as women, and suggest this is one explanation for women in the lowest socioeconomic group receiving more statins than men in similar economic circumstances — despite women being at much lower risk of death from CHD. Men with a mental health problem were less likely than women with a mental health problem to seek professional assistance (ABS 1998) and, in

Victoria, the probability of never having seen an eye care provider was higher among men than women (Keefe et al. 2002).

In some sections of the community, cultural or other belief systems may create a reluctance to seek assistance. People may delay longer after the onset of symptoms before presenting to a health service, and after presentation, may reject intensive curative treatment, or decide not to complete therapies (Dr John Condon, Senior Research Fellow Menzies School of Health Research, Darwin, pers. comm., 24 March, 2005; Fisher and Weeramanthri 2002).

Other influences on the propensity to present to a health service or to choose a particular treatment include convenience (such as time away from work or family), and perceptions about trade-offs between length and quality of life.

... consumers with chronic illnesses, such as HIV or cancer, often feel over-burdened with tests and procedures as it is, and will carefully choose when and under what circumstances they may agree to a procedure which may involve inconvenience, hospitalisation, personal expense, or the risk of side effects. One recent example hinting at this is a report suggesting that uptakes of chemotherapy and radiation therapy are often low, despite clinical guidelines — and a number of experts have pointed out that this may be in part due to people with cancer deciding that they do not wish to undergo treatment. (National Association of People Living with HIV/AIDS, sub. PR58, p. 7)

Enabling factors

Wealth, education, residential location and proficiency in English influence patients' wherewithal to access health services and therefore medical technology. The characteristics of health practitioners and the diffusion of knowledge amongst providers also influence the uptake of new types of care. The nexus between income and education and the interaction between the process for listing of new medical technologies and their diffusion across the private and public sectors tends to reinforce the ability of more affluent and better qualified people to obtain the latest advances in health care. As noted by the South Australian Government:

People who are more socially advantaged are not only more able to afford to purchase technologies not yet available to the general public but are also more aware of the availability of a choice of treatments and more able to articulate and advocate for their interests. (sub. 35, p. 9)

Ability to pay

Less affluent patients are likely to experience delays in access to the latest medical technology, and some may miss out altogether depending on which new

technologies are registered and subsidised, and the length of time the registration and listing process takes.

There is an apparent trade-off between the equity and timeliness of access to medical advances. Prior to listing, the distribution of new technologies depends on a number of disparate funding sources. According to the National Association of People Living with HIV/AIDS, these include 'research programs, or grants at hospitals, universities or research centres, specifically earmarked monies (such as new technology grants), industry-assisted access schemes, or sometimes, as in the case of polylactic acid treatment for HIV facial wasting, the consumer simply has to pay for the technology themselves' (sub. PR58, p. 5). As noted in appendix I, prior to commencement of the Herceptin subsidy program, Herceptin was funded by the manufacturer (Roche) through clinical trials, and State Governments through hospitals. Other examples include robotic surgery, advances in neonatal and foetal care and genetic testing.

New medical technologies including foetal surgery and genetic screening and testing may be beneficial for some infants but costs and access to specialists may preclude them being available universally. (Health Services Development, Institute of Advanced Studies, Charles Darwin University, sub. PR48, p. 4)

Access to new medical technologies is likely to be horizontally inequitable⁴ until technologies are listed for subsidy by the Australian Government as funding arrangements are likely to vary across regions and communities. The timeliness of listing is discussed in chapters 9 and 10.

Less affluent patients are also likely to experience delayed access to new medical advances because the rate of uptake of new technology appears to be faster in private than public hospitals (chapter 4 and box 6.6). Rob et al. observe:

Elective surgery forms a major part of the business of private hospitals and there are clear incentives for the early adoption of new technology. (1998, p. 271)

Those on higher incomes and who live in the least socioeconomically disadvantaged areas are more likely to have private health insurance, and to be admitted to hospital as a private patient, or to use a private hospital (box 6.7).

More socioeconomically disadvantaged groups (such as Indigenous Australians and single pensioners) are less likely to be admitted as a private patient or to a private hospital and so depend on the uptake of new technologies by the public sector. Similarly, a higher proportion of patients from regional and remote areas are

⁴ Briefly, horizontal equity means that everyone faces the same access regime. In this case, horizontal equity would imply that everyone pays the same amount. Vertical equity refers to people having access on the basis of need, which might imply different access arrangements for different population groups.

admitted to public hospitals than private hospitals. People with existing medical conditions that preclude them from obtaining private health insurance are also less likely to receive the latest medical technologies.

Box 6.6 Private and public patient access to new technology

While complete data are not available, in private hospitals, it is estimated that around 90 per cent of patients receiving stents receive drug eluting stents compared with around one-half of public patients (BUPA Australia, sub. 28; MIAA, sub. 17; appendix H).

In 1996, the likelihood of angiography (a diagnostic imaging technique) or revascularisation (repair of the blood vessels to restore blood supply) in Victoria was between 50 and 120 per cent greater in the private than in the public sector, and somewhat greater for a private patient than a public patient in a public hospital (Hobbs et al. 2002). In part, the discrepancy between a public and private patient was explained by the age of private patients. However, standardising for age reduced, but did not eliminate, the discrepancy.

Similarly, rates of angiography, angioplasty and bypass surgery were two to three times more likely in the private compared with the public system for patients admitted to Queensland hospitals with AMI in 1998. These rates were adjusted for age, sex, rurality, hospital characteristics, and comorbidities (Coory et al. 2002).

According to Hall and Holman (2003), women with private health insurance or who were treated in a private hospital at the time of their primary breast cancer surgery were more likely to receive breast reconstructive surgery after surgery for breast cancer.

Laparoscopic cholecystectomy was a new technique for removing the gallbladder introduced into New South Wales in 1990. Rob et al. (1998) showed that it was introduced more rapidly in private than public hospitals and was also used more extensively in private hospitals.

A population based study in Victoria (Keeffe et al. 2002) found that the use of eye care services varied depending on whether people had private health insurance. Those with insurance were more likely to have seen an ophthalmologist, or both an ophthalmologist and an optometrist, whereas those without insurance were more likely to see an optometrist only. In addition, those without insurance were more likely never to have seen an eye care provider.

Use of phacoemulsification cataract extraction (PKE) increased between July 1994 and June 1999 at the Royal Victorian Eye and Ear (teaching) Hospital in Victoria, but spread faster among private patients. In 1994, PKE was used in 55.6 per cent of public, and 55.9 per cent of private patients undergoing cataract surgeries. By 1998, 90.5 per cent of public and 95.6 per cent of private patients had PKE surgery (Yi et al. 2001).

Box 6.7 Socioeconomic status, private health insurance coverage and use of private hospitals

There are direct links between income, the propensity to have private health insurance and the use of private hospitals.

- In 2003-04, the proportion of Australians covered by private health insurance increased with household income and with personal income (Denniss 2005a).
- In 2001, there was a positive correlation between the socioeconomic status of an area and the proportion of people living in that area claiming the private health insurance rebate as a premium reduction or through Medicare offices (Productivity Commission calculations based on Senate Community Affairs Legislation Committee 2003, and ABS unpublished).
- Those with English as a second language, lower levels of educational qualifications, those living in regional or remote areas, and those in the most disadvantaged socioeconomic groups were less likely to have private health insurance (ABS 2002a).
- Those from less disadvantaged socioeconomic regions are significantly more likely to be admitted to private hospitals than the Australia average, whereas people living in more disadvantaged socioeconomic regions are significantly more likely to be admitted to public hospitals compared with the Australian average (AIHW 2005b).
- Indigenous people are markedly less likely to be admitted to a private hospital (AIHW 2005b; SCRGSP 2005).

Education and health literacy

A number of studies have shown that more educated people have higher health services utilisation rates (box 6.8). Education is also likely to be associated with more timely access to the latest medical advances.

Glied and Lleras-Muney (2003) conjectured that people with higher educational attainment are more likely to access the latest technologies because they are more likely to be better informed about medical innovation, have a more positive view of the risks and benefits of medical innovation, may be more effective at searching for high quality providers and may be better able to understand and tolerate complex dosing regimes or side effects. In particular, more educated people are likely to have access to a range of information sources and be more proficient at using them. Steel et al. make the point that:

... in the early days of the service [testing for gene mutations associated with breast cancer], women had to be uncommonly 'aware' of the specific health issue of familial breast cancer in order to find their way to the clinics. (1999, p. 127)

In addition, more highly qualified people are generally more affluent and so likely to access new medical technologies earlier than others for reasons outlined above.

One plausible hypothesis [for the socioeconomic status effects on rates of invasive coronary procedures] is that affluent patients are more educated, articulate and demanding (and potentially more litigious) and hence more likely to receive invasive procedures than less affluent patients. (Coory et al. 2002, p. 233)

Similarly, Stocks et al. (2004) conjectured that men living in the most socioeconomically advantaged areas have relatively high rates of statin prescribing relative to their cardiovascular risk because greater education and wealth signal greater expectations about healthcare, and may also be associated with a greater likelihood that messages about men's health will be adopted.

Box 6.8 Education and access to healthcare

The Western Australian Aboriginal Child Health Survey (Zubrick et al. 2004) (conducted between May 2000 and June 2002) found that Indigenous children, whose carers had 13 or more years of education, were more likely to have seen a doctor than children whose carers had one to nine years of education.

Dracup et al. (1997) examined the factors contributing to delays in seeking treatment among patients with an evolving AMI in light of evidence that the shorter the interval between the onset of symptoms and when thrombolytic drugs are given, the better the outcome. They found that delay time increased amongst those with fewer years of education, lower income, transportation by private car rather than ambulance and cognitive or emotional responses to symptoms. (The study was structured so that distance was not a causative factor in time to receive treatment.) While their sample of patients was relatively small and made up mostly of older, male, married and white people, they observed that:

Very few patients knew about thrombolysis and its effectiveness in treating acute MI, but those who did presented sooner than those who did not. (Dracup et al. 1997, web version)

Patients with operable breast cancer diagnosed and treated in 1992 in the Greater Western region of Sydney who had higher education levels were more likely to have breast conserving surgery rather than mastectomy (after adjustment for age, stage and surgeon activity level) (Taylor et al. 1999).

Education and annual income levels were associated with use of counselling for BRCA1/2 gene mutations associated with breast and ovarian cancer in the United States (Armstrong et al. 2005 outlined in appendix L).

Residential location and proximity to health services

Medical technology advances in the future will benefit people more remotely located through providing services without the need for a physical visit to the doctor. However,

other advances in technology may provide most benefit to those who live close enough to a centre of health specialisation. (SA Government, sub. 35, p. 9)

The impact of a patient's residential location on his or her access to new medical technology is difficult to predict and confounded by a number of different factors.

Travel time and travel costs (including inconvenience and time spent away from family and friends) can present barriers to accessing some new medical technologies for those living in regional or remote areas, or outer metropolitan areas, or where location of supply does not match location of demand. The evidence of the impact of location on access to services is not unequivocal, however.

- For example, women living in rural or remote areas are more likely to have a mastectomy to 'avoid prolonged absence from family' (Cancer Council Australia submission to the Radiation Oncology Inquiry cited in Radiation Oncology Inquiry Committee 2002). On the other hand, while Kricker et al. (2001) attributed lower rates of mastectomy in urban areas compared with rural areas to less access to specialised care and adjuvant radiotherapy in rural areas, Taylor et al. (1999) found that distance from the patient's residence to a radiotherapy unit was not correlated with the mastectomy rate in the Greater Western region of Sydney in 1992.
- Rob et al. (1998) found evidence that living some distance away from hospitals offering laparoscopic cholecystectomy did not affect access to this treatment for public hospital patients. Among public hospitals in 1995, 85 per cent of inner metropolitan, 86 per cent of outer metropolitan and 58 per cent of rural hospitals were performing laparoscopic cholecystectomy. However, the same proportion of public hospital patients had laparoscopic cholecystectomy regardless of their residential location (Rob et al. 1998).
- According to Keffe et al. (2002), people living in rural areas were more likely never to have seen an eye care provider, and those in rural areas were more likely to have seen an optometrist only compared with people in urban areas who more often saw an ophthalmologist or both an ophthalmologist and optometrist.

Location is likely to be an important factor affecting access where: medical technology requires complex training and expensive equipment and therefore economies of scale are likely to exist; where there are benefits from grouping a new technology together with a number of related services (economies of scope) — for example, multidisciplinary assessment; or where there are benefits from learning and technological change through contact with others (centres of excellence). In these cases, the number of locations at which a new technology is offered will necessarily be limited and this may cause accessibility problems for those who are not close by (box 6.9).

Regional mismatches between supply of and demand for various types of health services may occur for a number of reasons, including practitioner preferences, regulation, and government policies and programs. For example, general practitioners are less likely to locate in outer metropolitan and regional and remote areas — areas of socioeconomic disadvantage (O’Dea and Kilham 2002; SCRGSP 2005).

In some cases, establishment of healthcare facilities in regional or remote areas is hampered by poor reliability of utilities such as electricity and water, variable water quality and difficulties retaining staff. Cass et al. (2001) noted this as part of their examination of regional variation in the incidence of end-stage renal disease (ESRD) in Indigenous Australians which they matched against the location of treatment centres. They found that standardised ESRD incidence among Indigenous Australians was highest in remote regions where it is up to 30 times the national incidence for all Australians. In addition, while the standardised incidence is lower in urban regions, it remains significantly higher than the national incidence. However, 48 per cent of Indigenous ESRD patients come from regions without dialysis or transplant facilities and 16.3 per cent from regions with only satellite dialysis facilities (Cass et al. 2001).

Innovations that reduce the need to visit a health practitioner (such as home-based testing and disease monitoring outlined in chapter 11) may improve access to medical technology by those who do not live in close proximity to health services. Telehealth and telemedicine may improve access to health services by those living in more remote areas (appendix K).

Proficiency in English

People from a non-English speaking background can have difficulties accessing healthcare generally, including new medical technology (see Keffe et al. 2002 in relation to eye care services in Victoria). For example, Indigenous Australians with cancer are diagnosed with more advanced disease and have a lower chance of survival once diagnosed than other Australians. The reasons for this differ depending on whether Indigenous people have an Indigenous first language or if their first language is English. A more advanced stage at diagnosis appears to explain the poorer chances of survival of Indigenous people whose first language is English. For those with an Indigenous first language, poorer treatment is one of several possible factors including cultural differences, although there is no evidence to confirm this (Dr John Condon, Senior Research Fellow Menzies School of Health Research, Darwin, pers. comm., 24 March, 2005).

Box 6.9 Impact of proximity to more specialised staff and facilities

McCredie et al. (1996) suggested that diagnosis and staging procedures for prostate cancer in rural areas in New South Wales in 1991 were less 'state of the art' than those in urban areas, partly because rural patients were treated by a general surgeon rather than a urologist, and because options for procedures and treatments in rural and remote areas are limited by the need for sophisticated equipment or lengthy travel to specialised units.

In the Greater Western region of Sydney in 1992, patients with operable breast cancer whose surgery was undertaken by a surgeon with a relatively high breast cancer caseload were more likely to have breast conserving surgery rather than mastectomy (Taylor et al. 1999). (The results were adjusted for age of patient and stage of cancer.)

Leitch (2003) noted the strong body of evidence showing that infarct angioplasty is a better treatment than thrombolysis and can improve outcomes in patients with myocardial infarction. However, while infarct angioplasty is a more expensive treatment and is more likely to be offered in metropolitan hospitals with cardiac catheterisation laboratories, pre-hospital thrombolysis is suitable for remote regions with long ambulance transport times. Pre-hospital thrombolysis is not available in some states of Australia, for example, in Victoria where Kelly et al. (2003) found that patients in rural areas were slower to receive in-hospital thrombolytic treatment for AMI than patients from large urban areas, leading to an increased risk of dying. Ho (2002) argued that the cost and quality benefits associated with centres for excellence in cardiac care need to be weighed against the negative health consequences for patients in less populated areas requiring emergency care.

Several international studies have found an association between the characteristics of the hospital where patients are initially admitted for AMI (including the volume of AMI cases, the specialty of the admitting doctor, facilities for invasive coronary procedures (ICPs), and distance to a hospital with ICP facilities) and the probability of undergoing an ICP (Coory et al. 2002). For example:

- According to a survey of implantable cardioverter defibrillator (ICD) centres in the United Kingdom, eligible patients in more disadvantaged areas were less likely to obtain ICDs partly because they were not appropriately identified and referred to ICD centres (Parkes et al. 2005).
- In Canada, AMI patients were more likely to receive coronary angioplasty or bypass surgery if they were initially admitted to a hospital with onsite catheterisation and or revascularisation facilities, or if they presented to a teaching hospital — regardless of whether the teaching hospital had specialist facilities. Patients were more likely to receive a procedure if initially admitted to a teaching hospital without invasive facilities compared with a community hospital with invasive facilities (Cox et al. 1994). The authors followed patients admitted to hospital with AMI for six months to see whether the type of hospital influenced whether a patient received a heart procedure. Results were adjusted for patient comorbidity and AMI complications.

Characteristics of health practitioners and the diffusion of knowledge amongst health providers

The characteristics and skills of health practitioners, together with the diffusion of knowledge about innovations in care amongst health providers, have an important impact on patients' access to new technology. Arguably, the skills and uptake of knowledge by GPs is especially important in Australia because they are the first point of access to the health system for the majority of Australians. A study of the distribution of the use of BRCA1/2 counselling in the United States also noted the potential importance of the characteristics of primary care physicians (Armstrong et al. (2005) outlined in appendix L).

The diffusion of knowledge across practitioners is not necessarily well understood and the interactions between patients and their healthcare providers is complex. Some examples of research on GP consultations are outlined in box 6.10.

Box 6.10 GP consultations

There are differences in the approach of female and male GPs in Australia. In 2000-01, female GPs tended to have significantly longer consultations with their patients than male GPs (Britt et al. 2002). In addition, research indicates that female GPs tend to conduct more complex consultations with their patients including management of more psychosocial problems (Britt et al. 2002).

According to Gruen et al. (2002), qualitative studies have shown that GP referral decisions are related not only to clinical factors and specialist availability, but also to the characteristics of the referring doctor, the patient, and the relationships the GP has with both patient and the specialist. The characteristics of both patients and their GPs are probably reflected in the findings of Furler et al. (2002), that people in socioeconomically disadvantaged areas visit GPs more often, but they are less likely to have a long consultation. While the higher GP visit rate for lower socioeconomic status groups probably reflects their greater need for care, Stocks et al. (2004) conjectured that the extra consultation time experienced by more advantaged patients could well be spent on preventive activities, implying that less advantaged patients may have had less preventive treatment. In their study of statin prescribing, Stocks et al. posed the question:

Do GPs who are still predominantly male, middle aged and middle class identify more strongly with their peers in a way that influences their preventive message and prescribing behaviour? (2004, p. 230).

6.5 Conclusion

Certain demographic groups are likely to experience delays in accessing new medical technology and it is apparent that, in some cases, individuals miss out. In particular, based on the examples provided in this chapter, use of acute health services by those living in regional and remote areas, Indigenous people and the elderly living in the most socioeconomically disadvantaged regions was frequently less than indicators of need would suggest was appropriate. For other types of service, there was some evidence that males and those in the most socioeconomically disadvantaged regions may not receive treatments that could benefit them. However, the sample of technologies selected for analysis was necessarily limited, so generalisations should be made with care. Further research would be useful.

The reasons for delays in access to new medical technology (and differences in patterns of utilisation of health services by different demographic groups) are complex and related to both demand and supply side factors. In general, technology is likely to diffuse later to the less affluent and less educated, and people who do not use or who are unable to use mainstream health services.

The speed with which new technologies diffuse amongst different patient groups is difficult to predict, but it could be several years before medical advances become pervasive. The impact of this on health outcomes across demographic groups has not been quantified. However, delays in the spread of new technology appear to contribute to continuing relative health disparities across the most and least disadvantaged in society (rather than absolute differences in health status).

Access to new medical technologies is particularly likely to be less equitable prior to their listing on the PBS and MBS by the Australian Government because of the disparate funding mechanisms that precede listing, including State Governments (often via public hospitals or State health programs), and medical companies (through clinical trials). These ‘pre-listing’ funding arrangements differ across geographic regions.

FINDING 6.1

The Commission found evidence that rates of use of some medical technologies were lower for Australians living in more socioeconomically disadvantaged areas (particularly the elderly in these areas), those residing in rural and remote areas, males, and Indigenous people. The reasons for this are complex and relate to both the demand for and supply of technology and healthcare more generally. Unequal use may be accentuated, at least initially, as new higher-cost technologies are introduced.

7 Cost effectiveness of advances in medical technology

This chapter relates to terms of reference (f), which requires the Commission to investigate the net impact of advances in medical technology on the overall cost effectiveness of healthcare delivery. It draws together the analysis of the previous four chapters, which examine the effect of advances in medical technology on the costs and benefits of healthcare.

7.1 Assessing aggregate net benefits of advances in medical technology

The cost effectiveness of advances in medical technology in Australia is of interest to policy-makers, medical practitioners and the general public who ultimately pay for those advances. As noted by the Australian Nursing Federation:

The focus must be on cost effectiveness as well as access to health enhancing initiatives. (sub. 26, p. 1)

To the extent that advances in medical technology have been cost effective, then they would have moved the allocation of the healthcare sector's resources towards more efficient uses compared with existing technologies and treatments. Nonetheless, even if spending on new technologies had provided relatively larger health benefits for every dollar spent on healthcare than existing technologies, it may not be the case that the value of the benefits exceeds the costs.¹ In other words, while an improvement in cost effectiveness brought about by advances in medical technology would be a step in the right direction, there could still be room for improving the cost–benefit ratio.

As discussed in chapter 1, in most markets increased expenditure would indicate increased consumer benefits and net social benefits overall. However, because the direct purchase of healthcare in Australia is mostly undertaken by third parties — governments and private health insurers — normal market tests tend not to apply.

¹ Assessment of the latter requires cost–benefit analysis, where costs and benefits are expressed in the same monetary units.

Even where consumers pay directly for health services, they may not have access to appropriate information. Consequently, consumers and their doctors often have little ability or incentive to weigh the costs of advances in medical technology against the benefits. This means that there can be no presumption that the benefits of extra spending have outweighed the extra costs.

Assessing the aggregate cost effectiveness of advances in medical technology requires an assessment of whether the overall cost per unit of healthcare benefit has fallen over time. This might occur through either benefits remaining the same and costs being lower, or costs increasing but benefits increasing by an even larger amount. As noted by the Victorian Department of Human Services (VDHS), the significant problems in quantifying aggregate benefits and costs of medical technology make such a comparison difficult:

Assessing the benefits and cost effectiveness of technological developments across all health settings and treatment types is a major challenge ... (sub. 24, p. i)

The magnitude of the challenge is brought out by the Commission's analysis in this study. Aggregate costs are difficult to gauge because of the difficulties in isolating advances in medical technology and attributing expenditure impacts (chapter 3). Accurately identifying and attributing the overall benefits of technologies is probably infeasible due to a number of reasons including a lack of longitudinal data and arguably insoluble problems in measuring and valuing health and other benefits (chapter 5).

Nonetheless, Commission modelling does suggest that advances in medical technology might have accounted for additional real spending of between \$220 to \$820 per person in 2002-03 compared with 1992-93. Though the range is wide, this puts into some perspective the order of magnitude of the benefits required to have made the extra spending worthwhile.

There have been some attempts to estimate aggregate costs and benefits of new medical technologies. They require assumptions to be made about the overall contribution of medical technology to observed indicators of health outcomes (such as improvements in longevity) and the value of human life.

A hypothetical, 'back-of-the-envelope' exercise undertaken by the VDHS (sub. 24) for this study, suggests that in Australia between 1992-93 and 2002-03, the benefits of medical technology might have outweighed the costs by a ratio of 2:1. Among other things, this exercise assumes that medical technology accounts for all increased health spending, is responsible for one-third of the gains in healthy life

years and that the value of an additional year of healthy life is \$100 000.² While attributing all of the increase in health spending to technology makes the calculations conservative, other assumptions, for example, about the value of an additional year of life and attribution of other benefits to technology, may do the opposite. That said, \$100 000 is within the range of other estimates of the value of an additional life year and studies of particular diseases have suggested that technology has been responsible for at least one-third of observed improvements in health outcomes (chapter 5).

As discussed in chapter 5, Access Economics (2003c) valued improved health in Australia between 1960 and 1999 at \$5.4 trillion or \$142 billion per year, or roughly \$7000 per person, in 1999. While the Commission's cost estimates are not strictly comparable with these figures, the order of magnitude of the difference at least indicates the probability that the benefits of medical advances have exceeded their costs.

Put another way, if an additional year of healthy life is valued at \$100 000, then extra spending per person per year of \$820 (the Commission's upper estimate of the expenditure impact of advances in medical technology) would need to extend their life expectancy by about three days for each year of the ten-year period analysed, or by 30 days in total for that decade. Obviously, such calculations are highly sensitive to the value placed on additional life years — lower values would require advances in medical technology to extend life expectancy further. Yet halving the statistical value of an additional life year to \$50 000 only increases to six the extra days required (per year) to make additional spending on those advances worthwhile. Such outcomes are well within feasible limits. As outlined in chapter 5, numerous studies demonstrate strong links between observed improvements in life expectancy and quality of life and advances in medical technology. Overall, life expectancy at birth has increased by almost three years over the past decade or by more than three months for each of those ten years.

Several overseas cost–benefit studies find that the aggregate benefits of medical technology exceed the costs. For example, Cutler and McClellan (2001) analyse five different types of medical condition, using US studies undertaken between the 1950s and 1990s. They find that the benefits from lower infant mortality and improved treatment of heart attacks combined are sufficient to equal all of the increase in healthcare expenditure during the period (assuming that other technologies have not imposed offsetting negative impacts). Accordingly, they conclude that the benefits from increased medical spending have been worth the cost.

² Medical technology is assumed to be responsible for half of the fall in mortality and disability rates, with two-thirds of the resulting increase in life years being healthy.

An alternative to aggregate cost–benefit analysis is ‘bottom up’ cost-effectiveness analysis — that is, to assess the cost effectiveness of individual technologies and/or broad categories of technology. The presumption would be that, to the extent that individual technological advances used in Australia were relatively cost effective, their aggregate impact would have been also.

7.2 Cost-effectiveness analysis

Cost-effectiveness analysis provides a method of evaluating the *relative* healthcare outcomes of various technologies, without placing monetary values on benefits. The outcomes of a particular intervention are expressed as the cost per unit of benefit. Benefits can be expressed as lives saved, illnesses diagnosed, repeat procedures avoided or quality-adjusted life-years (QALYs) among others (chapter 5).³

In principle, interventions can then be ranked according to their cost per unit of benefit, facilitating comparisons across different types of interventions. For example, the cost effectiveness of selective serotonin reuptake inhibitors (SSRIs), statins and joint replacement can be compared. Alternatively, two interventions for the same condition can be compared directly by using an incremental cost-effectiveness ratio which measures the cost difference per unit of benefit between them. An intervention is more cost effective than another if its cost per unit of benefit is lower, or if it produces more units of benefit in total for a fixed amount of spending.

However, there are many challenges in assessing the cost effectiveness of technologies, relating to difficulties in applying the technique as well as inherent limitations of the analysis:

- A major limitation is that some benefits may not be adequately captured because of the nature of the benefits or uncertainty about health impacts over time.
- Another is that the impact of a technology typically is highly sensitive to the risk status and condition of the patient receiving treatment.
- Because the benefits of a medical intervention are likely to be more uncertain and accrue in the future compared with the costs, the timeframe over which the assessment is made is important, as is the rate at which future effects are discounted. Unforeseen side effects may also emerge. Hence, important considerations for cost-effectiveness analysis include the treatment of time and uncertainty.

³ Where cost effectiveness is expressed in terms of cost per QALY, it is sometimes referred to as cost–utility analysis, because QALYs are designed to capture relative utility or wellbeing of an individual in different health states. How well they achieve this is a matter of debate (chapter 5).

- The choice of comparator therapy is also critical. For instance, comparing a new technology to doing nothing (assuming doing nothing costs nothing and is ineffective) will show the new technology in a better light than comparing it with a simpler and less expensive, yet effective, alternative therapy. Indeed, even where a new therapy is compared with the prevailing alternative treatment, it is possible that another, more cost-effective treatment exists, which is not being used due to lack of resources or public funding. (This could occur where a therapy lacks a sponsor or champion, or if it does not fit within existing technology assessment guidelines and, hence, misses out on reimbursement.)

The sensitivity of cost-effectiveness estimates is brought out by an assessment by the National Institute for Health and Clinical Excellence (NICE) of dual chamber pacemakers, where estimates of the cost per QALY ranged from £5500 to £36 000, depending on assumptions about the cost of the technology, the severity of the patient's condition and the length of the period under review (box 7.1). Indeed, data limitations meant that NICE was able to estimate the cost per health gain for only half of the technologies on which it issued guidance between April 1999 and March 2001 (Wanless 2001).

Box 7.1 Sensitivity and limitations of cost-effectiveness analysis — the example of dual chamber pacemakers

NICE assessed the cost effectiveness of dual chamber pacemakers relative to single chamber pacemakers. Its assessment produced a range of estimates (see below) depending on the severity of the patient's condition, costs of the technologies and the time period under consideration.

<i>Scenario</i>	<i>Incremental cost-effectiveness ratio £ per QALY</i>
1. Base case	8500
2. A reduction in the severity of the patient's condition (an increased likelihood of mild pacemaker syndrome resolving itself without any treatment)	36 000
3. An increase in costs (from minimum prices to maximum)	34 000
4. An increase in the time period for assessing benefits (from 5 to 10 years)	5500

Source: NICE (2005b).

7.3 Cost effectiveness of broad categories of technology

Most studies of the cost effectiveness of broad categories of medical technology have been undertaken overseas and tend to have focused on pharmaceuticals, mainly because of data availability. Two main methods for assessing cost effectiveness are used:

- econometric analysis (Lichtenberg 2001; 2002b); and
- literature reviews (Coyle and Drummond 1993; Neumann et al. 2000).

Both approaches generally find that technological advances in healthcare have been cost effective, although some studies are somewhat more cautious than others (box 7.2).

Box 7.2 Cost effectiveness of classes of technology

In an econometric analysis of drugs, using the US Medical Expenditure Panel Survey, Lichtenberg (2001; 2002b) proxies the 'newness' of technologies according to the time since a drug was approved by the Food and Drug Administration. He shows that newer drugs cost more than older drugs but are also of higher quality. Newer drugs reduce the total cost of treatment, mainly through reductions in hospital expenditure, and thus would be cost effective. Lichtenberg does not test the robustness of his results to variations in the sample.

Coyle and Drummond (1993) use a literature review approach to assess the cost effectiveness of drugs in the United States. They find that drug interventions are generally more cost effective than no intervention. Drugs are also at least as cost effective as other interventions in some cases. However, they find that more expensive drugs are more cost effective than cheaper drugs in fewer than half of the studies examined. Further, they caution that their sample may be biased in favour of finding that drugs are cost effective because studies with positive results are more likely to be published.

Neumann et al. (2000) analyse results of 228 published cost-effectiveness studies from a range of countries of pharmaceuticals and other technologies including surgical, diagnostic and screening procedures, and devices. They rank the median cost effectiveness by category of technology (table 7.1). Immunisation ranks as more cost effective than other categories of intervention. Surgical procedures, pharmaceuticals, screening, public health programs, health education and diagnostic procedures are closely grouped and, on average, would appear to be relatively cost

effective in the sense that that they buy an additional QALY at relatively low cost.⁴ Devices appear to be somewhat less cost effective on the whole. Of course, the estimates will reflect the sample of technologies analysed within each category and, therefore, may not be representative.

Table 7.1 Median cost-effectiveness ratios by technology type

<i>Intervention type</i>	<i>Number of ratios</i>	<i>Median cost effectiveness^a US\$</i>
Immunisation	38	2000
Care delivery ^b	36	6000
Surgical	128	10 000
Pharmaceutical	251	11 000
Screening	72	12 000
Other public health ^c	8	15 000
Health education/counselling	28	20 000
Diagnostic	83	20 000
Device	22	40 000
Various	3	68 000
Medical procedure ^d	42	140 000
All interventions	647	12 000

^a Dollars per QALY saved, in 1998 US dollars. ^b Includes interventions defined by setting of care (for example, intensive care unit versus standard ward treatment). ^c Includes interventions not classified elsewhere (examples include fortification of cereal grain product with folic acid versus no program and the use of driver airbags versus no airbags in automobiles). ^d Includes nondiagnostic, nonscreening, nonsurgical procedures (such as blood transfusions).

Source: Neumann et al. (2000).

Analysis undertaken for this study of new pharmaceuticals used in Australia suggests that newer drugs are higher cost but generally are effective. There is also evidence of some offsetting hospital cost savings through reduced separations for some conditions (chapter 4). Moreover, since 1992-93 all new pharmaceuticals listed on the Pharmaceutical Benefits Scheme (PBS) must be assessed for cost effectiveness relative to the prevailing therapy,⁵ providing support for the proposition that as a group, new pharmaceuticals are likely to have been cost effective. However, there are several possible qualifying factors. For example, in

⁴ The cut-off will depend on the *value* placed on benefits. As discussed in chapter 5 and appendix B, there are various methods of capturing the value of life, but all have limitations. In the United States, US\$100 000 is commonly used as the statistical value of an additional year of life based on studies of how much compensation individuals demand in return for being exposed to an increase in the risk of death or injury.

⁵ Under the Pharmaceutical Benefits Advisory Committee (PBAC) guidelines, the comparator required to be the existing alternative therapy (drug or non-drug), although, as noted above, it is possible that more cost effective non-drug treatments are not being used because of lack of resources or no patient subsidy.

practice, there is evidence of ‘leakage’ of some drugs (such as statins and SSRIs) to patient groups who do not meet prescription guidelines and for whom benefits, and relative cost effectiveness, may be lower on average than suggested by clinical trial data (chapter 6 and appendixes F and G).⁶

New drugs not listed on the PBS but made available through hospitals (for example, some cancer treatments and anaesthetic agents) may also have been evaluated by State Governments or hospitals themselves, though these processes are not as well defined as Pharmaceutical Benefits Advisory Committee (PBAC) processes. However, as discussed in chapter 4, limited public hospital budgets may create a bias towards the introduction of technologies that reduce hospital outlays, and these technologies may or may not provide the most cost effective treatments from a longer-term, whole-of-community perspective.

Cost-effectiveness assessment of new medical and diagnostic procedures is undertaken by the Medical Services Advisory Committee (MSAC) prior to listing on the Medicare Benefits Schedule (MBS). MSAC also assesses some devices on request though these are not listed on the MBS. But MSAC does not assess all new procedures, making it somewhat more difficult to conclude that new procedures on average have promoted cost effectiveness of healthcare delivery (chapter 10). That said, as discussed below, many new procedures appear to provide additional QALYs at comparatively low cost compared with existing treatments, with some estimated to be cost saving.

Less information is available about the cost effectiveness of devices and prostheses used in Australia. While MSAC may review cost effectiveness of new devices on request, until 2005, there was no systematic approach to assessing their effectiveness let alone cost effectiveness (chapter 10). However, as discussed below, particular devices and prostheses currently in use are estimated to buy an additional year of healthy life for a comparatively small amount.

7.4 Cost effectiveness of individual technologies

Drawing together available cost-effectiveness estimates for a range of individual technologies could provide some indication of whether newer technologies are likely to have improved overall cost effectiveness of healthcare delivery in Australia. It should be borne in mind, however, that not all new technologies used in Australia have been assessed in either local or overseas settings. This might reflect a lack of data, or that the nature of benefits is such that they cannot easily be captured

⁶ It is feasible that in some circumstances, prescription of drugs outside guidelines *promotes* cost effectiveness where new beneficial applications of drugs emerge from clinical practice.

in summary health measures such as QALYs. Even where assessments have been made, results may not have been reported (possibly because they are not favourable).

Cost-effectiveness estimates for a range of technologies used in Australia are presented in table 7.2, based on their cost per QALY and drawn from different dates, locations and settings. The table highlights the wide dispersion in estimates across different technologies and even for particular technologies. Estimates for some technologies suggest that they ‘buy’ a QALY very cheaply — implying good value for money. Indeed, some technologies are assessed as cost saving (they provide a given unit of benefit for *less* money than the alternative) — laparoscopic cholecystectomy and cochlear implants for profoundly deaf children, for example. Improved anaesthetic agents are also likely to fall in this category.

To the extent that cost-saving technologies and technologies that provide an additional year of quality-adjusted life for a comparatively small sum have been widely adopted, replacing less cost-effective treatments (including no treatment in some cases), the overall cost effectiveness of providing healthcare services will have improved.

As discussed in chapter 4, over the past ten years there has been a significant increase in expenditure on medicines including statins, anti-hypertension treatments such as beta blockers and angiotensin-converting enzyme (ACE) inhibitors, asthma medications including corticosteroids, and SSRIs for treatment of depression. *Prima facie*, each of these new therapies would appear to be relatively cost effective, providing further support for the notion that medical advances have provided value for money. Many new surgical procedures and prostheses and devices also appear to be relatively cost effective — cataract surgery, hip and knee replacements, laparoscopic surgery and cochlear implants, for example.

But conclusions can only be made from table 7.2 to the extent that the technologies have been used in Australia in a similar way to that underlying the cost-effectiveness estimate. This is highlighted by the fact that estimates for many individual technologies exhibit a wide range depending on, for example, patient age, disease indication or risk status, as well as the selected comparator therapy. Several case studies undertaken for this study cite evidence that new technologies are sometimes being used in Australia in ways that might not be cost effective compared with alternative treatments — for example, the prescription of statins to low-risk patients (appendix F) and of SSRIs to people with mild depression (appendix G), and use of prostate specific antigen tests for prostate cancer screening (appendix J). In other cases, potentially cost effective use of technologies by some patient groups may not be occurring to the extent indicated by their assessed clinical need.

Table 7.2 Cost effectiveness of selected technologies

<i>Technology [comparator in square brackets]</i>	<i>Source</i>	<i>A\$ per QALY (2002 prices)^a</i>
<i>Screening/prevention program</i>		
Nicotine patches, by age group [no patches]	Fiscella & Franks 1996	7400–17 400
Diabetes type 2 screening, 5-yearly, by age [no screening]	Chen et al. 2001	11 000–52 000
Colorectal cancer screening of 50 year old persons by gender [no screening]	Whynes et al. 1998	3350–4900
Genetic testing for breast cancer by risk category [no testing]	Tengs & Berry 2000	4900–2 300 000
<i>Pharmaceutical/vaccination</i>		
SSRIs [no depression treatment]	Revicki et al. 1995	4600
ACE inhibitors for ages 65+ with heart failure [placebo]	Anderson et al. 2000	4200–5100
Beta blockers current population use [no beta-blocker use]	Phillips et al. 2000	6000
Statins for secondary prevention, by age [no statins]	McMurray 1999	13 000–25 000
Bisphosphonates, by age/fracture risk [no treatment]	Jonsson et al. 1999	29 400–108 500
Inhaled corticosteroids for mild to moderate asthma [no corticosteroids]	Paltiel et al. 2001	20 000
Herceptin/paclitaxel for metastatic breast cancer [paclitaxel alone]	NICE 2002a	82 400
Pneumococcal vaccination for ages 65+ by country [no vaccine]	Ament et al. 2000	500–65 000
<i>Procedures with or without device/prosthesis</i>		
Cataract surgery (phacoemulsification and intraocular lenses), various utility weights/costs [no surgery]	Busbee et al. 2002	1900–5900
Hip replacement (average cost prosthesis) [no replacement]	Segal et al. 2004	8100
Knee replacement (average cost prosthesis) [no replacement]	Segal et al. 2004	11 000
Bypass surgery for ischemic heart disease patients [medical management including aspirin and/or statins over various periods]	Cleland & Walker 1998	25 000–65 000
Angioplasty with stent for men aged 60 years [angioplasty without stent]	Bosch et al. 1998	6400
Laparoscopic surgery (cholecystectomy) [open surgery]	Cook et al. 1994	Cost saving
Cochlear implant, profoundly deaf child/adult [no implant]	Lea & Hailey 1995	Cost saving–26 000
Drug eluting stents (various weights for disutility of restenosis and different waiting periods for revascularisation) [bare metal stents]	Hill et al. 2004	50 000–2 200 000

^a Nominal values are converted to real values using GDP deflators from the relevant country, re-based to 2001-02, and then converted to Australian dollars using purchasing power parity exchange rates. Only approximate values are given.

Estimated costs per QALY for some technologies — such as coronary artery bypass grafts and Herceptin — appear to be relatively high. For some of these technologies, the evidence is equivocal or, as yet, incomplete. For example, trials on Herceptin are continuing (appendix I) and the benefits of drug eluting stents (DES) will take time to emerge (appendix H). Thus, high estimated costs per QALY must be treated with some caution and do not necessarily mean that curtailment of use of the technology in question would increase social net benefits. It is quite possible that cost-effectiveness ratios of many new technologies (especially procedures) will improve over time as the technology is refined and better targeted, and as clinicians develop their skills and techniques. Indeed, for many procedures, development can only occur ‘on-the-job’. For many drugs and devices, competition will induce prices to fall over time and consequently improve cost-effectiveness ratios.

In addition, the individual and social impacts of a particular technology may not be adequately captured in the QALY measure. For example, using QALYs to capture the benefits of interventions for treating chronic diseases, where quality of life is more important than survival, is problematic (chapter 5). QALYs also may not fully capture the benefits of preventative measures or new therapies that improve compliance (for example, treatments that are more convenient for patients), or which reduce patient recovery times. For example, cost-effectiveness estimates for statins used for primary prevention based on QALYs are much higher than those for secondary treatment. This may simply reflect lower cost effectiveness in primary prevention, but it may also reflect in part inherent difficulties in using QALYs. For example, expressing the cost effectiveness of DES in terms of cost per QALY is highly sensitive to the weight given to the disutility of further procedures, the avoidance or deferral of which is the principal intended benefit of DES. Nor can QALYs capture other dimensions of healthcare outcomes including social ‘spillover’ and distributional effects.

7.5 Conclusion

At the aggregate level, based on commonly-used estimates of the statistical value of an additional year of healthy life and reasonable assumptions about the link between technology and observed improvements in health outcomes, arguably advances in medical technology have provided value for money. However, it is not possible to provide a precise estimate of the impact of advances in medical technology on overall cost effectiveness of the healthcare system.

Analysis of categories of technologies supports this general conclusion. Given rigorous cost-effectiveness assessment of most new pharmaceuticals and many new

medical and diagnostic procedures in Australia, it is reasonable to conclude that advances in these technology categories have been broadly cost effective.

Estimates of cost effectiveness of individual technologies, where they are available, also suggest that many advances used in Australia are likely to have been cost effective relative to alternative treatments.

However, cost-effectiveness estimates typically display a wide range, depending on the patient group and selected comparator therapy. Cost-effectiveness outcomes in practice and over time are also likely to differ from assessments based on controlled trial settings. Indeed, it is virtually impossible to conclude that a particular technology will *always* be cost effective or, for that matter, not cost effective — this will depend on who is receiving it and the cost effectiveness of available alternative treatments.

There is evidence, for example, that some technologies are not being used as cost effectively as they might. In some cases, this is because they are supplied to low-risk groups or used inappropriately, in others, because they are being under-used by some patient groups with apparent clinical need. There is also evidence that some technologies diffuse into practice without assessment and with little known about their cost effectiveness. The cost effectiveness of others may come to be surpassed by newer technologies yet they remain in wide use.

FINDING 7.1

While it is not possible to establish with precision the overall net benefits of new technologies or their net impact on the overall cost effectiveness of the healthcare system, arguably they have provided value for money, particularly given the high value people place on maintaining good health.

But the cost effectiveness of particular technologies varies widely and is highly sensitive to use of the technology — some technologies range from being highly cost effective for some patient groups but not for others compared with available alternative therapies. The cost effectiveness of some technologies in use in Australia is unknown. Evidence suggests that there may be scope to improve net social benefits from advances in medical technology through better targeting of those technologies.

The critical role of health technology assessment in Australia in providing relevant information for promoting cost effective use of new technologies is assessed in the following three chapters.

8 Health technology assessment in Australia: an overview

The terms of reference (d) ask the Commission to identify existing mechanisms and processes¹ for ensuring cost effectiveness in the use of medical technology, and any gaps in those processes. This chapter outlines, at a broad level, the key elements of health technology assessment (HTA) in Australia (additional detail is provided in the next two chapters) and summarises some of the key gaps identified in HTA processes.

The HTA process for pharmaceuticals in Australia is well established, with drugs subject to extensive pre-market testing for safety and efficacy since the early 1960s. Australia was also the first country to prepare formal guidelines and to introduce a mandatory requirement for the economic evaluation of new pharmaceuticals in the early 1990s (Dickson et al. 2003).

In contrast, formal HTA processes for other medical technologies (such as procedures and devices) have been established more recently. According to Weedon (1999), HTA for non-pharmaceutical technologies was introduced in Australia in the early 1980s.

The broad conceptual elements of HTA processes are similar for pharmaceuticals and other medical technologies such as devices. However, there are important differences between the types of technology that may warrant different application of HTA (chapter 10).

Information and communications technology (ICT) developments in healthcare are not currently subject to HTA processes in Australia as such but may be subject to other assessments on a project-by-project basis (for example, assessment of *HealthConnect* is discussed in chapter 10 and appendix K).

¹ The Commission has interpreted the term ‘process’ to refer to a series of steps or stages that seek to deliver an output or outcome and the term ‘mechanism’ to refer to the institutional structure (such as a committee, group or organisation) that participates in the process.

8.1 Defining health technology assessment

HTA refers to the processes and mechanisms designed to ensure safety, efficacy, effectiveness² and cost effectiveness in health service delivery. HTA is the systematic process of identifying new medical technologies, evaluating their key dimensions and effects, and monitoring their diffusion into clinical practice.

There are a number of questions that HTA of a new medical technology may seek to answer: (i) is the new medical technology safe? (ii) does it work? (iii) is it cost effective? (Anderson et al. 1999). These questions can be translated into the following key objectives for HTA:

- safety;
- efficacy;
- effectiveness;
- benefits; and
- cost effectiveness.

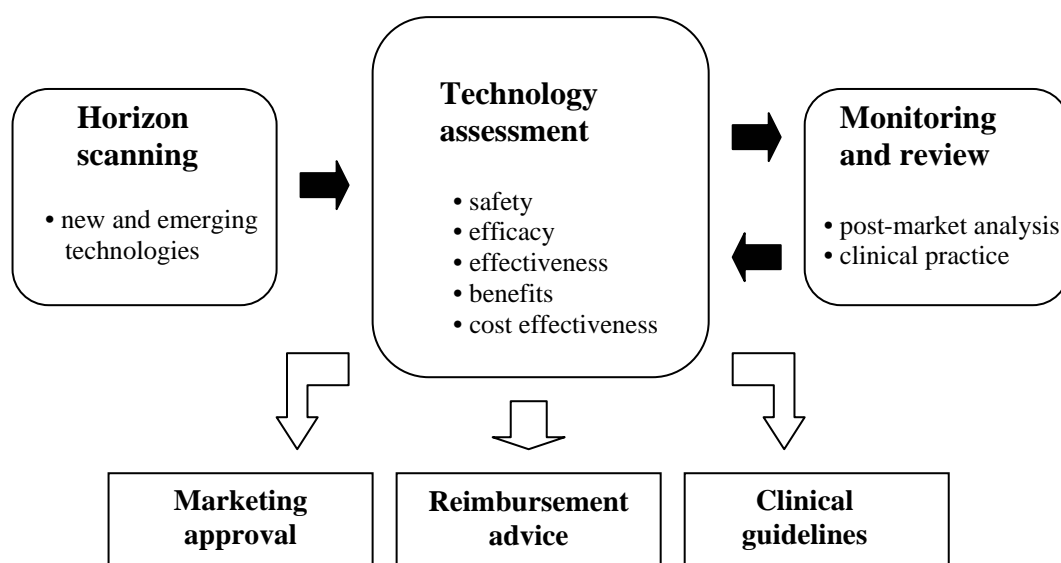
The HTA process generates or assembles information which is used to make policy, funding and clinical decisions. As noted by the Centre for Health Economics Research and Evaluation (CHERE, sub. 9), HTA is an overarching determinant of policy and practice. Ideally HTA should comprise three main stages (figure 8.1):

- horizon scanning — an ‘early warning’ system to identify new and emerging medical technologies that may have a significant impact on the healthcare system;
- technology assessment — the in-depth evaluation of the key attributes (safety, efficacy, quality, effectiveness and, in some cases, cost effectiveness) of new technologies; and
- monitoring and review — periodic re-assessment of a technology’s use in practice, such as its rate of diffusion and how it has affected the healthcare system (for example, in terms of costs and health outcomes).

Key aspects of these three stages are outlined in section 8.3.

² Efficacy and effectiveness both relate to the health benefit of a therapy, but under different sets of conditions. A therapy is efficacious if it produces a health benefit in a defined population in controlled or ideal conditions. A therapy is considered effective if it produces a health benefit in uncontrolled or routine circumstances (DoHA 2003c).

Figure 8.1 **Stylised process of health technology assessment**



8.2 Identifying gaps in HTA processes

The Commission has been asked in the terms of reference to identify ‘gaps’ in Australia’s HTA mechanisms and processes. The principal criterion for identifying a gap is where application of an improvement in HTA processes could efficiently facilitate the socially optimal use of medical technologies. That is, the limitations and costs of HTA (including the potential cost of delaying the introduction of a new technology) as well as the potential benefits and any other alternatives would have to be taken into account. Full assessment of every technology without regard to the cost of the assessment would not be desirable.

The key elements of pharmaceutical HTA mechanisms and processes analysed as part of this study include:

- institutional arrangements (HTA agencies or committees and their functions);
- assessment methodology (type of evaluation, range of benefits included in evaluations and choice of comparator);
- the assessment process (timeliness, mutual recognition, transparency, consultation, appeals mechanisms and Cabinet approval); and
- the post-assessment process (monitoring and re-assessments).

For each of these elements, qualitative evidence and quantitative indicators (where available) were collected and examined. Participants in this study also pointed out

potential gaps or deficiencies in current HTA mechanisms and processes. HTA processes were analysed and compared to good regulatory design and good practice principles used in Australia and overseas to help identify the gaps or deficiencies in HTA.

8.3 Overview of HTA arrangements

This section discusses the three stages of HTA arrangements that are outlined in figure 8.1.

Horizon scanning

Horizon scanning is an ‘early warning’ system used to identify new and emerging medical technologies³ that may have a significant impact on the healthcare system. As such, it can provide important and timely information on new technologies to decision makers (OECD 2005a).

There are two publicly-funded horizon scanning centres in Australia:

- the Australian Safety and Efficacy Register of New Interventional Procedures — Surgical (ASERNIP-S); and
- the National Horizon Scanning Unit (NHSU).

Established in 1998, ASERNIP-S aims to assess new surgical procedures prior to their widespread introduction into surgical practice. The organisation is funded by the Australian Government and administered by the Royal Australasian College of Surgeons (RACS). ASERNIP-S, together with RACS, set up the New and Emerging Techniques — Surgical (NET-S) project in 1999 to conduct horizon scanning for new and emerging surgical procedures which involve alterations to tissue volumes or the implantation of devices through an incision.

ASERNIP-S scans for new surgical procedures in a large number of speciality areas, including general surgery, cardiovascular surgery, gynaecology, neurosurgery, ophthalmology, transplantation, plastic and reconstructive surgery, urology and robotic surgery.

³ New technologies are defined as those in the early stages of adoption whereas emerging technologies are those that have not yet been adopted in the healthcare system. Horizon scanning may also involve preliminary assessments of prioritised technologies (which examine clinical need, safety, effectiveness and cost) when there is limited information on these attributes.

The NHSU, created in 2003, alerts the health departments of the Australian Government, the States and Territories, and New Zealand to new and emerging technologies that may impact on their public healthcare systems within a three year time horizon (NHSU 2004). The activities of the unit (and the horizon scanning activities of ASERNIP-S) are overseen by the Health Policy Advisory Committee on Technology (HealthPACT).

The horizon scanning activities of the NHSU cover devices, diagnostics and programs. Under these broad categories, the NHSU has specified major types of technologies that it intends to identify, register and assess (table 8.1).

Table 8.1 Technologies covered by the NHSU

<i>Devices</i>	<i>Diagnostics</i>	<i>Programs</i>
Non-diagnostic equipment	Diagnostic imaging	Health promotion
Drug delivery systems	Diagnostic testing methods	Public health
Monitoring systems	Diagnostic implants	Novel health service delivery
Therapeutic inserts	Gene-based diagnostics	Information management
Prostheses	Genetic markers	Individual-based programs
Bioengineered surface products	Tumour markers	
Tissue regeneration	Screening tests	
Biomaterials		
Non-diagnostic imaging		

Source: NHSU (2004).

ASERNIP-S and NHSU form part of the Australian and New Zealand Horizon Scanning Network (ANZHSN) which was established in 2003 by the Department of Health and Ageing (DoHA), the Australian Health Ministers Advisory Council (AHMAC) and the Medical Services Advisory Committee (MSAC).

ASERNIP-S and NHSU use various strategies to identify new and emerging medical technologies, such as searching the scientific and medical literature, scanning marketing approvals and trial registers, and through direct communication with clinicians. ASERNIP-S adds identified surgical techniques to the NET-S database and the NHSU adds other identified technologies to its Horizon Scanning Register.

Identified new and emerging technologies are then prioritised according to pre-defined criteria. Those that meet a pre-determined 'priority threshold' undergo a preliminary assessment and a prioritising summary is prepared. These summaries are forwarded to HealthPACT on a quarterly basis. Those technologies that do not meet the threshold are marked for monitoring or archiving. Horizon scanning reports are prepared on request from HealthPACT. On average, the NHSU prepares about 6–8 reports a year (NHSU 2004).

Prioritising summaries and horizon scanning reports address clinical need, safety, effectiveness and the cost impact aspects of the identified technology. Horizon scanning reports also seek to establish the availability of cost-effectiveness evidence, but usually there is a paucity of such evidence in the early stages of diffusion or pre-diffusion of a new technology. The documents also look at ethical, religious or cultural dimensions where relevant.

On occasion, it may be unclear whether horizon scanning for a particular procedure should be performed by ASERNIP-S or the NHSU. For example, there may be potential for overlap on implantable devices. The general rule is that ASERNIP-S will undertake the horizon scan if the procedure involves an incision. There appears to be considerable cooperation and communication between the two centres which would help to clarify responsibilities in ambiguous cases.

However, there are some omissions in coverage by current horizon scanning mechanisms. New and emerging pharmaceutical products (including drugs, vaccines and blood products) are not currently included within the specified groups of medical technologies examined by these centres (table 8.2). In addition, while the NHSU covers 'information management', it is not known whether this extends to technologies such as electronic prescribing systems for pharmaceuticals.

Table 8.2 Coverage of medical technologies by horizon scanning agencies, selected countries

<i>Agency^a</i>	<i>Country</i>	<i>Drugs</i>	<i>Procedures</i>	<i>Devices</i>	<i>Specialty areas</i>
ASERNIP-S	Australia		✓	✓	Surgery
NHSU	Australia		✓	✓	Non-surgical
CETAP	Canada	✓	✓	✓	All
DACEHTA	Denmark	✓	✓	✓	Oncology
FSIOS	Switzerland	✓	✓	✓	All
NHSC	UK	✓	✓	✓	All
UHC	US	✓	✓	✓	All

^a See abbreviations list for full titles.

Sources: Douw et al. (2003); NHSU (2004).

Some participants, such as Wyeth Australia (sub. PR57) and Dr Thomas Faunce (sub. PR60), saw a need for horizon scanning of emerging pharmaceuticals. Horizon scanning of pharmaceuticals is conducted in several other countries. For example, the Canadian Emerging Technology Assessment Program (CETAP) compiles emerging drug lists and the National Horizon Scanning Centre (NHSC) in

the United Kingdom identifies, tracks and assesses new pharmaceuticals (table 8.2; appendix C).

FINDING 8.1

Existing horizon scanning units in Australia — in contrast to practices in a number of overseas countries — do not cover new and emerging pharmaceuticals (including drugs, vaccines and blood products).

Technology assessment

Technology assessment involves in-depth evaluation of the attributes and potential effects of new technologies, based on more evidence than is typically available at the horizon scanning stage. The key attributes of the technologies examined include safety, efficacy, quality, effectiveness and, in some cases, cost effectiveness. The assessment process is evidence-based, placing significant weight on clinical studies which are assessed by expert panels or committees. The process generates information which is used to make decisions on marketing approval and reimbursement, and which also could be used to prepare clinical guidelines for medical practitioners.

Many agencies and committees, at the national, state and individual hospital levels, undertake HTA (figure 8.2). Some assessment also occurs in the private sector. The agencies involved in, and the assessment processes for HTA of pharmaceuticals differ significantly from those used for procedures, prostheses and devices.

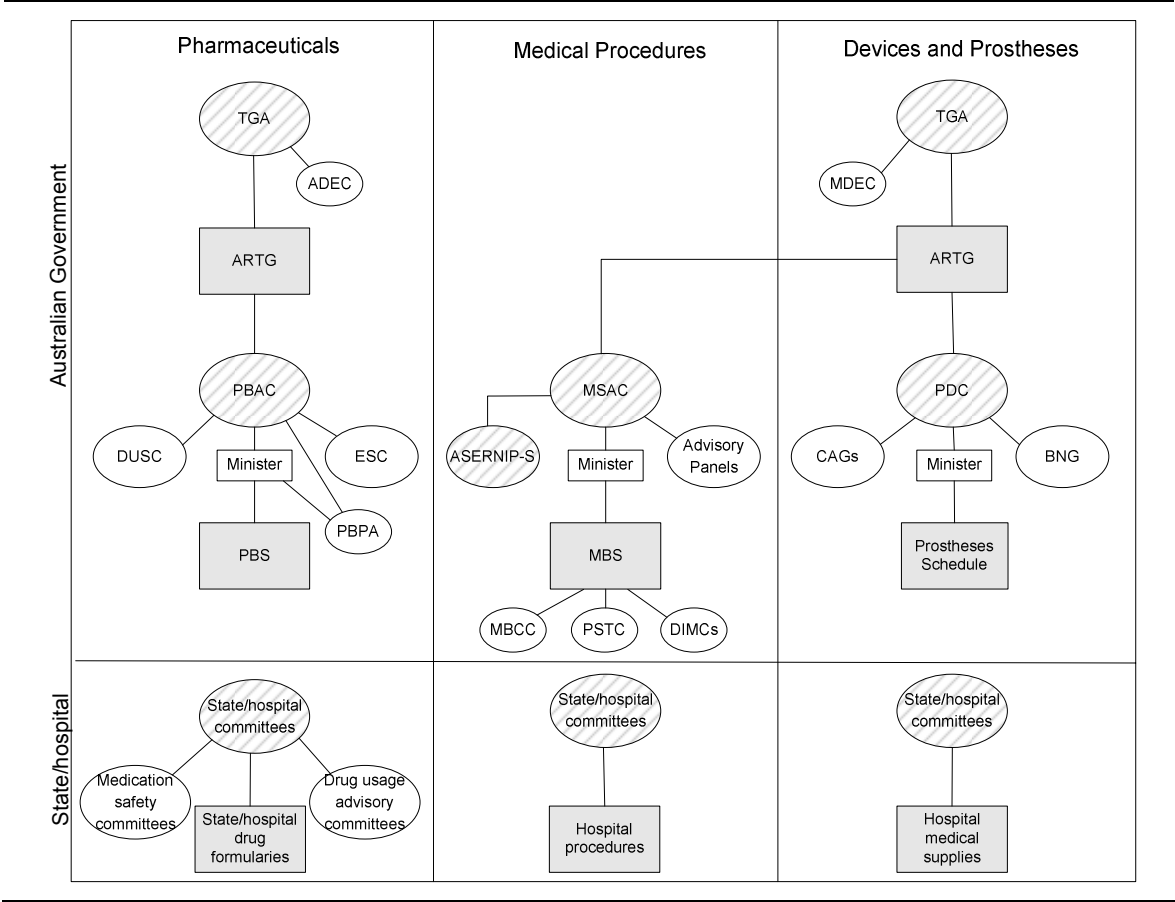
Key agencies involved in the assessment of pharmaceutical products at the national level are the:

- Therapeutic Goods Administration (TGA);
- Pharmaceutical Benefits Advisory Committee (PBAC); and
- Australian Technical Advisory Group on Immunisation (ATAGI).

Key agencies involved in the assessment of procedures, prostheses and devices at the national level include the:

- TGA;
- MSAC;
- ASERNIP-S; and
- Prostheses and Devices Committee (PDC).

Figure 8.2 HTA agencies and committees, by broad type of technology and jurisdiction^a



^a See abbreviations list for full titles.

Table 8.3 lists the technologies assessed by these HTA agencies, as well as their key assessment criteria. An outline of the responsibilities of these HTA bodies is provided below, with additional information about HTA for pharmaceuticals and other medical technologies in the following two chapters.

In addition to the roles of the national agencies, advisory committees have been established at the individual State/Territory, and at individual hospital, levels for the assessment of pharmaceuticals and procedures and devices. Further, in some cases, private health insurers also undertake assessment of new drugs or medical devices or services.

Table 8.3 Key assessment criteria, national HTA mechanisms

<i>Agency or committee</i>	<i>Technologies assessed</i>	<i>Safety</i>	<i>Clinical efficacy</i>	<i>Clinical effectiveness</i>	<i>Cost effectiveness</i>
TGA	Medicines and devices ^a	✓	✓		
PBAC	Pharmaceutical products			✓	✓
MSAC	Procedures, devices and equipment	✓		✓	✓
ASERNIP-S	Surgical procedures	✓	✓		
PDC	Devices and prostheses		✓		
ATAGI	Vaccines	✓	✓		✓ ^b

^a The TGA also covers blood, tissues and cellular therapies (DoHA, sub. 34). ^b PBAC will assume responsibility for assessing the cost effectiveness of new vaccines in 2006 (DoHA 2005d).

Therapeutic Goods Administration

The TGA is responsible for assessing the safety and efficacy of new therapeutic goods, whether the suppliers are seeking reimbursement from government or other sources. The TGA, however, is not required to consider the cost effectiveness of pharmaceutical products. The *Therapeutic Goods Act 1989* (Cwlth) defines a therapeutic good as anything used for the prevention, diagnosis or treatment of disease and other bodily conditions. As a result, the TGA is required to assess drugs, medical devices, blood, tissues and cellular therapies (DoHA, sub. 34).

The TGA regulates the overall supply of therapeutic goods through three main processes:

- pre-market evaluation;
- licensing of manufacturers; and
- post-market surveillance.

Before a product can be released to the market, the TGA must undertake an assessment. Products assessed as having a higher level of risk (including most prescription medicines) are evaluated for quality, safety and efficacy. If approved by the TGA, these products are included on the Australian Register of Therapeutic Goods (ARTG) as ‘registered’ products. Products assessed by the TGA as lower risk are evaluated for quality and safety only. If approved by the TGA, they are

included on the ARTG as 'listed' products. At 30 June 2004, there were about 10 500 registered medicines and around 16 600 listed medicines on the ARTG (TGA, pers. comm., 23 May 2005).

Under the new regulatory system for medical devices⁴ introduced in 2002, devices are classified according to the level of risk, the manufacturer's intended use and degree of invasiveness in the human body (table 8.4). Higher risk devices (such as Class III items and Active Implantable Medical Devices (AIMDs)) are subject to more stringent forms of conformity assessment (required of the manufacturer) than lower risk devices (such as class I and class II items) (TGA 2003). For higher risk devices, the TGA evaluates data on design, materials and testing, manufacture and quality control, biocompatibility, pre-clinical tests and human clinical trials. Class III items and AIMDs typically account for only a small proportion of device applications processed by the TGA.

Table 8.4 TGA classification system for medical devices

<i>Class</i>	<i>Examples</i>
I	Cotton wool, gauze dressings, scalpels
IIa	Crowns, dental drills, hearing aids, suction catheters
IIb	Blood bags, condoms, external pacemakers, ventilators
III	Absorbable sutures, breast implants, heart valves, stents
AIMD	Drug infusion devices, impulse generators

Source: TGA (2003).

The TGA checks whether the conformity assessment, undertaken by the manufacturer, has been applied and whether assessment procedures are appropriate. The manufacturer is required to demonstrate that the medical device conforms to the TGA's safety and performance principles that apply to all devices (TGA 2003). Upon TGA certification of the manufacturer's conformity assessment, the device is listed on the ARTG. There were around 27 500 devices on the ARTG at 30 June 2004 (TGA, pers., comm., 23 May 2005).

The TGA also licenses Australian manufacturers of therapeutic goods to ensure that their manufacturing processes comply with principles of good manufacturing

⁴ The *Therapeutic Goods Act 1989* (Cwlth), in essence, defines a medical device as any instrument, apparatus, appliance, material or other article intended by the supplier to be used on humans for the diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap. The definition also encompasses devices for the investigation, replacement or modification of the anatomy or a physiological process and for the control of conception (TGA 2003).

practice. In addition, once technologies are approved, the TGA conducts post-market surveillance and testing of products to ensure compliance with legislation. It also conducts investigations of reported problems.

In making its decisions, the TGA is advised by a range of other committees, such as the Australian Drug Evaluation Committee (ADEC) (pharmaceuticals) and the Medical Device Evaluation Committee (MDEC) (medical devices). In the case of prescription medicines, ADEC advises the TGA on aspects such as the quality, safety and efficacy of any drug referred to it for evaluation. ADEC is assisted by the Pharmaceutical Sub-Committee (TGA 2005).

A new regulatory system for medical devices was introduced in 2002 which saw MDEC replace the Therapeutic Device Evaluation Committee which had been operating since 1987. MDEC provides advice to the Minister for Health and Ageing (the Minister) and the TGA on safety, quality, performance and timely availability of medical devices (TGA 2005). The Committee is supported by the Office of Devices, Blood and Tissues (ODBT) within the TGA.

Pharmaceutical Benefits Advisory Committee

Once the TGA has approved a drug for marketing, the sponsor (usually the manufacturer) may apply to PBAC for listing the drug on the Pharmaceutical Benefits Scheme (PBS). PBAC provides the main route for assessing the cost effectiveness of medicines as it makes recommendations to the Minister on which medicinal products should be available for subsidy under the PBS. PBAC is assisted by two sub-committees: the Economics Sub-Committee, established in 1993, which reviews clinical and economic evaluations (including of cost effectiveness) and the Drug Utilisation Sub-Committee (Sansom 2004).

Following amendments to the *National Health Act 1953* (Cwlth) (National Health Act) in the late 1980s, PBAC has been required to consider the effectiveness and cost of a drug proposed for PBS listing compared to alternative therapies. In preparing their submissions to PBAC, sponsors are assisted by the PBAC Guidelines (DoHA 2002b).⁵ As well as making recommendations to the Minister about which drugs should be subsidised, PBAC also recommends maximum quantities and repeats, and may recommend restrictions on the indications. It also provides advice on any other matters referred to it by the Minister.

If PBAC recommends a listing, the Pharmaceutical Benefits Pricing Authority (PBPA) uses PBAC's advice to formulate a recommendation to the Minister on the

⁵ PBAC Guidelines are currently under revision, focusing on the analysis of clinical outcomes and valuation of health outcomes.

price at which the drug should be listed for subsidy. Although HTA information is used, price determination strictly speaking is not part of the HTA process. Price negotiations with the manufacturer are conducted by DoHA. Additional information about price determination is provided in chapter 9.

The PBS is a major government program with expenditure of around \$5.6 billion in 2003-04 (DoHA 2004g). In recent years, public sector spending on pharmaceuticals has accounted for more than 50 per cent of total pharmaceutical spending in Australia (table 8.5).

Table 8.5 Pharmaceutical expenditure, public and private sectors, Australia, 2002-03

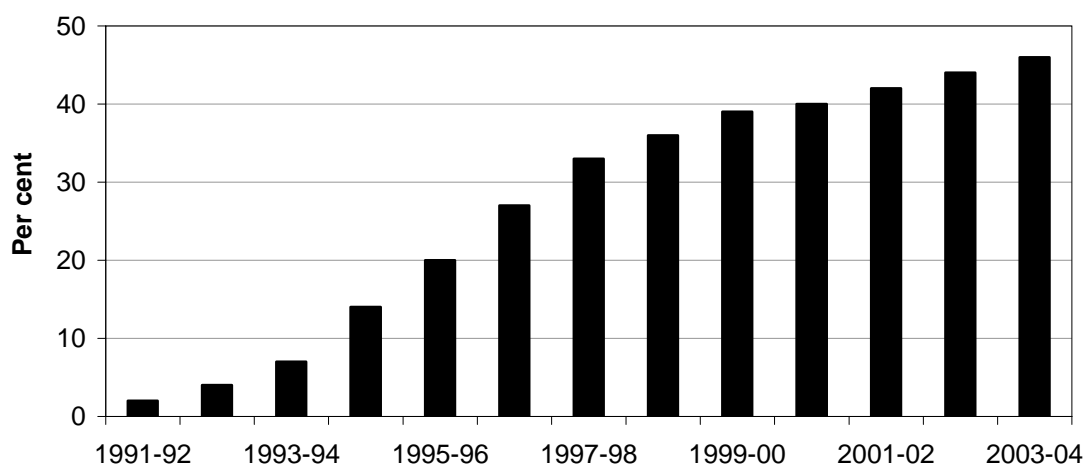
	<i>Expenditure</i>	<i>Share of total</i>
	\$m	%
Public sector		
Australian Government ^a	5127	46.9
Public hospitals	919	8.4
Private sector		
Individuals ^b	4731	43.3
Health funds	52	0.5
Other	96	0.9
Total	10 925	100.0

^a Predominantly the PBS. ^b Includes patient co-payments (\$1046 million) as well as expenditure on private prescriptions and over the counter medicines (\$3686 million).

Sources: AIHW (2004a) and (2004b).

The number of drugs listed on the PBS has grown from 139 drugs in the first year of its operation in 1948 to about 650 drugs (in 1600 dosage forms) in 2004 (Sansom 2004). The proportion of all PBS-listed pharmaceuticals subjected to economic evaluation was 46 per cent in 2003-04, compared with 4 per cent in 1992-93 when the requirement for economic evaluation became mandatory (figure 8.3). More than 50 per cent of drugs listed have not been assessed for cost effectiveness and, of those drugs that have been assessed, relatively few have been re-assessed by PBAC after listing (chapter 9). According to DoHA (sub. PR56), the proportion of drugs subjected to cost-effectiveness assessment will increase gradually over time as more drugs are assessed and as some older drugs are de-listed.

Figure 8.3 Proportion of PBS drugs subjected to economic evaluation
1991-92 to 2003-04



Data source: DoHA (2004g).

Medical Services Advisory Committee

New medical services need to be examined by MSAC which makes recommendations to the Minister on whether a new procedure should receive public funding, including listing on the Medicare Benefits Schedule (MBS) (box 8.1). MSAC also may recommend interim funding for promising technologies that require further data collection to establish their safety, effectiveness and cost effectiveness. In addition, MSAC's advice may be relevant to the States and Territories in relation to public hospital systems.

Box 8.1 Medicare Benefits Schedule

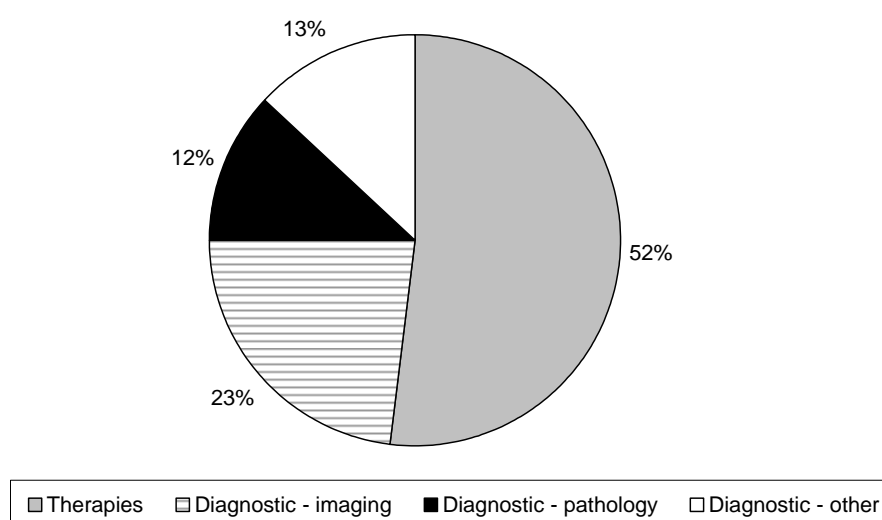
The Medicare Benefits Schedule (MBS) lists and describes the medical and diagnostic services for which a Medicare benefit is payable by the Australian Government, the amount of that benefit, and any conditions on the use of that service. The MBS applies to medical services and hospital services for private patients. The MBS accounted for \$8.5 billion of Australia's health expenditure in 2003-04. There are more than 4500 individual items listed on the MBS and supplementary schedules. The MBS also contains a large number of medical procedures that are commonly used in clinical practice, however, many of these have never been subjected to cost-effectiveness assessment by HTA bodies.

Source: DoHA (2004g).

Established in 1998 (its predecessor was the Australian Health Technology Advisory Committee (Weedon 1999)), MSAC advises the Minister on the safety, clinical effectiveness and cost effectiveness of new and existing medical technologies in response to submissions from the medical industry or references from government. It examines procedures, diagnostic tests and devices but not pharmaceuticals.

In total, MSAC had completed around 70 evaluations by the end of June 2004 (DoHA 2004g; MSAC 2004a). Around half of MSAC's evaluation work relates to therapies (many involving surgical procedures) and the other half to diagnostic procedures (figure 8.4). The range of procedures that MSAC can potentially examine is quite broad, given that the MBS includes medical services such as professional attendances, diagnostic procedures, therapeutic procedures, dental procedures, pathology and miscellaneous services.

Figure 8.4 **Broad types of technology assessed by MSAC^a**



^a Includes evaluations that were completed or ongoing as at end December 2003.

Data source: Kearney (2004).

Unlike pharmaceutical assessment, where evaluations are the responsibility of drug manufacturers or suppliers, MSAC funds and organises assessments of new medical procedures. Contracted evaluators undertake the majority of the assessment, overseen by an advisory panel comprising experts in the technology under examination. The experts are selected from nominations provided by relevant medical colleges and/or specialty groups. A consumer representative and a person with knowledge of health finance and/or epidemiology may be included on an advisory panel. The panel is chaired by a member of MSAC. If a new procedure

involves new medical devices or pharmaceuticals, these would generally need to be approved by the TGA before the procedure may be eligible for MSAC assessment.

DoHA is conducting an administrative review of MSAC's activities and intends to report its findings to the Minister in 2005.

Australian Safety and Efficacy Register of New Interventional Procedures – Surgical

In addition to its horizon scanning activities, ASERNIP-S assesses the safety and efficacy of selected new surgical procedures and also undertakes review work for MSAC. Nominations of surgical procedures for review by ASERNIP-S arise from various sources including RACS, specialist societies, hospitals, consumer groups and individuals. Once systematic reviews are endorsed by the RACS Council, they are disseminated to relevant groups of the RACS, hospital credentials committees, consumer groups and government agencies.

ASERNIP-S (sub. PR50) also manages research audits arising from ASERNIP-S and MSAC systematic reviews, which indicate the need for additional local evidence to determine the value of particular new procedures for use in the Australian healthcare system.

Australian Technical Advisory Group on Immunisation

Established in 1997, ATAGI provides advice to the Minister on technical and scientific elements of the National Immunisation Program and the Australian Standard Vaccination Schedule (DoHA, sub. 34). ATAGI considers vaccines likely to be approved for use in Australia and liaises with the TGA and DoHA on matters regarding the availability, safety and clinical effectiveness of vaccines. It also maintains and updates the Australian Immunisation Handbook on behalf of the National Health and Medical Research Council (NHMRC).

ATAGI's role in assessing the cost effectiveness of new vaccines will be transferred to PBAC in 2006 (DoHA 2005d).

Prostheses and Devices Committee

A significant and growing amount of expenditure applies to medical devices and prostheses,⁶ which became subject to new regulatory requirements in 2004-05 (chapter 10).

Once a prosthesis or device has been listed on the ARTG, manufacturers or suppliers may apply to list the item on the Prostheses Schedule. The PDC (which replaced the Private Health Industry Medical Devices Expert Committee) was established in 2004. It advises, and make recommendations to, the Minister on the listing of new prostheses and the setting of benefit levels that private health insurers need to cover for their members for new and existing prostheses.

The number of items listed for reimbursement on the Prostheses Schedule has expanded significantly since its establishment. It currently lists around 9000 items compared to only a small number of items in 1985 (HoR 2004). This reflects increasing numbers of new products, product variations and relatively few deletions from the Schedule.

Additional information about HTA arrangements and pricing mechanisms that apply to prostheses and devices is contained in chapter 10.

State/Territory and hospital advisory committees

Public hospitals account for about 8 per cent of pharmaceutical expenditure in Australia (table 8.5). Some State Governments have established advisory committees and working groups to assess requests to use new medicines or other medical technologies in hospital settings. For example, the Victorian Policy Advisory Committee on Technology (VPACT) was created in 2004 to promote a systematic approach to the introduction and use of new and existing health technologies in Victoria. VPACT has a range of roles, from horizon scanning to assessment and monitoring (box 8.2). The Victorian Medicines Advisory Committee (VMAC) is also being created to provide advice on strategic directions and policy development for the safe, efficient and effective use of medicines within Victoria (VDHS, sub. 24).

⁶ Prostheses include items such as artificial joints, intraocular lenses and cardiac pacemakers that can be implanted during a surgical procedure.

Box 8.2 Victorian Policy Advisory Committee on Technology

The committee's role is to advise and make recommendations on:

- mechanisms for early identification of new technologies and clinical practices with potential implications for public health services;
- assessment of clinical and cost effectiveness of new and existing technologies and clinical practices;
- policies and procedures for best practice for the introduction and use of new and existing technologies and clinical practices in public health services; and
- requirements for evaluating and monitoring the introduction and use of new technologies and clinical practices in public health services.

Source: VDHS (sub. 24).

Similar mechanisms exist in Queensland, Western Australia and, more recently, South Australia. The Queensland Hospitals Drug Advisory Committee (QHDAC) maintains and reviews the State-wide formulary which lists therapeutic substances available for use in Queensland hospitals and institutions (Queensland Health 2004). The Western Australian Drug Evaluation Panel (WADEP) was established in 2002 to provide independent advice on the clinical and cost effectiveness of drugs proposed for use in Western Australian public hospitals. In South Australia, a Sub-Committee for New Technologies under the Clinical Senate (SCNT) was established in 2004 to examine the efficacy and cost effectiveness of medical machines, therapeutic agents or new techniques. The South Australian Government stated that:

For State public systems, there is no national comprehensive centralised system for review of new technologies once they have been passed by the TGA. Smaller reference groups have been created in many jurisdictions to address this need. South Australia has established a Sub-Committee for New Technologies under the Clinical Senate. (sub. 35, p. 7)

These committees typically consider applications for formulary listing of high cost (high price and/or high volume) and highly specialised drugs, such as anti-cancer agents, anti-infective agents, anti-rejection agents for organ transplant patients, and agents to treat rare diseases. For instance, in assessing a drug for listing on the Queensland drug formulary, QHDAC requires information on safety, effectiveness and cost effectiveness (Queensland Health 2004). VMAC and WADEP have broadly similar roles. Thus, many of the State-based drug advisory committees examine new drugs using similar criteria as the TGA and PBAC. There also appears to have been duplication of effort within some States in areas such as hospital medication safety (chapter 9).

In addition, advisory committees that examine medical procedures exist at the State and hospital levels. For example, VPACT considers all types of clinical diagnostic and treatment interventions. Some health services in Victoria also have established internal committees to oversee the introduction of new medical procedures. The Alfred Innovations Committee at Bayside Health and the New/Clinical Interventional Procedures Committee at Southern Health consider evidence of efficacy, clinical effectiveness and cost effectiveness of new procedures, among other things (VDHS, sub. 24).

Private health insurers

Private health funds provide cover for a range of hospital and medical services and some pharmaceuticals. Although health funds rely primarily on government HTA processes, they may undertake in-house assessment of new drugs or of particular medical services and devices (such as coronary stents). These assessments generally occur in response to clinicians' demands for health funds to cover a new technology prior to the outcome of PBAC, MSAC or PDC processes. In some cases, private health insurers may consider providing coverage for drugs in indications other than those approved by PBAC, or they may examine low-volume technologies (such as bone-lengthening devices) for which manufacturers or suppliers might not seek listing on the MBS or Prostheses Schedule and, therefore, which may not be formally assessed by MSAC or the PDC.

Monitoring and review

Some post-assessment monitoring and review functions are performed by HTA agencies (such as DoHA and the TGA) and by health funds. However, not all aspects of HTA processes in Australia are subject to systematic monitoring and review. The main aspects covered by monitoring activities in Australia include drug safety, use and expenditure. Monitoring may indicate when a more detailed review is needed, for instance, a re-assessment may be triggered if utilisation trends in practice diverge greatly from those predicted. Re-assessments consider new evidence that has become available since the initial technology assessment, which may lead to revisions in indications, restrictions, reimbursement and clinical guidelines.

Monitoring and review functions are discussed further in the following two chapters.

8.4 Key gaps

While some gaps or issues in HTA are specific to the different technologies (these are discussed in the next two chapters), several overarching themes emerge:

- fragmentation and duplication of HTA activities;
- the relationship between HTA and health funding arrangements;
- lack of transparency in HTA processes;
- insufficient opportunities for community consultation during HTA;
- HTA of combined technologies; and
- development of advice and clinical guidelines.

Fragmentation and duplication

Figure 8.2 highlights the complexity and overlap of HTA responsibilities. Different streams of HTA activity relate to separate categories of technology, in part reflecting the different assessment processes required for different technologies. However, HTA committees in different jurisdictions appear to cover the same types of technologies. For example, MSAC covers new procedures at the national level for private patients whereas VPACT in Victoria and SCNT in South Australia cover similar technologies within their respective jurisdictions.

There is fragmentation of HTA effort along sectoral lines (that is, according to whether the technology is used in the private or public sector). Key national advisory committees, such as PBAC and MSAC, only focus on assessing drugs and procedures seeking listing on reimbursement schedules — the PBS applies mainly to patients outside hospital settings and the MBS applies to medical services and hospital services for private patients. Consequently, these committees do not assess a range of technologies that may be used in public hospital systems around Australia. The South Australian Government (sub. 35) noted that for State public systems, there is no national comprehensive system for the review of new technologies once they have been approved for use by the TGA.

To address this gap in clinical and/or cost-effectiveness assessment for State public hospital systems, some States have established their own advisory committees (see above). The Australian Healthcare Association noted that:

Already, NSW and Victoria are establishing committees and/or processes to do this, whereas it would be preferable for national standards, in both the public and private sectors, to be generated, from MSAC and PBAC decisions. (sub. 25, pp. 5–6)

The VDHS (sub. 24) argued that while there are potential risks and benefits for States in the adoption of a national approach to HTA, it warrants further examination. This may involve ascertaining how existing activities could be improved and what additional activities need to be established. Commenting on medical procedures and devices, ASERNIP-S (sub. PR50) indicated that HTA could be conducted more strongly at a national level. However, while a national approach may reduce duplication of HTA effort, a potential risk with centralised approaches is that they may seek to impose mandatory requirements which would limit the flexibility of jurisdictions.

Some participants pointed to areas of potential overlap or ambiguity across various HTA committees at a jurisdictional level. Regarding the assessment of medical devices, the MIAA (sub. 17) claimed that there were overlapping roles among five separate entities at different levels of government. Professor Brendon Kearney of the Institute of Medical and Veterinary Science stated:

There is ... scope for significant rationalisation of responsibilities for conducting these [HTA] activities whilst maintaining and developing the network of contractors skilled in Health Technology Assessment. (sub. 41, p. 1)

In addition, Professor Kearney (sub. 41) observed that the variation in standards and approaches used by various HTA bodies in Australia causes some significant inconsistencies. According to ACT Health (sub. 11), the divisions in Federal–State responsibilities have led to considerable duplication of effort in the evaluation of new technologies and inconsistent uptake across the country and between sectors.

The fragmented HTA effort in Australia has cost and time implications for sponsors, patients and government. If manufacturers or sponsors of new technology are required to deal with numerous committees, this can increase regulatory compliance costs. It may also delay the introduction of new treatments, with adverse impacts on patient outcomes and company revenues. In addition, there is the administrative cost to government of funding multiple HTA agencies/committees.

Overall, the evidence points to the opportunity for an overarching framework for coordinating HTA activities at a national level. The recent establishment of HealthPACT seems to be a step in this direction. The VDHS (sub. 24) noted that HealthPACT was established in recognition of the fact that the States and Territories did not have a structure for input into the national new technology agenda. Part of HealthPACT's role is to provide a forum to collaborate and exchange information nationally and internationally.

However, in its current form HealthPACT may be constrained in promoting greater coordination and prioritisation of HTA activities in Australia. Its terms of reference

do not explicitly include these objectives. Some participants also expressed concerns about governance and funding arrangements. Dr Jeff Brownscombe (sub. PR55) noted that HealthPACT is a subcommittee of MSAC which raises important governance issues, such as whether this is the appropriate reporting structure. The VDHS (sub. 24) also questioned whether current levels of funding would enable HealthPACT to provide ongoing robust advice to government.

Several participants pointed to Canada, the United Kingdom and New Zealand as examples for coordinating HTA activities (box 8.3; appendix C). While these countries may provide some lessons for Australia, it should be kept in mind that HTA arrangements in these countries have been shaped by their respective healthcare systems and that their processes have weaknesses as well as strengths.

Box 8.3 Overseas approaches to HTA coordination

Canada

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) coordinates HTA priorities across jurisdictions, undertakes assessment activity and functions as a clearinghouse for HTA results. CCOHTA works in cooperation with provincial HTA agencies in Canada to minimise duplication with other national and provincial organisations.

United Kingdom

The National Institute for Health and Clinical Excellence (NICE) was established to appraise new healthcare technologies of importance to the National Health Service in England and Wales. Although HTA activities continue to be undertaken by health authorities and other organisations, there is reduced need for these bodies to appraise technologies that are referred to NICE. The broad range of medical technologies examined by NICE may avoid the coordination issues that arise from multiple agencies evaluating combined technologies.

New Zealand

The approach recommended by the National Health Committee in New Zealand is to promote robust decision-making processes for new health interventions throughout the health sector. It has indicated that, while the appropriate level for most decisions is considered to be the local or regional level, some collaborative and national processes also are needed. As such it has recommended that a national forum be established for decisions about emerging or high profile technologies.

Sources: appendix C; NHC (2005); Sanders (2002).

FINDING 8.2

Australia's HTA effort is fragmented along jurisdictional (national and State/Territory) and sectoral (public and private) lines. Complexity and duplication also reflects ad hoc development of HTA in reaction to technological advances and the budgetary pressures they have brought. This has led to apparently inefficient duplication of HTA effort and fragmented diffusion of knowledge and experience, creating unnecessary additional costs and delays.

While recognising the need for some flexibility in the application of HTA at the State/Territory and individual institutional level, there is potential for a more coordinated approach to assessing and sharing information about new technologies. A system-wide review looking at overlaps and opportunities for greater efficiency would seem to have merit. There would appear to be significant benefits available from adopting an over-arching framework for coordinating HTA activities at a national level.

HTA and health funding arrangements

The fragmentation of HTA effort stems primarily from the funding and administrative arrangements for health services in Australia, in particular, the current Federal–State division of responsibilities. The Commission (PC 2005b) has highlighted problems arising from the current intergovernmental division of responsibilities for key health services in its recent review of National Competition Policy reforms.

Some participants also claimed that the division of Federal–State responsibilities in the health area has impeded the effectiveness of HTA. The Australian Diagnostic Industry Association stated that:

An unhelpful 'funding silos' mentality and compartmentalised responsibilities within and across jurisdictions including within and across Commonwealth, State and Territory jurisdictions continue to preclude effective evaluations of health care services and costs. (sub. 12, p. 4)

Most HTA committees operating in Australia are aligned with areas of government expenditure responsibility. This has the potential to lead to rigidities which may prevent resources shifting to their most effective use. The OECD (2005a) noted that in many countries (including Australia), drug budgets are separate from hospital budgets and there is little opportunity to transfer resources across budgets to fund gains in patient health and overall efficiency. Budgetary systems also tend to focus on short-term expenditure impacts rather than the longer-term benefits that may result from cost-effective health spending.

Another issue arises if HTA is undertaken by bodies that are also responsible for expenditure on the assessed technologies. For example, pharmaceutical HTA is often undertaken by organisations that are also responsible for expenditure on the assessed technologies (such as public hospitals, and health departments at the State/Territory and Australian Government level). Medicines Australia (2002) argued that there is a lack of separation and independence of the PBS-listing process from the policy and budgetary functions of DoHA. It also claimed that the Pharmaceutical Evaluation Section, at least in part, carries out the statutory function of PBAC:

The Pharmaceutical Evaluation Section (PES), the Secretariats for the Economics Subcommittee, the PBAC and PBPA are all located in the Pharmaceutical Benefits Branch, which also has policy and budgetary responsibilities. (Medicines Australia 2002, p. 43)

There is a risk with HTA being carried out by bodies that are also responsible for expenditure on the assessed technologies that the HTA process will be influenced by short-term fiscal imperatives. This may occur if these organisations face incentives to meet a budget objective, rather than an objective of fostering optimal use of technology. There may then be an incentive to give less weight to patient benefits, future cost savings or savings elsewhere in the healthcare system than the immediate objective of containing current expenditures. Thus current institutional arrangements have the potential to blur the boundary between evidence-based assessment of what is in the community's best interests and shorter-term budgetary management.

FINDING 8.3

Where HTA is undertaken by organisations that also have expenditure responsibilities, this may lead to tensions between different objectives: that is, between facilitating optimal use of medical technology and controlling health expenditure.

Transparency

There have been ongoing concerns about the transparency and accountability of HTA mechanisms for pharmaceuticals and other medical technologies. A key issue with respect to pharmaceuticals is the level of disclosure by ADEC and PBAC relating to their recommendations to accept or reject drugs for listing on the ARTG and PBS respectively, the reasons for these recommendations, and the data upon which recommendations are based.

In assessing new drugs, the TGA and PBAC rely on a substantial amount of data provided by pharmaceutical companies or sponsors. This information is generally

supplied on a commercial-in-confidence basis because companies want to safeguard their intellectual property and competitive advantage from rivals. Another reason for confidentiality may be to allow the medical investigators who produced the data the opportunity to publish their findings in medical and scientific journals. The incentive to publish would be weakened if the data were released into the public domain during the assessment process. Aside from the content of submissions, the very fact that a sponsor has made a submission to PBAC is confidential information.

While the TGA and PBAC generally do not disclose clinical or cost-effectiveness data, some information is published regarding their recommendations. However, the level of disclosure is poor compared to the requirements of other regulatory processes in Australia, and overseas — such as the Food and Drug Administration (FDA) in the United States. Emeritus Professor Mervyn Eadie, former chairman of ADEC, has stated:

Unlike the situation which applies for regulatory bodies in certain overseas countries, virtually none of the information held by the TGA is currently made available publicly. Much of it will never appear in the medical literature. The cost-effectiveness data considered by the [PBAC], when recommending that a drug be listed on the [PBS], are also secret. (Eadie 2002, p. 78)

The TGA publishes ADEC's positive recommendations on its website and in the Commonwealth of Australia *Gazette*. However, the published information is very limited. The recommendations identify the generic name, trade name, method of delivery and type of application (new chemical entity, new indication, new dosage form, new strength, or change in patient group). The statements do not outline the reasons for recommendations or refer to any data, nor do they identify rejected applications. In contrast, the FDA posts a range of documentation for many approved drugs on its website.⁷

Although DoHA previously published only positive PBAC recommendations, since 2003 it has published all PBAC recommendations on its website. The information identifies the drug and its form, the drug use and type, the proposed listing or request, and a brief description of the PBAC outcome. While this is an improvement on previous practice, the statements only provide summary information on PBAC's recommendations. DoHA (sub. PR56) claimed that the reason for limited disclosure is that sponsors require material in submissions to PBAC to be treated as commercial-in-confidence.

⁷ The documentation may include approval letters, printed labels, medical reviews, chemistry reviews, pharmacology reviews, and correspondence between the FDA and applicants.

Aside from improving public scrutiny of the PBS-listing process, the disclosure of relevant clinical and economic information may have additional benefits. According to the Australian Medical Association, this information would help medical practitioners improve patient management and outcomes (Glasson 2004). Moreover, such data could inform prescriber and consumer education campaigns and allow these programs to be coordinated with the listing of new drugs (Harvey 2002).

Greater disclosure by PBAC is expected to result from the Free Trade Agreement signed by Australia and the United States in 2004. The Australian Government has agreed that:

- details of PBAC recommendations will be made available to the public in a timely manner following each PBAC meeting;
- a Public Summary Document will be generated to provide to the public information pertaining to PBAC recommendations; and
- the information will include sufficient clinical, economic and utilisation data to enable stakeholders to understand submissions to PBAC and PBAC's view of those submissions (Abbott 2005a).

Provided that these measures are implemented appropriately, this should improve public understanding and discussion of PBAC's recommendations as well as enhancing accountability. The new process will be reviewed 12 months after implementation to examine whether the objectives of transparency and accountability are being met.

MSAC (2003) considers that it provides transparency by following a standard evaluation cycle in consultation with stakeholders (including applicants and DoHA officials). MSAC publishes a range of information, including:

- lists of medical procedures submitted for assessment;
- final assessment reports and associated summaries;
- brief minutes from its meetings; and
- performance information in annual reports.

Even though such information is made available, there have been criticisms about the transparency of the MSAC process arising from the assessment of Positron Emission Tomography:

Despite claims that the MSAC process is "open and transparent", all committee meetings were conducted in camera, and the minutes published on the DoHA website are an incomplete summary of the full minutes obtained under the Freedom of Information Act. (Ware et al. 2004, p. 628)

MSAC is more transparent than the PBAC in terms of the public release of information. In contrast to PBAC, MSAC lists on its website the medical procedures that have been submitted for assessment, enabling interested parties to identify items on MSAC's work program. MSAC publishes its final assessment reports which generally detail the approach taken to the assessment as well as the results, conclusions and recommendations. To make HTA results more accessible to the community, some participants argued that there is a need to prepare report summaries in clear, plain language.

However, like PBAC, MSAC tends to release information only when the assessment process has been completed and the Minister has made a decision. As noted below, MSAC draft assessment reports are not released for public comment.

FINDING 8.4

The level of information disclosure by the TGA and PBAC regarding drug evaluations generally has been poor compared with some processes overseas and accepted good regulatory practice. Improved disclosure by PBAC is expected to result from new arrangements under the Australia–United States Free Trade Agreement.

While MSAC is somewhat more transparent than PBAC, MSAC tends to disclose information only when the assessment process has been completed.

FINDING 8.5

A stated intent of restrictions on PBS-listed items is to improve cost effectiveness based on clinical grounds. However, as the deliberations of PBAC are not public, it is difficult to determine whether it has imposed restrictions on certain drugs purely for fiscal reasons.

Consultation

Consultation occurs between sponsors and the TGA during the market registration process mainly to clarify issues and requirements. However, the Commission understands that there currently is no consumer representative appointed to ADEC, one of the TGA's advisory bodies. For MDEC, the TGA's other key advisory body, there is a regulatory requirement for consumer involvement. In July 2006, a new Trans Tasman Therapeutic Products Agency will become operational to replace the separate functions of the Australian TGA and its New Zealand counterpart (Pyne 2005b). Its advisory committees are expected to include consumer representatives.

Consultation also occurs between sponsors and PBAC as part of the PBS-listing process. Medicines Australia (2002) noted that there had been a number of improvements to the consultation process, including the offer by PBAC to allow for more written responses by sponsors in all steps of the evaluation process. Consumer involvement in the PBS-listing process occurs primarily through membership of PBAC. Apart from medical professionals and health economists, PBAC includes at least one consumer representative as required by the National Health Act. This model of consumer participation — with or without statutory backing — has been adopted by Australian national advisory committees for other medical technologies. For example, MSAC's advisory panels generally include consumer representatives even though there is no regulatory requirement to do so.

An important issue facing consumer representatives on advisory committees is the extent to which they are permitted to consult with external parties. In the case of PBAC, the National Health Act requires that members must not disclose any confidential information. Numerous participants told the Commission that these confidentiality requirements hamper the ability of consumer representatives to consult with other consumer and patient groups.

Although PBAC receives input from its consumer representative, the drug evaluation process generally involves little wider consultation. As reported by the National Centre for Social and Economic Modelling (NATSEM, sub. 1), PBAC accords a high priority to industry and expert consultation but there is limited public consultation. Dr Jeff Brownscombe (sub. PR55) supported the need for greater consumer consultation. The National Association of People Living with HIV/AIDS (sub. PR58) also observed that, within the drug approvals system, there is no real capacity for consumer groups to provide direct evidence or advice on the relative value of new technologies.

Similarly, the MSAC consultation process is largely confined to applicants and DoHA officials. While consumer representatives participate on MSAC advisory panels, they may be constrained in consulting with other consumers by confidentiality requirements. Bright noted that:

On many occasions, consumer representatives on Medical Services Advisory Committee (MSAC) supporting committees have raised issues about the confidentiality requirements associated with the subject matter and work of these committees. (Bright 2003, p. 25)

It would seem that a major gap in the MSAC process is the lack of consultation with patient/carer groups or the broader public. During the assessment process, MSAC does not invite public comment from groups in the community who may have an interest in the technologies being evaluated. Moreover, draft assessment reports, which include MSAC's interim views on new procedures, are not published.

Advisory committees play a significant role in HTA processes in some other countries. In the United States, consumer and patient representatives have served on FDA advisory committees for many years (appendix C). And, in the United Kingdom, the National Institute for Health and Clinical Excellence (NICE 2004b and c) has developed a process of targeted consultation. Professor Karen Facey noted that:

NICE ... strove to achieve transparency and create dialogue and participation of all stakeholders including professionals, patients and industry throughout the HTA process. (sub. 39, p. 4)

NICE invites submissions from all patient and/or carer groups involved in the appraisal (appendix C). Medicines Australia (sub. PR62) commented that consumers also can participate in NICE processes through the Patient and Public Involvement Unit and the Citizens Council. This extent of consultation may be easier because NICE does not make explicit recommendations regarding the funding or pricing of new technologies.

There are several possible reasons for limiting consultation to sponsors and experts. As noted above, sponsors may be reluctant to release certain scientific and commercial information into the public domain. The designers of the process may have considered that, given the technical nature of clinical and economic evaluations, there was little to be gained from broader consultation. Public consultation would also consume more time and resources, so limitations may have been imposed to keep the process more manageable and timely.

That said, public consultation is a feature of good regulatory design and is used for other regulatory processes both in Australia and overseas, such as those in the infrastructure industries of electricity, gas and water. As part of these processes, public comment may be invited on draft reports, guidelines, decisions and determinations. The regulators of these industries also receive commercially-sensitive information that is used to develop regulatory frameworks.

While an appropriate form of public consultation would add to time and administrative costs, it is likely to yield useful information including the importance or value of particular medical services to the community. The benefits of public consultation, such as community acceptance of new technologies, have also been noted by the OECD (2005a, p. 65), which said that ‘many OECD countries have started to recognise the importance of including patient or citizen values in decision making’.

Unlike some overseas HTA processes, Australian drug approval processes — including ADEC and PBAC — currently provide little opportunity for consultation with patient groups or the general public. ADEC also lacks a consumer representative.

The MSAC assessment process, like the PBAC process, allows little opportunity for consultation with patient groups or the general public.

Combined technologies

As most HTA processes in Australia are delineated by technology type, the evaluation of combined technologies is likely to involve more than one HTA body. However, this can result in coordination difficulties, confusion and delays in assessing a new technology, as appears to have happened with drug eluting stents (DES) — a drug-device combination (box 8.4). The new listing arrangements for prostheses seek to clarify whether a new device requires MSAC assessment.

Another class of combined technologies is diagnostic-treatment combinations.⁸ The diagnostic and treatment components respectively may involve the use of drugs, devices, equipment or clinical procedures. Several participants expressed concerns that the components of these technologies are not being assessed for subsidy in an integrated manner. Failure to consider all components of diagnostic-treatment combinations can create inconsistencies that impede access to cost-effective technologies.

An example of a diagnostic-therapy combination is that of *trastuzumab* (Herceptin) and associated diagnostic tests (appendix I). As discussed in appendix I, the apparent lack of coordination between the subsidy program for Herceptin and subsidies for the diagnostic tests to establish patient suitability is problematic given the importance of targeting such an expensive drug. The separation of the tests from the subsidy program may reflect different institutional processes governing decisions about subsidies for drugs and pathology. The latter are generally the responsibility of committees related to MSAC, whereas drugs are the concern of PBAC.

⁸ Diagnostic tools may be used to identify medical conditions as well as monitor the progress of patients during and after treatment.

Box 8.4 HTA chronology of the drug eluting stent (DES)

The Cypher DES which elutes *sirolimus* (Rapamune) onto the surface of the coronary artery initially achieved listing on the ARTG in 2000-01. However, the TGA indicated that deficiencies in the TGA's risk classification system at that time resulted in the sub-optimal pre-market assessment of many clinically important devices, which would encompass DES.

Subsequent changes to the Therapeutic Goods Regulations 1990 permitted a more detailed assessment of DES. The Cypher DES was registered on the ARTG in June 2002 following an evaluation of pharmaceutical chemistry, toxicology, clinical data, engineering and biomaterials data by the Drug Safety Evaluation Branch and the Office of Devices, Blood and Tissues.

DES also created challenges in the sequencing of HTA assessment. Normally, safety assessment must be completed before an item may be listed for reimbursement purposes. However, the Cypher DES was added to Schedule 5 (the Prostheses Schedule under the National Health Act) in February 2002 before it was unconditionally approved by the TGA. *Sirolimus* had previously been approved for a different indication — the prevention of organ rejection for kidney transplant patients. PBAC did not assess *sirolimus* specifically for the prevention of restenosis prior to DES being listed on the Prostheses Schedule.

- | | |
|----------------------|--|
| 2000-01 | <ul style="list-style-type: none">• Cypher DES listed as a non-current entry on ARTG.• <i>Sirolimus</i> added to ARTG. |
| February 2002 | <ul style="list-style-type: none">• Cypher DES listed on Prostheses Schedule.• MSAC completes horizon scanning report on DES. |
| June 2002 | <ul style="list-style-type: none">• Cypher DES listed as a registered device on ARTG following change in Therapeutic Goods Regulations 1990. |
| June 2003 | <ul style="list-style-type: none">• Taxus DES registered on ARTG. |
| February 2003 | <ul style="list-style-type: none">• MSAC receives first reference to assess DES. |
| August 2003 | <ul style="list-style-type: none">• Taxus DES listed on Prostheses Schedule. |
| December 2003 | <ul style="list-style-type: none">• MSAC receives second reference to assess DES (subsuming the first reference). |
| April 2005 | <ul style="list-style-type: none">• MSAC publishes final assessment report on DES. |

Additional information about DES is provided in appendix H.

Sources: appendix H; DoHA (sub. PR56); MSAC (2005); TGA (pers. comm., 4 February 2005).

A further example of diagnostic-treatment combinations is that of bone mineral density testing and *alendronate sodium* (Fosamax) (box 8.5). Dr Enku Kebede-Francis (sub. 33) argued that both components should be subsidised to help prevent osteoporosis and bone fractures.

Box 8.5 Diagnostic-treatment combinations: bone mineral density testing and Fosamax

Fosamax belongs to the *bisphosphonates*: a class of drugs used to treat osteoporosis and Paget's disease of the bone. Fosamax is currently available under the PBS only to people that have had a fracture attributable to osteoporosis. However, it has been suggested that these drugs could provide greater benefit if taken by people at risk, prior to sustaining an injury. Dr Enku Kebede-Francis claimed 'in this case, prevention is better than cure' (sub. 33, p. 1).

The Australian Fracture Prevention Summit recommended that patients found to be high risk (women over 50 with a sufficiently low bone density) have subsidised access to *bisphosphonates* (Ebeling et al. 2002). The Summit also recommended wider availability of MBS rebates for bone mineral density (BMD) tests to identify those at high risk of a fracture.

In 2003, Merck Sharpe Dohme submitted an application to PBAC to make Fosamax available to patients that have not had a fracture but who meet age and BMD criteria. Although PBAC claimed in its recommendation that 'the principle of combining age and baseline mineral density is a welcome step forward' (PBAC 2003, p. 2), it rejected the application on the basis that it is difficult to identify the patients most likely to benefit and consequently its cost effectiveness is uncertain.

Osteoporosis Australia has lodged an application with MSAC to have the BMD tests subsidised by Medicare, however, their decision has been deferred.

While PBAC, MSAC and the PDC define which technologies they cover, these definitions may be too broad to determine which agency should undertake the evaluation of combination technologies. Where there is ambiguity or where there are strong linkages between technologies, there is a need for existing HTA committees to work together on assessments to avoid duplication. The Commission was told that communication between PBAC and MSAC has improved in recent times. Further, some HTA committees are seeking to create more clarity; for instance, the PDC secretariat recently prepared a checklist for determining whether a device should be assessed by MSAC (DoHA 2004f). DoHA (sub. PR56) noted that guidelines are currently being developed to identify when combined technologies should be considered by PBAC or MSAC.

It is possible that the distinction between pharmaceuticals and medical devices will blur even further in the future (chapter 11). For example, pharmacogenetics is likely

to increase linkages between diagnostics and therapies. If technology convergence continues, HTA agencies and committees will face an increasing number of ambiguous cases. The Australian Healthcare Association (sub. 25) noted that new medical technologies in the development pipeline will warrant closer coordination between HTA bodies.

FINDING 8.7

As different HTA agencies and committees examine particular types of medical technology, conducting effective HTA of combined technologies (such as new drug/device combinations and targeted therapies combining diagnosis and treatment) can pose challenges and lead to delays. With greater technology convergence expected in future, coordination difficulties and delays are likely to be magnified.

Clinical advice and guidelines

At a national level, the NHMRC develops guidelines that aim to translate clinical research into practice. The NHMRC noted that:

[It's] role in this process is to peer evaluate the most current knowledge and present it in more accessible forms such as guidelines and advice. (sub. 36, p. 5)

The Health Advisory Committee of the NHMRC manages and coordinates the development of health advice in various forms including clinical practice guidelines and public health guidelines in areas such as health procedures, health promotion and infection control. The NHMRC also encourages the development of evidence-based guidelines by expert bodies. These externally-developed guidelines must meet NHMRC requirements and standards in order to be approved (NHMRC 2005).

In the case of pharmaceuticals, the Australian Government established the National Prescribing Service (NPS) in 1998 to promote quality use of medicines. Among its key functions, the NPS aims to improve the quality of prescribing by health professionals by providing accurate, reliable and timely information on medicines. For example, the NPS regularly publishes the *Australian Prescriber*, which provides educational information about drugs and therapeutics. It also provides decision support through the provision of information at the point of decision making (NPS 2003).

At the State level, some advisory committees have prepared clinical advice and guidelines for drugs used in hospitals. For example, the Western Australian Drug and Therapeutics Committee commented on the use of Cox-2 inhibitors (*celecoxib* and *rofecoxib*). The advice included information on toxicity, efficacy and cost

effectiveness. The New South Wales Therapeutic Advisory Group has produced a number of guidelines for general practitioners.

Some States also have developed policies to guide the use of new procedures or prostheses in their public hospital systems. For example, the VDHS (sub. 24) noted that, for the first time in Victoria, an explicit policy has been adopted for the use of stents in coronary angioplasty. Moreover, a key role of VPACT (see above) is to advise and make recommendations on the dissemination of information on the introduction and use of new and existing technologies and clinical practices.

However, some participants saw a greater role for clinical guidelines to facilitate the appropriate use of new medical technologies. Commenting on the use of prostheses in the private sector, the Australian Health Service Alliance stated that:

... it is extremely difficult to control usage without clear clinical practice guidelines being available. Health funds have seen a significant increase in the use of technology due to clinical changes in prostheses use. (sub. 14, p. 1)

Despite national and State efforts, the development of clinical guidelines in Australia does not appear to be sufficiently linked to HTA processes. As the VDHS (sub. 24) noted, a gap in HTA arrangements is the lack of a systematic process to translate information from technology assessment into practice guidance. Some participants pointed to NICE in the United Kingdom as an example where formulation of clinical guidelines is an integral part of the HTA process. It is also important that guidelines are prepared in a form that is both understandable and accessible to users.

FINDING 8.8

There appears to be no systematic national process for the development of clinical practice guidelines linked to HTA processes and cost-effectiveness assessment.

8.5 Summary

Australia is considered a world leader with regard to HTA. Nonetheless, the Commission has identified some potential areas for improvement. HTA processes are complex and fragmented, reflecting overlapping responsibilities of different levels of government and different processes for different types of medical technologies. This has led to poor coordination and duplication of some HTA activities.

The ‘silo’ approach that characterises existing HTA arrangements may impede the efficient assessment of emerging technologies, such as targeted therapies and

drug-device combinations. Moreover, some key HTA processes lack transparency in decision making and allow little opportunity for community consultation. Enhanced transparency and consultation could promote public acceptance of decisions and allay concerns that HTA is simply being used to control spending.

The Commission sees scope for a more systematic and coordinated approach to HTA and clinical guideline development across the public and private sectors and across levels of government — while recognising the need for some flexibility in the application of HTA at the individual State/Territory and institutional level.

The following two chapters raise some other issues specific to HTA of different categories of technology.

9 Health technology assessment: pharmaceuticals

This chapter examines key elements of existing mechanisms and processes for the health technology assessment (HTA) of pharmaceuticals and potential gaps in these processes, as required by the terms of reference. It discusses issues related to particular categories of pharmaceuticals (section 9.1), methodological issues (section 9.2), procedural issues (section 9.3) and post-assessment processes (section 9.4). HTA processes regarding medical procedures, devices and information and communications technology (ICT) are discussed in chapter 10.

9.1 Assessment processes

As discussed in chapter 8, the HTA process for pharmaceuticals in Australia is long established, with safety and efficacy assessment dating back more than 40 years. Economic assessment of pharmaceuticals, introduced in 1993, is a more recent requirement of the HTA process.

The Victorian Department of Human Services (VDHS, sub. 24) noted that Australia is recognised as a leader in using HTA to inform funding decisions. And, according to the Centre for Health Economics Research and Evaluation (CHERE):

... [Australia's] reputation as a world leader in the production and use of evidence to influence supply and uptake rests on two Australian Government policy processes; namely PBAC [Pharmaceutical Benefits Advisory Committee] and MSAC [Medical Services Advisory Committee]. (sub. 9, p. 7)

Similarly, GlaxoSmithKline Australia (sub. 21) referred to Australian health authorities as international leaders in the adoption and adaptation of cost-effectiveness analysis techniques in the assessment of new medicines. However, participants also pointed to a number of potential gaps or deficiencies in current HTA mechanisms and processes relating to:

- hospital medicines;
- targeted therapies;
- vaccines; and

- complementary medicines.

These issues are discussed in turn below.

Hospital medicines

Use of pharmaceuticals by public patients in public hospitals is generally funded by State and Territory Governments. Public hospitals spent around \$919 million on pharmaceuticals in 2002-03, representing about 15 per cent of total government expenditure on medicines (chapter 8). The Australian Government also funds some highly specialised drugs issued by public hospitals to outpatients, admitted patients on discharge and day patients.¹

However, while most drugs used in public hospitals have to be approved by the Therapeutic Goods Administration (TGA),² many of these drugs are not listed on the Pharmaceutical Benefits Scheme (PBS). For example, the official formulary for drugs approved for use in Queensland public hospitals and institutions includes a large number of non-PBS pharmaceuticals (Queensland Health 2004). Similarly, around half of the high-cost drugs (such as oncology and immunosuppressive agents) approved for use in many Victorian public hospitals are listed on neither the PBS nor under section 100 of the *National Health Act 1953* (Cwlth) (table 9.1).

Table 9.1 **High-cost pharmaceuticals, Victorian public hospitals, 2003-04^a**

	<i>Pharmaceuticals</i>	
	no.	%
PBS ^b	35	47.3
non-PBS	39	52.7
Total	74	100.0

^a High-cost pharmaceuticals are defined as those with an acquisition cost of greater than \$1000 per treatment episode. ^b Includes drugs provided under section 100 of the *National Health Act 1953*. The Minister may make special arrangements for providing pharmaceuticals to people who live in isolated areas or who cannot conveniently or efficiently be provided with the required pharmaceuticals.

Source: VicTag (2004).

¹ Under the Australian Healthcare Agreements, the Australian Government, the States and Territories are reforming the supply of pharmaceuticals to patients in public hospitals. The reforms involve extending the PBS to admitted patients on discharge and outpatients, and to provide access to chemotherapy drugs for day patients of public hospitals (HIC 2004).

² The TGA (2004a) may allow access to unapproved medicines (that is, not included on the Australian Register of Therapeutic Goods — ARTG) under a number of mechanisms including: clinical trials (also generally requiring the approval of the TGA and ethics committees), the Special Access Scheme, Authorised Prescribers and importation for personal use provisions.

That many hospital drugs are not listed on the PBS may indicate that they have never been assessed by the Pharmaceutical Benefits Advisory Committee (PBAC) for clinical or cost effectiveness. For drugs designed primarily for hospital use, pharmaceutical companies may have little incentive to make submissions to PBAC because the PBS subsidy does not generally apply in the hospital context. It is also possible that PBAC has assessed some of these drugs but did not recommend them for listing.

As PBAC generally assesses drugs that will be dispensed outside of hospital systems, this has led some States and hospitals to establish their own drug advisory committees — resulting in duplication of HTA effort within and across States (chapter 8).

FINDING 9.1

PBAC does not assess all medicines used in hospital settings for clinical and cost effectiveness. This has led to duplication of HTA effort across and within States.

Targeted therapies

Many participants argued that new targeted drug therapies are likely to present significant challenges for the PBS-listing process. GlaxoSmithKline Australia (sub. 21) claimed that the PBS will come under increasing pressure to fund new innovative, targeted therapies for the prevention and treatment of previously unmanageable diseases. This issue also has been recognised by members of PBAC (Sansom 2004).

New targeted therapies differ from conventional drugs listed on the PBS in that they are designed for use in a discrete well-defined group of patients who have specific biological markers. Several such drugs have been listed on the PBS in recent years, including:

- *imatinib* (Glivec) for use in the accelerated and blast phases of chronic myeloid leukaemia; and
- *gefitinib* (Iressa) for the treatment of non-small cell carcinoma of the lung in particular patients.

Although these new therapies are targeted at relatively small numbers of patients, they tend to be very expensive. For example, Glivec costs more than \$45 000 per patient per year and Iressa costs more than \$50 000 per patient per year (Hall et al. 2005). As the number of targeted therapies is anticipated to increase in the future, some participants, including the National Centre for Social and Economic

Modelling (NATSEM, sub. 1) argued that alternative evaluation and funding approaches are needed.

PBAC's general approach to assessing targeted therapies is to identify those patient subgroups for whom the drug is most cost effective compared to the standard alternative treatment. Patient groups may be defined by molecular markers of disease severity, underlying disease mechanism or treatment prognosis (Hall et al. 2005). In recommending a drug for PBS listing, PBAC may include restrictions and conditions in order to target specific groups of patients. PBAC recently has used a new approach to enable the listing of new biological agents for managing rheumatoid arthritis.

Vaccines

The HTA process for evaluating vaccines is less developed than that for pharmaceuticals, with the Australian Technical Advisory Group on Immunisation (ATAGI) only being established in the late 1990s (chapter 8). One of its main functions is to examine the cost effectiveness of new vaccines. In making recommendations on vaccine listing and funding to the Minister, ATAGI takes into account safety and efficacy, cost effectiveness as well as other factors such as the preventable burden of the disease targeted by the vaccine (Burgess 2004).

Some participants pointed to challenges associated with evaluating and funding the new generation of vaccines. The Department of Health and Ageing (DoHA, sub. 34) argued that future funding decisions regarding vaccines are likely to become progressively more difficult, observing the trend towards purchasing increasingly expensive vaccines. Unlike older vaccines, which target common diseases and tend to be lower cost, newer vaccines are targeted at individuals with rarer conditions such as meningococcal C.

This concern, among other reasons, may have led to the recently announced changes in ATAGI's advisory role. While ATAGI will have an ongoing role in providing evidence-based advice on the medical administration of vaccines, from 2006 PBAC will assume responsibility for evaluating the cost effectiveness of new vaccines. According to DoHA (2005d), this change is intended to provide a more consistent and transparent process for recommending vaccines for federal funding.

Complementary medicines

Some participants contended that complementary medicines are not adequately assessed for effectiveness. For example, Dr Michael Loughnan stated that:

There appears to be an insatiable appetite for alternative medicine treatments, even when the evidence is lacking and the client bears all costs. (sub. 10, p. 1)

These therapies may include herbal medicines, vitamin and mineral supplements, nutritional supplements, traditional Chinese medicines, homoeopathic medicines and aromatherapy oils.

Complementary medicines are generally not subjected to the same level of evaluation for safety and efficacy as prescription pharmaceuticals. Most complementary medicines are listed products (chapter 8) on the Australian Register of Therapeutic Goods (ARTG) because they are considered to have a low risk of producing adverse effects. These medicines are not routinely evaluated before listing, but must conform with the requirements of the Therapeutic Goods Regulations 1990. Only a very small number of complementary medicines are registered products on the ARTG (chapter 8). To be registered products, the TGA must be satisfied that the specific claims of efficacy in treatment or prevention of disease are supported by adequate evidence (McEwen 2004).

Following the recall in April 2003 of more than 1600 complementary medicines manufactured by Pan Pharmaceuticals Limited, the Australian Government established the Expert Committee on Complementary Medicines in the Health System (ECCMHS 2003). The Committee found that while the two-tiered (registered and listed products), risk-based regulatory system was generally sufficient and relevant to meet appropriate standards of quality, safety and efficacy for complementary medicines, some enhancements were required to reinforce regulatory controls for listed complementary products and to improve transparency. The Committee noted that:

... consumers may not be aware that listed medicines have not been evaluated by the national regulator for efficacy before their supply. ... there is an ethical responsibility on government to ensure that consumers are informed about this difference between listed and registered complementary medicines. (ECCMHS 2003, p. 16)

To be a candidate for PBS subsidy, a complementary medicine must be a registered rather than a listed product. DoHA (sub. PR56) noted that, if PBS listing is being sought, complementary medicines would be subject to the same evidentiary requirements that PBAC applies when evaluating prescription medicines.

Despite the widespread use of complementary medicines,³ there is significantly less evidence available on their clinical or cost effectiveness than that for prescription pharmaceuticals. Some researchers have identified a need for more evidence on the effectiveness of natural remedies (Bensoussan and Lewith 2004; Pirotta et al. 2000). However, there is little incentive for companies to fund clinical trials for these remedies partly because the primary ingredients are often readily available substances that are not protected by patents.

9.2 Methodological issues

The Commission's analysis and participants' comments identified potential deficiencies in the methodology of HTA processes in Australia in the following areas which predominantly relate to clinical and cost-effectiveness requirements:

- type of clinical evaluation;
- choice of comparator;
- outcome indicators;
- form of economic evaluation;
- indirect benefits;
- discounting;
- cost-effectiveness thresholds; and
- targeting.

Type of clinical evaluation

The PBAC Guidelines state a strong preference for economic evaluations based on 'head-to-head' randomised trials (DoHA 2002b). This type of trial directly compares therapy involving the proposed drug with therapy involving an appropriate main comparator. The Guidelines specifically indicate that PBAC will accept and give consideration to other forms of evidence where no head-to-head trials are available.

However, some participants expressed concern that given this preference for randomised clinical trials, little weight may be given to other forms of studies. For instance, Medicines Australia (sub. 30) claimed that PBAC discounts other study

³ In 2000, it was estimated that 52 per cent of Australians used at least one non-medically prescribed complementary medicine and that 23 per cent consulted at least one complementary healthcare practitioner (ECCMHS 2003).

designs that might be more appropriate than randomised clinical trials for the clinical outcome of interest. Some study designs other than randomised clinical trials include non-randomised controlled trials, cohort studies, case control studies and case series (box 9.1).

Box 9.1 Study designs

Clinical trial: a study that tests a drug or other therapy to assess its safety, efficacy and/or effectiveness by comparing one or more intervention groups with one or more control groups. Clinical trials encompass randomised trials and controlled clinical trials. While all randomised trials are controlled, not all controlled trials are randomised.

Cohort study: a study in which a defined group of people (the cohort) is followed over time and outcomes are compared in subsets of the cohort who were exposed or not exposed, or exposed at different levels to an intervention or other factor of interest.

Case control study: a study in which the past history of exposure to a factor of interest (such as a particular therapy) is compared between cases (who have the outcome or disease) and controls (who resemble the cases but do not have the outcome or disease).

Case series: a study which reports the results of the use of a particular intervention in a series of patients. A case report is the description of a single clinical case.

Sources: DoHA (2003c); Mowatt et al. (1997).

While there is no absolute requirement to submit clinical trial evidence, most sponsors endeavour to provide such evidence. About 86 per cent of the submissions made to PBAC up to the late 1990s were based on randomised clinical trials and, of these submissions, around one-quarter included the results of meta-analyses⁴ (Henry and Hill 1999).

Randomised clinical trials are generally considered to be the ‘gold standard’ in objective evidence. The National Health and Medical Research Council (NHMRC) has ranked different types of clinical evaluation by the strength of evidence each approach generates (table 9.2) — although these levels of evidence are under review. Similar standards of evidence have been developed in other countries (Agency for Healthcare Research and Quality 2002; Gray 1997; US Preventive Services Task Force 1989).

⁴ Meta-analysis is the systematic, organised and structured evaluation of a problem of interest using information from relevant randomised clinical trials. It includes qualitative and quantitative components (DoHA 2003c).

Table 9.2 NHMRC levels of evidence^a

<i>Level</i>	<i>Type of evidence</i>
I	A systematic review of all relevant randomised controlled trials.
II	At least one properly designed randomised controlled trial.
III-1	Well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Comparative studies with concurrent controls and allocation not randomised (cohort studies), case control studies, or interrupted time series with a control group.
III-3	Comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
IV	Case series, either post-test or pre-test and post-test.

^a The levels of evidence are currently under review.

Source: NHMRC (1999).

The level of evidence relates to the study design, or method used to compile evidence from more than one study (such as meta-analysis). Randomised clinical trials are ranked as providing the strongest form of evidence (Levels I and II) whereas comparative studies or case series are considered weaker forms of evidence (Levels III-2, III-3 and IV). This is principally because clinical trials are less likely to be affected by bias or systematic error than most other study designs.

However, some health experts argue that there is undue emphasis on conducting clinical trials. For example, Professor Hall argued that the notion that evaluation requires controlled trials has distracted from the use of observational data and ignored useful developments in other fields (PC and Melbourne Institute of Applied Economic and Social Research 2002).

Clinical trials have some limitations. As patients in trials have been selected using specific criteria, it may be difficult to generalise the results to the whole patient subpopulation with the ailment under examination. For instance, drug trials often exclude people who have comorbidities (that is, two or more diseases) but, if these comorbidities are relatively common, such exclusion criteria may significantly limit the generalisability of the trial outcomes (Seale et al. 2004).

Moreover, clinical trials often do not provide evidence on ‘soft’ benefits such as convenience and compliance (that is, the extent to which patients adhere to the prescribed course of treatment). For example:

... while compliance with the various statins ... ranged from 90% to 94% during the course of the trials, analyses of administrative databases in Canada and the United States revealed that only half of statin-treated patients were still taking their medication 1 year after it was prescribed. (McAlister et al. 1999, p. 1376)

Compliance also has been an issue with antidepressants. As noted in appendix G, compliance can be improved with the simpler dosing regimes of selective serotonin reuptake inhibitors.

Clinical trials can be quite costly to run. The Director of the NHMRC Clinical Trials Centre noted that the cost of a randomised clinical trial which evaluates a moderate treatment effect on important clinical outcomes may range from \$1 million to more than \$50 million (Simes 2002). Large-scale trials that involve several thousand people being monitored for 4–6 years typically cost around \$20–50 million (McNeil et al. 2003).

As pointed out by McNeil (1998), study designs other than randomised clinical trials are more prone to bias or systematic error. That said, such studies might provide useful evidence on benefits (such as convenience and levels of compliance) in ordinary treatment settings.

Choice of comparator

In preparing a submission for PBAC, a critical decision facing the sponsor is choosing a comparator (that is, an existing therapy that will be compared to the new drug). The PBAC Guidelines recognise that selection of the main comparator can be difficult (DoHA 2002b). The main comparator is required to be the existing therapy (drug or non-drug) that the new drug is likely to replace. In practice, the comparator is usually the PBS-listed drug for the same indication that is prescribed for the largest number of patients.

However, some participants contended that the PBAC Guidelines unduly limit the choice of comparator. Medicines Australia (sub. 30) stated that disagreement with PBAC over the choice of comparator is one of the major reasons cited by industry for unsuccessful or delayed PBS submissions. Of concern to industry is that by following the PBAC Guidelines, this often results in the selection of a cheaper generic drug⁵ as the main comparator. This drug may have been on the PBS for many years and, being out of patent, has been subject to competition which drives its price towards marginal cost of production. Companies claim that newer drugs are disadvantaged in cost-effectiveness assessments because they tend to be higher cost relative to these generic comparators.

However, it seems entirely reasonable that selection of an appropriate comparator should be based on the clinical context in which the new drug will be used. In this

⁵ Generic drugs are bioequivalent copies of original drugs that are out of patent.

context, the age, patent status or price are not the relevant criteria for selecting a comparator. DoHA noted that:

The PBAC guidelines have less to do with generic or cheaper alternative comparators but more to do with the clinical decision making framework relating to how the drug and its comparator are likely to be used. (sub. PR56, p. 6)

The US Panel on Cost Effectiveness in Health and Medicine pointed out that, as a rule and as a minimum, studies should compare the intervention to existing practice addressing the health problem (Gold et al. 1996). In the case of pharmaceuticals, this generally would be the current standard or most common drug treatment for the same indication. That said, where there are several close substitutes to the new drug, there may be a case for selecting more than one comparator. This is permitted by the PBAC Guidelines (DoHA 2002b).

Price determination

Although HTA information is used for reimbursement purposes, price determination is not strictly speaking part of the HTA process. PBAC listing recommendations are forwarded to the Pharmaceutical Benefits Pricing Authority (PBPA) for price-setting purposes. The PBPA is a non-statutory body with the objective of securing a reliable supply of pharmaceutical benefits at the most reasonable cost to Australian taxpayers and consumers. It comprises representatives from the pharmaceutical industry, consumer groups and government officials. In considering the price of items, the PBPA considers PBAC advice on clinical and cost effectiveness, the price of alternative brands and drugs in the same therapeutic class, cost data and a range of other factors. DoHA (sub. 34) uses PBPA recommendations to negotiate prices with manufacturers.

The PBPA uses a number of mechanisms to contain the price of products listed on the PBS. These include the therapeutic group premium policy, brand premium policy, weighted average monthly treatment costs and price–volume agreements. The PBPA also conducts annual reviews of the prices of all items on the PBS and manufacturers often request pricing reviews as a result of new clinical data becoming available (DoHA, sub. 34).

Reference pricing

Some participants claimed that the therapeutic group premium policy (which is one form of reference pricing) is suppressing drug prices with potentially adverse consequences for future drug research and development. Medicines Australia (sub. 30) argued that, under this policy, generic drug price reductions are driving price reductions for similar ‘in-patent’ medicines post listing.

Under reference pricing, the Australian Government pays a subsidy equal to the lowest priced drug (the reference price) in the relevant group of drugs. That is, for drugs considered by PBAC to be no worse in terms of safety and efficacy, the lowest price drug or brand sets the benchmark price for other brands of that drug or other drugs of similar safety and efficacy. There are currently around 100 reference priced groups of drugs on the PBS (DoHA, sub. PR56).

Pharmaceutical companies are permitted to set prices above the reference price under the therapeutic group premium and/or brand premium policies, but patients must pay the premium as well as the PBS co-payment. In practice, most drugs are priced at the reference price or have a relatively small price premium (Birkett et al. 2001).

Price–volume agreements

Price–volume agreements are used by the PBPA to manage risk where there is potential for high volume sales, uncertainty over future usage, or concern about the drug being used outside the approved indications for PBS subsidy. Under these arrangements, the agreed price of a drug is based on a forecast volume of sales. If actual sales volumes exceed the forecast, the price applying to the unanticipated usage is revised downwards, often to the price of the drug that the new agent replaces.

Outcome indicators

Final health outcomes are typically measured in terms of mortality rates, life-years saved or quality-adjusted life-years (QALYs) (chapter 5). In clinical trials, it is common to use surrogate indicators because final health outcomes usually cannot be determined during the trial and would require tracking the progress of patients post trial. However, there is uncertainty in extrapolating from surrogate indicators to final health outcomes.

In adopting a surrogate indicator, a key area of uncertainty is the assumption made about the benefits of a drug beyond the end of the clinical trial. For some conditions, the relationship between the surrogate and final outcomes has been well investigated by clinical research. Medicines Australia (sub. 30) argued that numerous studies in the cardiovascular field have demonstrated the link between surrogate indicators, such as cholesterol and blood pressure levels, with long-term morbidity and mortality rates.

For other conditions, the strength of the relationship between surrogate indicators and final health outcomes may be less certain. For instance, recent clinical trials of

medical treatments for pulmonary arterial hypertension have used various surrogate indicators as the primary outcomes of interest. Many trials have used exercise-related measurements, such as the six-minute walk test, as the primary end point. But Hoeper et al. (2004) noted that this test has not been validated as a surrogate indicator in patients with less severe disease.

Although the PBAC Guidelines (DoHA 2002b) encourage sponsors to consider which outcome indicators are most appropriate, some participants claimed that PBAC prefers final outcome measures. NATSEM stated that in the case of *trastuzumab* (Herceptin) which treats metastatic breast cancer:

... survival was measured from the clinical trials. However, it appeared that the PBAC wanted (empirical) data on survival over a longer-term timeframe but, as the drug was essentially still in development, such long term 'hard' data wasn't available. (sub. 1, p. 27)

Medicines Australia (sub. 30) also noted that large clinical studies with long-term final outcomes data are rarely complete at the time of PBS listing. As a result, surrogate indicators often are used in clinical trials for some disease areas.

According to DoHA (sub. PR56), PBAC does take surrogate indicators into consideration but these indicators should be validated where feasible. This is consistent with recommended scientific practice. Bucher et al. (1999) noted that a surrogate outcome will be reliable only if there is a validated causal connection between change in the surrogate and change in the clinically important outcome, and if the surrogate fully captures all of the effects of treatment on that outcome.

Verifying the link between surrogate and final outcomes in many cases requires further clinical research and data collection. Possible approaches include extending the duration of clinical trials, conducting follow-up studies, using overseas studies, and establishing disease registers to obtain data on longer-term outcomes.

FINDING 9.2

While validation of surrogate indicators is clearly important, it can add to the costs and duration of the HTA process with the potential to delay the introduction of some beneficial drugs. Where drugs hold significant promise of being cost effective, they could be listed on the PBS on the condition that special post-market monitoring of cost effectiveness be undertaken over a defined period.

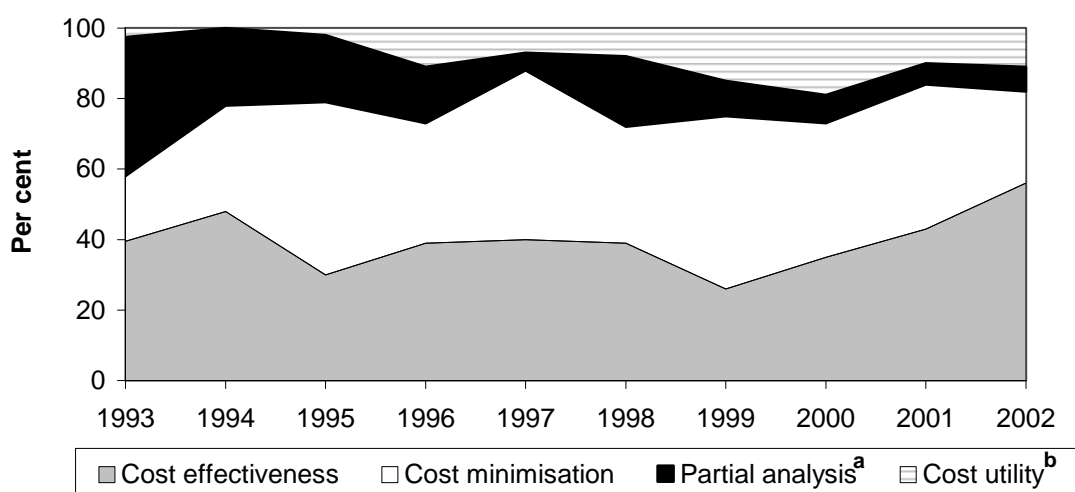
Type of economic evaluation

Various methods of economic evaluation are used in HTA under different circumstances. The key methods include cost-minimisation analysis,

cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis. While PBAC Guidelines indicate when a particular form of economic evaluation may be appropriate (DoHA 2002b), the sponsor decides which type of evaluation will be used in a submission.

Most submissions to PBAC have used cost-minimisation or cost-effectiveness analyses (figure 9.1). The cost-minimisation approach applies where the proposed drug is regarded as no worse than the comparator in terms of effectiveness and toxicity. This means that the drug is unlikely to be granted a higher price than the comparator. The cost-effectiveness or cost-utility approach may apply when the proposed drug is regarded as having significant clinical advantages over the comparator. In this case, the increase in benefits must be quantified and weighed against any increase in costs (DoHA 2002b).

Figure 9.1 Type of evaluation in submissions to PBAC, 1993 to 2002



^a Partial or qualitative analyses are where a price advantage is usually being sought on the basis of incomplete data. ^b Cost-utility analysis compares therapy involving the proposed drug with therapy involving its main comparator in which costs are measured in monetary terms and outcomes are measured in terms of extension of life and the utility value of that extension (such as quality-adjusted life-years).

Data sources: DoHA (pers. comm., 18 February 2005); DoHA (2003c).

Sponsors' use of cost-minimisation analysis may be associated with the development of 'me-too'⁶ and generic drugs. According to Lofgren (2002), many 'me-too' products considered by PBAC since 1993 have been listed on the basis of cost minimisation. Since 1999, the proportion of submissions using cost-effectiveness analysis has increased. This trend suggests that sponsors consider their newer products to have significant clinical advantages.

⁶ 'Me-too' drugs are modified versions of existing drugs which produce the same or similar effects as existing drugs.

However, the PBAC Guidelines do not encourage sponsors to use cost–benefit analysis (DoHA 2002b). This stance appears to be based on PBAC’s concerns about the difficulties of valuing health outcomes and its lack of confidence in claims about indirect costs and benefits.

Indirect benefits

Drug treatments, in addition to providing clinical benefits, may generate indirect benefits such as cost savings elsewhere in the healthcare system. New pharmaceuticals may reduce the need for surgery and hospitalisation, possibly leading to budgetary savings or freeing up capacity to treat more patients. By returning patients to good health and extending their lives, drugs can increase the effective labour supply and potentially overall production. As noted in appendix B, there are different ways of allowing for these effects.

Hospital savings

The PBAC Guidelines permit economic evaluations to consider any changes in the use of resources that are likely to result from a drug’s introduction. These may include altered use of other drugs, medical and other related social services. The Guidelines also request sponsors to estimate separately the financial impacts of a new drug for ‘government health budgets’, including savings in medical costs met by the Australian Government or State Governments from fewer competing procedures (DoHA 2002b, p. 43).

Despite the Guidelines allowing the inclusion of some indirect impacts, the pharmaceutical industry is concerned that cost offsets — such as reduced hospital costs and carers’ costs — are not given sufficient weight by PBAC (Medicines Australia, sub. 30). Such statements were disputed by DoHA (sub. PR56) which claimed that PBAC does consider reduced hospital costs in its assessment of economic benefits.

As PBAC deliberations are confidential, it is not possible to determine directly the weight that is placed on sponsors’ estimates of hospital savings. That said, the extent to which PBAC considers such savings is believed to depend largely on several factors:

- whether it accepts the rationale for including such benefits;
- its assessment of the reliability of the financial estimates prepared by sponsors; and
- the analytical perspective that it adopts.

Some participants claimed that the use of some new drugs does not result in financial savings in the hospital system that can be returned to government for other uses. For example, Professor Karen Facey asserted that:

... money is spent to gain additional benefit for the patient or health care savings (fewer bed days) but the latter are not realised because resources are used elsewhere. (sub. 39, p. 1)

However, where new pharmaceuticals have freed up resources in public hospitals, these resources can be used to treat more patients. Thus, an absence of realised financial savings in hospital budgets does not equate to an absence of benefits.

In submissions to PBAC, sponsors generally use modelling techniques to estimate hospital savings. There are significant challenges in producing precise and reliable estimates of these effects. Such estimates are often based on quantitative modelling which uses incomplete datasets and numerous assumptions, opening the scope for a wide range of estimates. Partly because of the uncertainty surrounding modelling results, PBAC may give little weight to this evidence.

Nonetheless, offsetting savings are an important element of the overall cost impact of many new pharmaceuticals (chapter 4), and such impacts should — as far as possible — be taken into account. Indeed, a societal perspective would see PBAC consider the impacts of a new drug throughout the economy. It is not clear whether PBAC adopts such a perspective in its deliberations.

Gains in productive capacity

The Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32) contended that PBAC does not generally allow indirect benefits (such as avoiding productivity losses) in its consideration of submissions. Similarly, Wyeth Australia (sub. PR57) argued that the benefits of innovative pharmaceuticals would be even more substantial if indirect impacts outside the healthcare sector (for example, productivity) were considered.

Although sponsors can incorporate anticipated changes in productive capacity in a separate analysis, it appears that PBAC gives little or no weight to this type of benefit. The PBAC Guidelines state that:

... [cost–benefit analysis] often relies heavily on calculations of indirect costs and benefits, principally changes in production capacity. Such analyses are not likely to be helpful to PBAC in its deliberations. (DoHA 2002b, p. 66)

More specifically, the Guidelines do not encourage sponsors to treat changes in productive capacity as an outcome of drug therapy. This is based principally on the view — as stated in the Guidelines — that absence from work due to illness can be

covered by excess capacity in the workforce or by drawing on the pool of unemployed.

However, this is not a robust argument for discounting gains in productive capacity. The ability to return to work constitutes a benefit for individuals and hence society, although economic evaluations would need to avoid double counting such benefits. As noted in chapter 5 and appendix B, several methods have been developed to incorporate gains in an individual's productive capacity in economic evaluations but there remain unresolved issues about the extent to which quality of life measures capture these impacts. That said, quality of life measures do not take into account broader impacts such as carer's costs or the impact on other workers (chapter 5).

FINDING 9.3

The extent to which PBAC takes into account potential indirect benefits of medicines, such as hospital or aged care cost savings or the ability of patients to return to work, is unclear. While a lack of hard and relevant data and methodological issues complicate measurement of these impacts, discounting them on the grounds that unrealised savings should not be counted (because freed up hospital beds are used for other patients), or that any individual can be withdrawn from and replaced in the workforce without cost, is misconceived.

Discounting

The PBAC Guidelines require that sponsors estimate the present value of future costs and health outcomes of a new pharmaceutical, using a real discount rate of 5 per cent per annum (DoHA 2002b). As PBAC will evaluate new vaccines for cost effectiveness from 2006, Wyeth Australia (sub. PR57) expressed concern that discounting has the effect of reducing cost-effectiveness estimates for preventative programs (such as vaccination) where the costs are borne upfront and the benefits are distributed over many years. It suggested that a separate discount rate be applied to economic evaluations of vaccines.

The choice of discount rate is an issue of ongoing debate in the area of economic evaluation. As discussed in appendix B, there are different theoretical bases for selecting a discount rate. This has created difficulties for analysts in reaching agreement on what is the most appropriate rate for healthcare interventions in general — let alone for particular types of medical technologies.

There is no single standard rate applied in practice. As noted in appendix B, a survey of healthcare evaluations in the United States, United Kingdom and Canada found that base real discount rates varied between 0 and 7 per cent with the most commonly used being 0, 3 and 5 per cent. The US Panel on Cost Effectiveness in

Health and Medicine recommended that 3 per cent be used as the appropriate real discount rate, but also recommended analysis using 5 per cent as many previous studies have used that rate. Moreover, the US Panel recommended sensitivity analysis for rates between 0 and 7 per cent (appendix B).

FINDING 9.4

Where the choice of discount rate heavily influences the results of an economic evaluation, there is a strong argument (accepted in several other countries) for considering sensitivity analysis using a range of discount rates. This analysis would be in addition to the base case using the discount rate recommended by PBAC.

Cost-effectiveness thresholds

Medicines Australia (2002) argued that PBAC should publicly articulate its threshold for an acceptable cost-effectiveness ratio and outline its reasons for setting this threshold. NATSEM stated that:

It is widely accepted that the PBAC works on a cost-effectiveness ratio of \$40–50,000 per quality life year gained. This compares unfavourably to cost-effectiveness ratios used overseas, although it has to be recognised that the thresholds for assessing cost effectiveness as a basis for accepting or rejecting an application for government funding are highly controversial. (sub. 1, p. 29)

There has been some analysis of the cost-effectiveness data contained in submissions to PBAC. George et al. (2001) examined submissions made to PBAC between January 1991 and June 1996, compiling ‘league tables’ using cost per life-year gained and cost per QALY gained. Although cost per life-year gained varied substantially among recommended submissions, PBAC tended to reject submissions at higher levels of cost per life-year gained (table 9.3).

George et al. (2001) did not find an explicit threshold beyond which PBAC was unwilling to recommend listing. But they did find levels at which, between 1992 and 1996, PBAC appeared unlikely to recommend a drug for listing (if the additional cost per life-year gained exceeded \$76 000) and unlikely to reject a drug (if the additional cost per life-year gained was less than \$42 000).⁷ DoHA (sub. PR56) indicated that PBAC does not have a single threshold it considers to be an ‘acceptable’ cost-effectiveness ratio.

⁷ In 1998-99 prices.

Table 9.3 Summary analysis of cost-effectiveness ratios, selected submissions to PBAC, 1991 to 1996

	<i>Submissions recommended</i>	<i>Submissions rejected</i>
Mean ^a	\$46 321	\$110 239
Median	\$26 800	\$76 284
Range	\$5517 to \$229 064	\$42 697 to \$256 950
Coefficient of variation ^b	114.7	77.4

^a Both means are higher than the medians owing to several submissions with very high cost per life-year gained. There is a statistically significant difference between the means at the five per cent level. ^b Standard deviation divided by the mean expressed in percentage terms.

Source: George et al. (2001).

There are arguments for and against articulating a threshold. It could be argued that publishing a threshold may clarify requirements (that are currently implicit) and provide guidance to drug companies in preparing submissions. According to Medicines Australia (2002), it is unclear what PBAC considers is an acceptable incremental cost-effectiveness ratio.

While it might be possible to set a cost-effectiveness threshold, there may be significant uncertainty around this point estimate. Sansom (2004) noted that this uncertainty is often related to the clinical data, or reflected in the sensitivity of the economic modelling results. Dr Thomas Faunce (sub. PR60) argued that requiring PBAC to publish cost-effectiveness thresholds would create a false and distorting certainty for subsequent applicants.

Moreover, PBAC examines factors other than cost effectiveness. As DoHA (sub. PR56) noted, PBAC considers a number of dimensions not all of which are quantitative in nature, such as:

- severity of the condition treated;
- presence of effective alternatives;
- ability to target therapy to those likely to benefit most;
- equity;
- comparative cost effectiveness;
- comparative health gain; and
- affordability to the individual and the healthcare system.

That said, it seems plausible that concern about the factors that PBAC takes into account when making its decisions could be alleviated by improving the

transparency of the process and greater disclosure of cost-effectiveness data and assumptions regarding their recommendations in individual circumstances.

Targeting

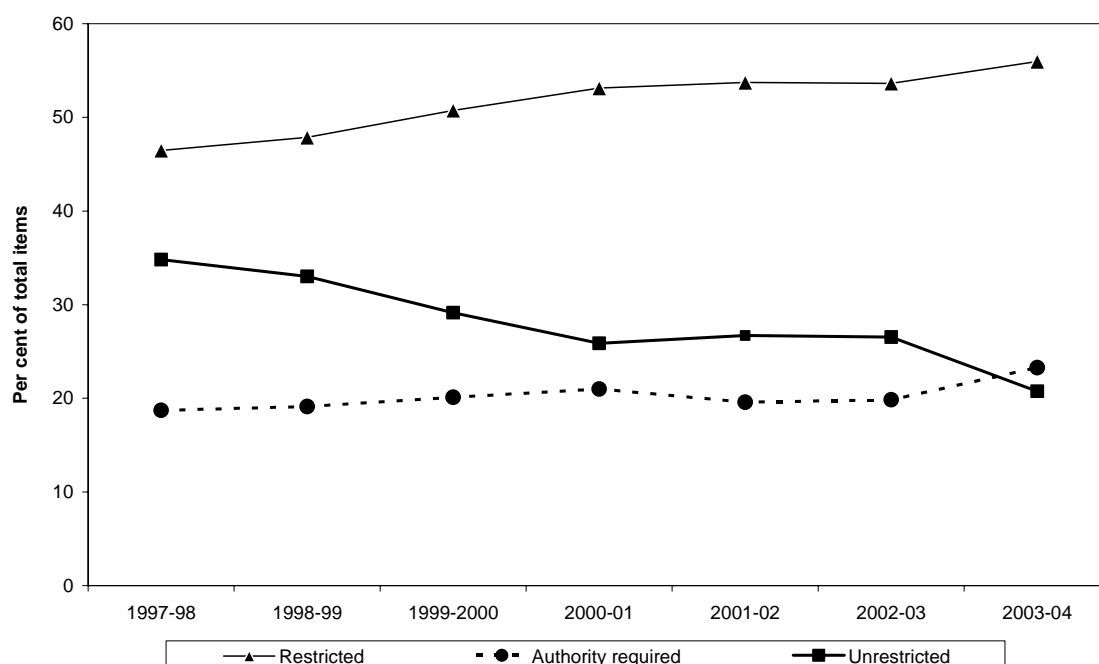
It is rare that a treatment can be shown to be clinically and cost effective for an entire population of patients (Centre for Health Economics, sub. 2). This indicates that some form of targeting may often be required.

PBAC targets patient groups by imposing restrictions on the use of a drug. A restricted drug will only be subsidised for a particular condition or purpose, whereas an unrestricted drug is subsidised for the entire range of TGA registered indications. For drugs requiring authorisation, medical practitioners must obtain prior approval from the Health Insurance Commission (HIC) before pharmacists can dispense them. Restricted and authority-required items together accounted for around 80 per cent of the items available on the PBS in 2003-04 (figure 9.2).

According to Sansom (2004), the PBAC will recommend listing a drug as a restricted benefit if the drug is deemed to be cost effective only in a limited number of the registered TGA indications. Examples of restricted benefits include *fentanyl* patches (an analgesic that treats severe pain) and *azithromycin* (an antibiotic that treats a range of infections). There are also qualifying criteria that patients must meet before lipid-lowering drugs (statins) can be prescribed under the PBS (appendix F). PBAC may place restrictions on drugs for reasons other than cost effectiveness; in the case of *azithromycin* the restricted listing also was sought to minimise the risk of the development of resistant common pathogens (Sansom 2004).

Some participants contended that these restrictions are aimed at managing the cost of the PBS program rather than cost effectiveness. Medicines Australia (sub. 30) claimed that the Australian Government had introduced a range of measures to control PBS spending including, among other things, restricted listings. Similarly, NATSEM (sub. 1) argued that the authority-required mechanism is used for cost containment purposes by limiting use to fewer patients.

Figure 9.2 PBS items, by type of restriction, 1997-98 to 2003-04



Data sources: HIC (2004; 2003; 2002; 2001b; 2000; 1999; 1998).

Restricted listings have increased as a proportion of total items listed on the PBS (figure 9.2). At the same time, unrestricted listings have declined from 35 per cent of total items in 1997-98 to 21 per cent in 2003-04. Some participants also pointed out that restrictions have become more detailed and complex. For example, the authority-required restrictions for *pioglitazone hydrochloride* which is used to treat type 2 diabetes are one page in length (DoHA 2004i). In the case of *etanercept* (Enbrel) which is used to treat several conditions including rheumatoid arthritis, clinicians are required to complete, in their own handwriting, an eight-page form for evaluation by the HIC before the prescription can be written.

9.3 Procedural issues

A number of procedural issues are discussed below, including:

- timeliness;
- administrative and compliance costs;
- mutual recognition processes;
- appeals processes; and
- Cabinet approval processes.

Timeliness

While timely access to medicines for consumers and the community is an objective of the National Medicines Policy (DoHA 1999), there are claims that some assessment processes are slow. For instance, ACT Health (sub. 11) pointed to substantial lags between approval of new high-cost drugs by the TGA and approval for the PBS.

Some participants expressed concern that the re-introduction of the 17-week meeting cycle has reduced the number of PBAC meetings from four to three a year. Consequently, if a submission is rejected, there is reduced opportunity to make a re-submission later in the year. NATSEM (sub. 1, p. 31) reported that if ‘you missed one meeting then there could be significant delays’ before a submission receives PBAC consideration.

Other participants pointed to variability in processing time. According to NATSEM (sub. 1), application for PBS listing can take from a few months to several years. Wyeth Australia (sub. PR57) noted that, for some new biological agents, the time taken from TGA approval to PBS listing has varied considerably; for instance, *adalimumab* (Humira) took only seven months whereas *etanercept* (Enbrel) took 40 months.

Undue delays in approval processes can impose costs on various parties:

- processing delays may withhold the clinical benefits of new drugs from patients who may be suffering pain and discomfort and whose condition could deteriorate while waiting for drugs to be approved. The Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32) claimed that current delays in approving drugs were creating potentially avoidable but significant problems in terms of patient outcomes;
- pharmaceutical companies forego revenue; and
- State and Territory Governments and private health insurers may have to carry the costs of providing some drugs while submissions await PBAC consideration. (This may be a possible reason, among others, for the evaluation of some drugs by State-based advisory bodies or health funds (chapter 8)).

The TGA reported that, in the past decade, all drug submissions have been processed within the relevant statutory time limits (table 9.4). According to DoHA, all major submissions to PBAC (lodged by the due date) have been considered at the subsequent PBAC meeting; that is, within the same meeting cycle (DoHA, pers. comm., 9 April 2005). For some drugs recommended by PBAC, it may take more than one cycle before they are listed on the PBS.

Table 9.4 Statutory processing times for drug evaluations by the TGA

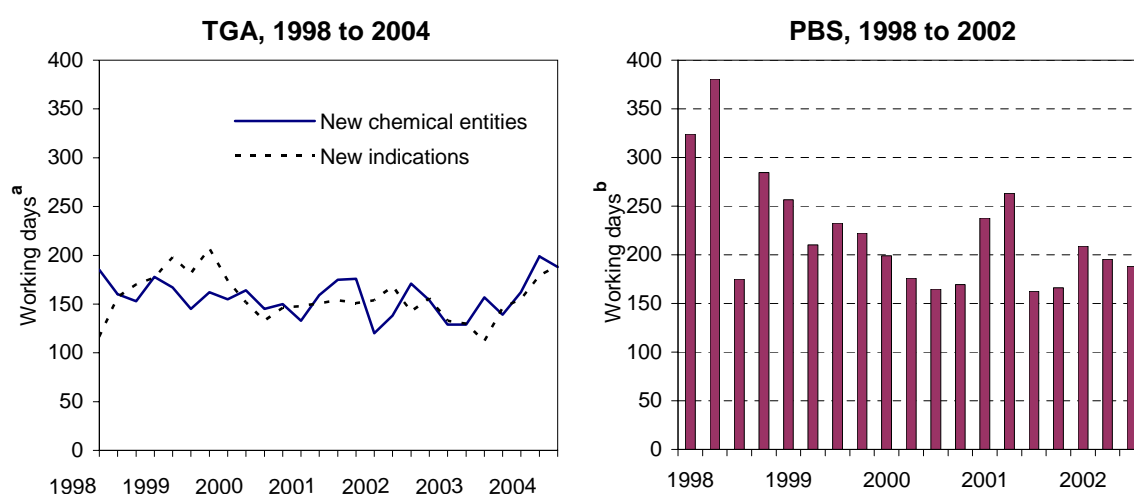
Category	Description	Statutory time limit
		Working days ^a
1	Applications for new chemical entities, new dosage forms, new strengths, new indications and new generics.	255
2	Applications that have been previously approved in two acceptable countries. ^b	175
3	Applications involving changes to the quality data ^c of medicines already on the ARTG.	45

^a From date of acceptance of Category 1 or 2 applications. For Category 3 applications, from date of receipt of application or payment of evaluation fee (whichever is the later day). ^b Acceptable countries include Canada, Sweden, the Netherlands, United Kingdom and United States. ^c Quality changes may include, for example, changes in specifications of the active ingredient, method or site of manufacture of the active ingredient, shelf life, storage conditions and packaging as well as minor changes in formulation.

Source: TGA (2004c).

The time taken for new drugs to pass through the HTA process is a partial indicator of the efficiency of the process and is relevant to the objective of timely access to medicines. In recent years, the average time taken by the TGA to finalise applications for new chemical entities and new indications (prescription medicines) has fluctuated around 160 working days, mostly within the range of 100–200 working days (figure 9.3).

Figure 9.3 Average time taken to process drug submissions



^a The time taken between TGA acceptance of an application and the subsequent decision, measured in average working days, does not include the time taken by an applicant or sponsor in responding to a TGA request for more information. ^b The time taken, measured in average working days, between initial lodgement of a major submission and eventual listing on the PBS.

Data sources: DoHA (pers. comm., 9 April 2005); TGA (pers. comm., 23 May 2005).

Over the period 1998–2002, there has been much greater variability in the average time taken to process major submissions to PBAC, ranging from 160 to 380 working days. As the time between lodgement of a major submission and its consideration by PBAC is fixed within the meeting cycle, the observed variability may largely reflect the time consumed by post-PBAC processes including pricing negotiations and Ministerial approval. That said, there was a significant reduction in PBS processing times during 1999 and 2000.

Administrative and compliance costs

Apart from the costs associated with undue delays, HTA processes impose administrative costs on government as well as compliance costs on sponsors.

It is difficult to derive a precise estimate of the Australian Government financial contribution towards pharmaceutical HTA activities, because financial information published by DoHA does not differentiate HTA from other activities, nor does it separate HTA for drugs from that for other technologies (DoHA 2005d and 2004g). In its submission, DoHA (sub. PR56) reported that the cost associated with PBS-listing processes and activities was \$13 million in 2003-04. It is not known how much State and Territory Governments spend on HTA activities.

The Commission received limited quantitative information on the compliance costs incurred by the pharmaceutical industry. Regarding safety assessment, in 2003-04 the TGA received around \$41 million in user charges from the drug industry for evaluation services and annual charges to maintain listings on the ARTG (TGA, pers. comm., 23 May 2005). Regarding the PBS-listing process, Medicines Australia (sub. 30) claimed that HTA requirements are costly in terms of conducting specific trials in Australia to collect data and in terms of the highly skilled staff needed to analyse and model trial data and prepare submissions.

The introduction of fees in 2007-08 to have submissions considered by PBAC will add to compliance costs. The intention is to implement cost recovery for the administration of the PBAC and the PBS-listing process (DoHA 2005d). Common concerns about cost recovery by regulatory agencies are that it may weaken their independence and create perverse financial incentives such as regulatory creep and cost padding. In its report on cost recovery by government agencies, the Commission has argued that cost recovery arrangements can promote economic efficiency, provided they are appropriate and well-designed (PC 2001b). The key design principles recommended by the Commission were that agencies should consult with industry and incorporate measures that ensure transparency and accountability.

Mutual recognition

Under current arrangements, the TGA may consider applications for drugs that have been previously approved in two acceptable countries. These are known as Category 2 applications. The Minister has identified acceptable countries, for the purposes of providing evaluation reports, to include Canada,⁸ Sweden, the Netherlands, the United Kingdom and the United States (TGA 2004b). The benefit to sponsors and patients is that Category 2 applications are subject to a considerably shorter statutory evaluation time than Category 1 applications (table 9.4).

However, few Category 2 applications have been submitted in recent years. In the five years to 2003-04, there were only three Category 2 submissions compared with approximately 1700 Category 1 submissions (table 9.5). In addition, none of the Category 2 applications was approved. A possible explanation for the limited use of mutual recognition is that pharmaceutical companies may simultaneously submit applications to regulatory authorities in all markets around the world where they wish to sell their products, rather than taking a sequential approach, that is, obtaining approval in one country before making applications in other countries.

Table 9.5 New submissions of prescription medicines to the TGA^a
1999-00 to 2003-04

	<i>Category 1</i>	<i>Category 2</i>	<i>Category 3</i>
	No.	No.	No.
1999-00	362	0	839
2000-01	402	0	858
2001-02	323	0	783
2002-03	336	0	886
2003-04	254	3	1039

^a A submission may contain more than one application (product) and more than one application (product) type. See table 9.4 for definitions of Category 1, 2 and 3 applications.

Source: TGA (pers. comm., 23 May 2005).

While applications to the TGA may be supported by clinical trials comparing a new drug with a placebo, submissions to PBAC must compare a new drug with an existing standard treatment (drug or therapy) either directly or by using studies with a common reference.

⁸ Australia signed a Mutual Recognition Agreement (MRA) with Canada in 2005 that will enable both countries to accept each other's Good Manufacturing Practice (GMP) audits and inspections of the makers of prescription and over the counter medicines (Pyne 2005a). Australia also signed separate MRAs on GMP with the European Community and European Free Trade Association in 1999 (DoHA, sub. PR56).

According to the PBAC Guidelines, there is no expectation that companies will carry out head-to-head trials in Australia solely for the purpose of evaluation for submission to PBAC (DoHA 2002b). The Guidelines indicate that randomised trials conducted overseas of sufficient rigour are an acceptable basis for preparing an economic evaluation. Sponsors may need to adjust for differences in patient characteristics and clinical settings to make overseas results relevant to the Australian context.

Medicines Australia argued that conducting specific trials in Australia creates additional costs and delays in preparing submissions for PBAC:

... worldwide trials have become common and larger countries' requirements will always dominate over unique Australian requirements. It is therefore unrealistic to expect head-to-head randomised controlled data against a comparator appropriate for Australia for all medicines submitted for PBS listing. (sub. 30, p. 24)

There are significant challenges in transferring the results of pharmacoeconomic evaluations across countries. There are numerous sources of variation to consider when adapting an overseas economic assessment to another country's healthcare settings. The more obvious differences include unit costs and the prevalence and severity of a disease. Health policy settings, current medical practices and skill levels and resource usage patterns, which can differ greatly across countries, also need to be taken into account. The OECD (2005a) has suggested several strategies to facilitate the transfer of evidence between countries. Increased international collaboration also may assist this process (Dickson et al. 2003).

FINDING 9.5

Although mutual recognition has the potential to fast-track drug approval by the TGA, there has been limited use of these processes. While transferring pharmacoeconomic evaluations across countries is likely to be difficult, there are strategies available to facilitate the transfer of clinical evidence.

The appropriate use of overseas clinical studies potentially could generate resource savings and accelerate the preparation of submissions to the TGA and PBAC.

Appeals

TGA decisions regarding drug submissions are appealable to the Administrative Appeals Tribunal (AAT). Appeals can be initiated on the grounds that all relevant information was not considered. The AAT is an independent tribunal that reviews, on the merits, a broad range of decisions made by the Australian Government, including its Ministers, departments and agencies. The AAT decides whether the

correct, or preferable, decision has been made in accordance with the applicable law. It may affirm, vary or set aside the original decision.

The PBAC recommendation process, rather than the recommendation itself, is appealable in the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977* (Cwlth). For example, there were appeals to the Federal Court following PBAC not recommending the listing of *sildenafil* (Viagra) on the PBS, and PBAC recommending changes to the manner in which Zyban is supplied under the PBS (DoHA 2003b).

A new review mechanism for PBAC recommendations is being implemented under the Free Trade Agreement signed by Australia and the United States in 2004. This mechanism will be available to sponsors whose submissions have not resulted in a listing recommendation by PBAC. Under the proposed arrangements, a convenor will be appointed to manage the review function. The convenor appoints a reviewer selected from a panel of identified experts (including medical specialists, clinical trial experts, health economists, clinical pharmacologists and bio-statisticians).

In conducting the review, the reviewer will have access to all the information placed before PBAC by the applicant, as well as the details of PBAC's recommendations and the reports of PBAC's sub-committees. However, no new information is to be provided to the reviewer. The outcomes of the review will be published following the same principles that will apply to the PBAC process under the new transparency arrangements (Abbott 2005a) (chapter 8).

Cabinet approval process

Since 2002, the Australian Government has required consideration by Cabinet of high cost drugs before listing, that is, drugs that are expected to cost more than \$10 million in any of the first five years of listing.

Medicines Australia contended that this threshold, and other requirements, were introduced due to government concerns over the rapid growth in PBS expenditure following the listing of *celecoxib* (Celebrex) and *bupropion hydrochloride* (Zyban) (sub. 30). Some industry participants claimed that the \$10 million threshold may create further bottlenecks in the listing process in the future.

The recent *Review of Post-PBAC Processes* undertaken jointly by DoHA and Medicines Australia (2004) noted that the listing process is complex. For drugs requiring Cabinet approval, submissions must be prepared which involve detailed costing, clearances by senior executives in DoHA and agreement with central agencies. It also requires decisions by the Prime Minister and Cabinet Office about

the timing for consideration by Cabinet. The *Post-PBAC Review* recommended that the Pharmaceutical Benefits Branch streamline the process for preparing Cabinet submissions (DoHA and Medicines Australia 2004).

In response to concern about transparency of the Cabinet submission process, the review recommended a strategy for improving industry understanding of the process and communicating the status of DoHA submissions where appropriate. It also recommended steps to clarify the roles, responsibilities and accountability of the PBPA and the Pharmaceutical Benefits Branch within DoHA.

However, the *Post-PBAC Review* did not address the issue of the \$10 million threshold. It is not known whether the threshold is fixed indefinitely or will be adjusted periodically by the Government. If it is fixed in nominal terms, there is no allowance for inflation. This means that, if new drug prices and expected utilisation continue to rise (and assuming the number of submissions to PBAC does not fall), it is likely that a larger number of pharmaceuticals will require Cabinet approval. This has the potential to delay patient access to treatment, as well as postponing company revenue streams and deferring the financial impact on the PBS.

Another issue is the public funding of some medical technologies which HTA committees have not considered to be cost effective. NSW Health (sub. 20) pointed to the potential for formal HTA processes to be bypassed. A recent example is the case of the anti-cancer drug Herceptin. Although PBAC recommended against listing Herceptin on several occasions, the Australian Government subsequently established a separate program to provide the drug free of charge to eligible patients with late stage metastatic breast cancer (appendix I). The concern with approaches that seek to bypass existing HTA processes is that they may lead to a proliferation of different programs with varying levels of technology assessment, monitoring and review. This could result in anomalies across programs, additional administrative costs as well as undermining the effectiveness of major programs such as the PBS.

FINDING 9.6

The use of a fixed dollar threshold that is not periodically adjusted for the effects of inflation, is likely to see a greater number of drugs being considered by Cabinet, possibly creating delays in the PBS-listing process and limiting transparency of decision making.

FINDING 9.7

A major risk with governments at times bypassing existing HTA processes is that it may lead to a proliferation of different programs which could result in funding inconsistencies, additional administrative costs, and limit transparency of decision making.

9.4 Post-assessment processes

Once medicines have been approved for use in Australia, there are mechanisms at the national and State/Territory levels for monitoring and reviewing their safety and use.

Monitoring

As discussed in chapter 8, a key function of the HTA process is to monitor the diffusion of new and existing drugs. Monitoring may indicate when a more detailed review is needed and, in some cases, re-assessments of drugs occur, although on an *ad hoc* rather than systematic basis. The functions of the main agencies at the national and State levels involved in monitoring drug safety, use and expenditure are discussed below.

National advisory committees

In the area of safety and efficacy, the TGA conducts monitoring to ensure compliance with legislation, investigates reported problems and undertakes post-market testing on products. There were approximately 27 000 medicines on the ARTG at 30 June 2004 (TGA, pers. comm., 23 May 2005). Within the TGA, the Adverse Drug Reactions Advisory Committee (ADRAC) is responsible for monitoring ongoing drug safety in the post-marketing phase. ADRAC operates a voluntary reporting scheme, which encourages medical professionals to notify the committee of any adverse reactions to drugs (DoHA 2003a).

In the area of drug diffusion, the Drug Utilisation Sub-Committee (DUSC) of PBAC provides advice on estimates of use contained in submissions, collects and analyses post-listing data on drug utilisation, and makes international comparisons of drug utilisation (Sansom 2004). A key task of DUSC is to examine the utilisation of drugs or therapeutic groups of drugs, including those showing large changes in utilisation rates. Actual use often differs from that predicted in submissions. Based on unpublished data from DUSC, Birkett et al. (2001) found that use predicted in submissions to PBAC has been greatly underestimated for about one-third of submissions and greatly overestimated for about one-third.

There is ongoing monitoring of PBS expenditure by DoHA and central agencies.⁹ The strong growth in PBS spending in recent years has led to a number of measures

⁹ Including the Department of the Prime Minister and Cabinet, Department of Finance and Administration, and the Treasury.

aimed at enhancing the sustainability of the PBS program (DoHA 2003b). The HIC also monitors prescribing patterns in order to detect inappropriate servicing.

State-based advisory committees

At the State level, there are committees that monitor the safety and use of drugs, primarily in hospital settings. For example, the Victorian Medication Safety Committee (VMSC), established in 2003, seeks input from hospitals with experiences in medication safety, and shares strategies with all Victorian hospitals to improve outcomes. A further objective of the VMSC is to reduce duplication of efforts in developing strategies to common problems. The VMSC aims to address collectively a broader range of system errors than any individual hospital could address alone (VDUAC 2004). A similar role is undertaken in New South Wales by the SAFER Medicines Group (NSWtag 2004).

Although there is some communication between State-based committees, there appears to be a real opportunity for greater collaboration. The Victorian Therapeutics Advisory Group and New South Wales Therapeutic Advisory Group have jointly proposed that improvements in medication safety in Australian hospitals would be achieved by collaboration between the Australian Council for Safety and Quality in Health Care, State health departments and relevant State-based advisory groups (VDUAC 2004).

Monitoring of clinical and cost effectiveness

Once drugs are listed on the ARTG, there appears to be relatively little subsequent analysis of their clinical and cost effectiveness. A recent survey of clinical trial activity in Victoria found that post-market Phase IV trials represented a small percentage of all trials reported by Ethics Committees in Victoria (table 9.6). Responses from pharmaceutical companies indicated that pre-market Phase II and III trials accounted for the majority of their trial activity. A possible reason for low Phase IV trial activity is that companies are likely to focus on discovering and developing new drugs that may generate additional revenue streams in the future.

Instead of increasing the duration of pre-market trials, more emphasis could be placed on post-market monitoring. GlaxoSmithKline Australia (sub. 21) argued that faster listing of medicines could be combined with rigorous monitoring post-listing. CHERE (sub. 9) advocated conditional listing of new technologies where the evidence on cost effectiveness was uncertain, with a requirement for further data collection. This approach may be relevant where a drug shows promise of being more cost effective than the listed comparator but the available evidence is inconclusive. In this case, the sponsor could be required to conduct a Phase IV trial

as a condition of PBS listing. If the trial subsequently shows that the drug is not cost effective, the product would be de-listed or the price adjusted downwards. However, if the drug is found to be cost effective, it may warrant a price review.

Table 9.6 Distribution of clinical trial activity by phase of trial, Victoria

<i>Phase</i>	<i>Brief description^a</i>	<i>Ethics Committees^b</i>	<i>Pharmaceutical companies</i>	<i>Biotechnology companies^c</i>
		%	%	%
I	Trials involving human testing on small groups of volunteers	6	0-10	60-100
II	Trials involving groups of between 100–300 patients	17	20-50	10-60
III	Trials on a much larger scale (1000–3000 patients)	48	40-90	0-30
IV	Trials conducted after market release of drug or therapy.	6	10-20	0-10
Other		23	na	na

^a See chapter 11 for more detailed explanations. ^b The survey results relate to 2001. ^c Trials of drugs, vaccines, diagnostics and/or devices. **na** Not applicable.

Source: CTWG 2003.

Clinical outcomes also could be monitored using administrative databases. While Australia has numerous health service databases, there are various difficulties in using them for studying health outcomes. At the federal level, the HIC collects records of MBS services and PBS claims, but these records contain little clinical information. State and Territory health departments collect data on hospital admissions and, since the early 1990s, have collected hospital event data to form the National Hospital Morbidity Data Set (NHMDS). However, because the NHMDS is de-identified, its potential as a resource for outcomes analysis and a nationwide disease registry is lost (Kelman 2002).

Disease registries are a specific type of administrative database that collect clinical information about people diagnosed with a particular disease (box 9.2). For example, the Australian Rheumatoid Arthritis Association recently has set up a registry. There is potential to use such databases to track patient outcomes over the long term.

Box 9.2 **Disease registries in Australia**

Disease registries have been established for a number of diseases in Australia. Their general aim is to compile a database of all cases, within a given time and place, of a particular disease. Some examples of disease registries include:

- Australian Childhood Immunisation Register: the Health Insurance Commission collects data on the immunisation status of all children under seven years of age living in Australia. The register is used to monitor immunisation coverage levels, service delivery and disease outbreaks.
- Cancer registries: cancer is a notifiable disease in all States and Territories. There are State/Territory based registries as well as the national dataset maintained by the Australian Institute of Health and Welfare (AIHW).
- Diabetes register: the AIHW collects information from records of people using the National Diabetic Services Scheme and State based registers of the Australian Paediatric Endocrine Group.

The data collected by disease registries can be used for research, to provide clinical services, to develop and evaluate health prevention or intervention policies, and for administration purposes.

Source: ABS (2002c).

Despite the limitations of existing databases in Australia, there is scope to enhance their research value. CHERE (sub. 9) argued that these databases (including disease registries) could provide a powerful resource for analysis if the data were systematically linked. It pointed to Western Australia as a leader in health data linkage, having established a major linked database that includes hospital, maternity, cancer and deaths data. However, before greater linkage between databases can be achieved, there is a range of technical, legislative and privacy issues that would need to be addressed (appendix K).

Some participants suggested that monitoring of clinical outcomes could be part of performance-based agreements where companies are remunerated according to the health outcomes delivered by new drugs. For example, GlaxoSmithKline Australia (sub. 21) outlined an ‘outcomes guarantee’ arrangement whereby a pharmaceutical company and prescribing stakeholders agree on the outcomes that they expect from a medication for a given indication. If the medicine does not meet these expectations, the company refunds to the government the cost of the medicine. Outcome guarantees have been used in the United Kingdom for statins and agents for treating multiple sclerosis (GlaxoSmithKline Australia, sub. 21).

Review

Re-assessments can be used to make appropriate adjustments to policy, regulation and clinical guidelines in response to new evidence on safety, efficacy and effectiveness of pharmaceuticals.

Safety re-assessments of registered drugs have been triggered when new evidence has emerged. For example, in response to the recent safety concerns relating to the anti-inflammatory drugs *rofecoxib* (Vioxx) and Celebrex, the TGA initiated a review of all Cox-2 inhibitors. The TGA has fast-tracked the review and requested that the US research data be provided to it immediately, and has asked all other companies researching Cox-2 inhibitors to produce their results as a matter of urgency (TGA 2004b).

Participants raised few issues concerning TGA reviews, but pointed to two key issues regarding the re-assessment of PBS-listed items for acceptable cost effectiveness. First, some participants including ACT Health (sub. 11) and Dr Thomas Faunce (sub. PR60) noted that many drugs listed before 1993 had not been assessed for cost effectiveness. Indeed, more than half of PBS-listed items have not been subjected to the requirement for formal economic evaluation (chapter 8).

Second, of the drugs that have been assessed and listed since 1993, it appears that few have been subject to re-assessment of clinical and cost effectiveness by PBAC. The Cancer Council Australia and Clinical Oncological Society of Australia stated that:

Drugs currently approved by the [PBAC] are only evaluated in terms of cost effectiveness in initial controlled trials, with no follow-up to ensure they continue to provide value for money after their addition to the PBS. (sub. 32, p. 26)

GlaxoSmithKline Australia also pointed to the lack of a systematic re-assessment process:

Currently there is no ongoing system of regular reviews ... It may be that some medications are less cost effective now than they were early in release (for example, given advances in medical technology), or alternatively, ... some medicines are more cost effective (for example, as a result of post-marketing surveillance and additional data becoming available). (sub. 21, attach. 1, p. 28)

While DoHA has conducted some reviews of individual drugs or classes of drugs, these reviews have been *ad hoc* and often driven by budgetary concerns. In addition, the extent to which these reviews re-evaluated the evidence on clinical and cost effectiveness is unclear. Nonetheless, these reviews resulted in a number of

drugs being de-listed from the PBS, including some anti-inflammatories, some nasal sprays and medicines for minor nail infections and common stomach problems.

A more systematic form of re-assessment process would keep the PBS Schedule up to date and reduce potential inconsistencies. The 2005-06 Federal Budget included a measure for cost-effectiveness review of listed drugs (DoHA 2005d), although it is not known what this will entail. Some participants suggested that the inclusion of more than one comparator in submissions to PBAC could allow more listed drugs to be re-assessed over time. As systematic re-assessment of drug cost effectiveness is likely to add to administrative and compliance costs, this suggests that a prioritised approach is warranted.

FINDING 9.8

Once pharmaceuticals are listed on the PBS, there appears to be no systematic process for monitoring and re-assessing their clinical and cost effectiveness by PBAC. This represents an opportunity for improving existing processes.

The following chapter examines specific aspects of HTA processes for other medical technologies.

10 Health technology assessment: procedures, devices and ICT

This chapter outlines existing mechanisms and processes for health technology assessment (HTA) of medical technologies other than pharmaceuticals — that is, for procedures, medical devices (including prostheses) and information and communications technology (ICT) systems for health and medical applications. As outlined in chapter 8, HTA processes for these technologies differ significantly from those used for pharmaceuticals. This chapter also contains a discussion of potential gaps in these HTA processes, as required by the terms of reference.

10.1 Key differences in HTA between pharmaceuticals and other technologies

While HTA of pharmaceuticals in Australia is well established, formal HTA processes for other medical technologies (such as procedures and devices) have been established more recently (chapter 8).

Although the broad conceptual elements of the HTA process are similar for pharmaceuticals and other therapies, there are important differences between technologies that may warrant different application of HTA. For instance, medical devices and drugs differ in a number of key respects (table 10.1). While the safety and efficacy of pharmaceuticals are usually evaluated in isolation from other interventions, this is often not possible with medical devices. The performance of an implantable medical device depends not only on the device itself, but also on the skill of the attending surgical team. This can increase the complexity of conducting HTA of devices.

Clinical trials are commonly used to assess the efficacy and effectiveness of drugs whereas other study designs are often used to examine procedures and devices. In addition, product life cycles of medical devices are generally much shorter than drug life cycles, which also has implications for the HTA process.

Table 10.1 Differences between medical devices and pharmaceuticals

	<i>Medical devices</i>	<i>Pharmaceuticals</i>
Therapeutic effect	Effective by mechanical and/or electrical action	Effective when absorbed and metabolised by the body
Operator skill	Outcomes often depend on surgical skill	Rarely relevant
Product life cycle	Relatively short (2–4 years) ^a	Longer (10–20 years)
Physical infrastructure	Often necessary for delivery of treatment	Usually not required
Delivery environment	Often delivered in hospitals (public and private)	Usually administered in community settings
HTA processes	Recently established processes	Long-established processes
Evidence base	Good quality scientific data often not available	Good quality scientific data usually available

^a The Therapeutic Goods Administration observed that there are some devices (such as syringes, bandages, condoms and surgical instruments) which have changed little over the past 10–20 years (DoHA, sub. PR56).

Sources: Henry and Hill (1999); MIAA (sub. 17).

Thus, while useful lessons may be drawn from the experience gained from pharmaceutical assessment, they may not always be directly transferable to the assessment of other technologies.

10.2 Medical procedures

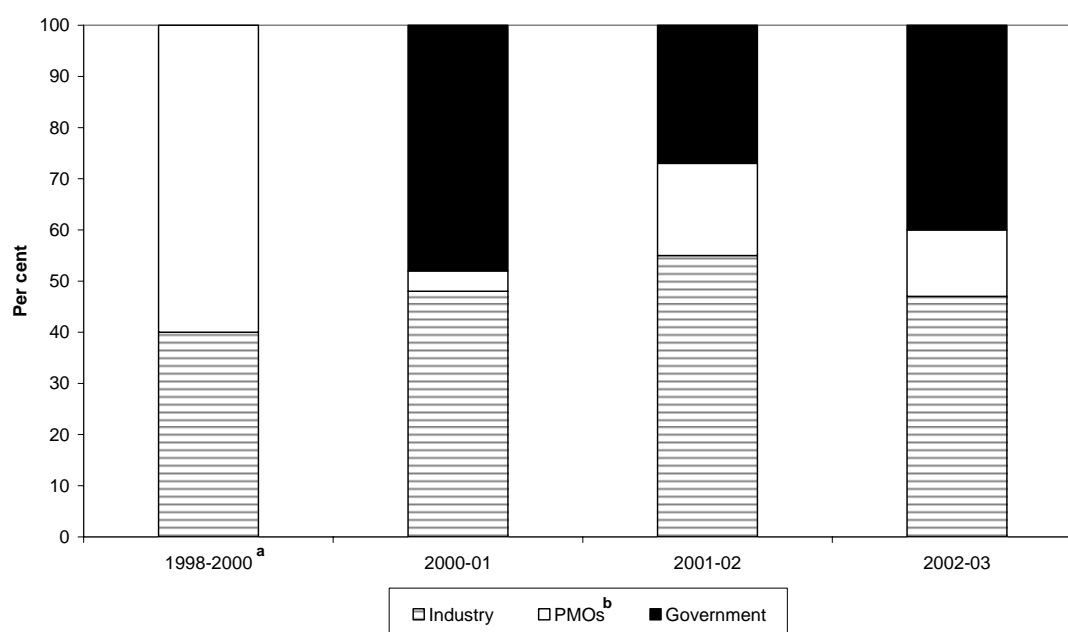
Participants raised a number of potential gaps or deficiencies in current HTA mechanisms and processes relating to medical procedures, including:

- differentiating new from existing procedures;
- type of clinical evaluation;
- type of economic evaluation;
- timeliness of process;
- administrative and compliance costs; and
- mutual recognition.

New versus existing procedures

The work program of the Medical Services Advisory Committee (MSAC) is largely driven by submissions received from the medical industry and references received from the Minister or the Department of Health and Ageing (DoHA) (figure 10.1). The Commission understands that most of these submissions and references have asked MSAC to evaluate new procedures. Thus, although MSAC can examine both new and existing procedures, its ability to undertake evaluations of existing Medicare Benefit Schedule (MBS) procedures is influenced by the types of submission and reference it receives.

Figure 10.1 Applications and references to MSAC, 1998-2000 to 2002-03



^a From April 1998 to June 2000. ^b Professional medical organisations and individuals.

Data sources: MSAC (2004a; 2003; 2001; 2000).

There can be difficulties in distinguishing new or novel procedures from existing procedures. This is because technological progress often takes the form of incremental modifications to existing procedures or devices rather than major advances, which tend to occur less frequently. Eucomed (2001) noted that the development of medical devices is characterised by a constant flow of incremental product improvements. If improvements to existing procedures are marginal or minor, they are unlikely to require full assessment by MSAC.

The incremental nature of technical progress also creates definitional and classification issues. For example, the Australian Diagnostic Industry Association (ADIA) stated that:

There are particular concerns that, as currently structured, the MSAC processes do not deal fairly or effectively with the separation and/or differentiation of ‘new’ activities and technologies from those processes which may be seen as refinements or enhancements of existing techniques or technologies. (sub. 12, app. 1, p. 2)

Some MBS service descriptors may be broad enough to encompass new procedures and devices. It is therefore possible that some new procedures that fit under an existing MBS procedure code may not have been assessed — or have been assessed only after the procedures have already diffused significantly into clinical practice. For example, laparoscopic gastric banding diffused into Australian practice before being evaluated by MSAC because MBS items for the surgical treatment of morbid obesity were broadly defined (MBS item numbers 30511 and 30512).

This also occurred with drug eluting stents (DES) which were being used in patients under an existing procedure code (MBS item number 35310) prior to their assessment by MSAC (chapter 8; appendix H). The National Centre for Classification in Health (NCCH) received a public submission requesting the creation of a new procedure code for DES in the ICD-10-AM,¹ which is closely aligned with the MBS in terms of numbering system and terminology (NCCH 2005). While the NCCH did not support the creation of specific codes for DES in ICD-10-AM, it indicated that the inclusion of the terms ‘drug eluting stent’ to existing stent codes would clarify code selection. The Coding Standards Advisory Committee of the NCCH has subsequently recommended against creating new codes for DES (appendix H).

FINDING 10.1

Some new medical technologies deemed to fit under existing MBS codes may not have been assessed or have been assessed only after significant diffusion has occurred.

Type of clinical evaluation

Like the Pharmaceutical Benefits Advisory Committee (PBAC) guidelines, there is a strong preference in the MSAC Guidelines for MSAC to base its decisions on data from randomised controlled trials (MSAC 2004b). This equates to Level I and II

¹ International Statistical Classification of Diseases and Related Health Problems — Tenth Revision — Australian Modification.

evidence using the National Health and Medical Research Council (NHMRC) evidence scale (chapter 9).

The Medical Industry Association of Australia (MIAA) argued that the NHMRC developed its evidence scale when the focus was on pharmaceuticals, and that applying this scale to surgical and diagnostic procedures was problematic:

Evidence of the clinical efficacy and safety of a medical procedure at the randomised, double-blinded, head-to-head Phase III clinical trial level is rare, and in many cases impractical. (sub. 17, p. 59)

NHMRC levels of evidence are currently under review, as they have been found to be restrictive for some purposes, especially where the areas of study do not lend themselves to randomised controlled trials (Coleman et al. 2005).

MSAC recognises that clinical trials are seldom used for operative procedures. Solomon and McLeod (1998) estimated that randomised controlled trials comprise only 3–9 per cent of clinical study designs across all areas of surgery, despite the rapid expansion in new technology in surgery. For the evaluation of new surgical and imaging procedures and diagnostic tests, the research literature is often confined to case series² or poorly-controlled clinical studies (Henry and Hill 1999).

While randomised controlled trials are routinely used to evaluate drugs, there appear to be some valid reasons for the low utilisation of such trials for procedures and devices. A key reason is that it may be difficult to isolate the effects of non-pharmaceutical technologies from other components of the care delivery system. The MIAA (sub. 17) noted that devices are often used in conjunction with other interventions (such as surgery, diagnosis or monitoring) and questioned whether it were possible to evaluate the specific effect of devices on health outcomes.

There are also technical, ethical and cost considerations. Some interventions cannot be ‘blinded’ either ethically or physically (Weedon 1999). In these cases, it is not possible to run double-blind trials which are designed to eliminate bias. In addition, clinical trials to evaluate surgical procedures typically involve greater costs than case series. According to Weil (2004), case series require fewer resources in terms of personnel and funds than do clinical trials.

However, Anderson et al. (1999) contended that while a number of problems might explain the shortage of rigorous surgical trials, most of these issues can be overcome. ASERNIP-S (sub. PR50) argued that an area requiring funding is the

² That is, the medical technology has been used in a series of patients and the results have been reported, but there is no separate control group for comparison (MSAC 2004b).

development of methodology for undertaking HTA, particularly where there is a paucity of higher level evidence as is commonly the case with surgical techniques and technologies.

Thus, the clinical evidence put forward to support medical procedures and devices has generally been of a lower level compared with that for pharmaceuticals. Case series have been the predominant research design for surgical interventions, but the results are prone to bias and difficult to generalise. Although the appropriate choice of study design depends on the specific circumstances, higher level evidence (such as clinical trials) is usually more costly to produce.

Type of economic evaluation

In addition to safety and clinical effectiveness, MSAC is required to consider the cost and cost effectiveness of the medical technologies it assesses. MSAC Guidelines set out the minimum economic information that MSAC requires from applicants (MSAC 2004b). These include capital costs, direct treatment costs, and indirect or broader costs. MSAC indicates that a societal perspective should be adopted regarding indirect costs, which means that costs incurred outside the healthcare sector and the time costs of patients and their families also may be included in applications. In this regard, MSAC appears to take a broader perspective than PBAC (chapter 9).

Unlike pharmaceuticals, there is no mandatory requirement for economic evaluation of all medical services submitted for MSAC assessment. If the proposed medical service is likely to be high cost or extensively used, MSAC may require a formal economic evaluation — providing that safety and clinical effectiveness have already been established (MSAC 2004b). MSAC determines the need for a full economic evaluation on a case-by-case basis.

MSAC allows a range of economic evaluation including cost-effectiveness analysis, cost-minimisation analysis, cost–utility analysis, cost–benefit analysis and other economic analysis. The type of economic evaluation chosen will depend on the nature of the new medical service and the available clinical and economic data. However, as noted above, the comparatively weaker evidence base for medical procedures and devices may impede the use of cost-effectiveness analysis.

Although applicants need only provide the minimum information requested by MSAC Guidelines, this may require MSAC to commission further work to assess new technologies more fully. Applicants have the option to submit more detailed applications (including data and analysis beyond the minimum requirements). This approach, while adding to applicants' costs, may reduce MSAC assessment times.

As discussed in section 10.5, for new technologies that show promise of being cost effective, there may be grounds for providing funding for a defined period during which further evidence can be gathered.

FINDING 10.2

The use of formal economic evaluation, such as cost-effectiveness analysis, is hampered by the generally weaker clinical evidence base that exists for medical procedures and devices, compared with that for pharmaceuticals. MSAC may commission further work in order to assess new technologies more fully.

Timeliness of process

Several participants claimed that the MSAC process is cumbersome and slow. The MIAA (sub. 17) stated that the process is characterised by delays and referral overkill, retarding timely access to effective technology. The ADIA stated that:

The, largely anecdotal, information we have received indicates that many practitioners believe that the MSAC process is slow, costly and unresponsive and generally not worth pursuing. Others believe it is a covert form of rationing by the Commonwealth, which is aided and abetted by inflexible bureaucratic processes. (sub. 12, app. 1, p. 2)

The Royal Australian and New Zealand College of Radiologists (RANZCR) contended that the MSAC process did not keep pace with the advent of new procedures:

Given the growth in new diagnostic and therapeutic techniques and devices, the MSAC process and the associated delays have also conspired to delay the introduction of new technologies and new applications of current technologies onto the publicly funded Medicare Benefits Schedule. (sub. 27, p. 2)

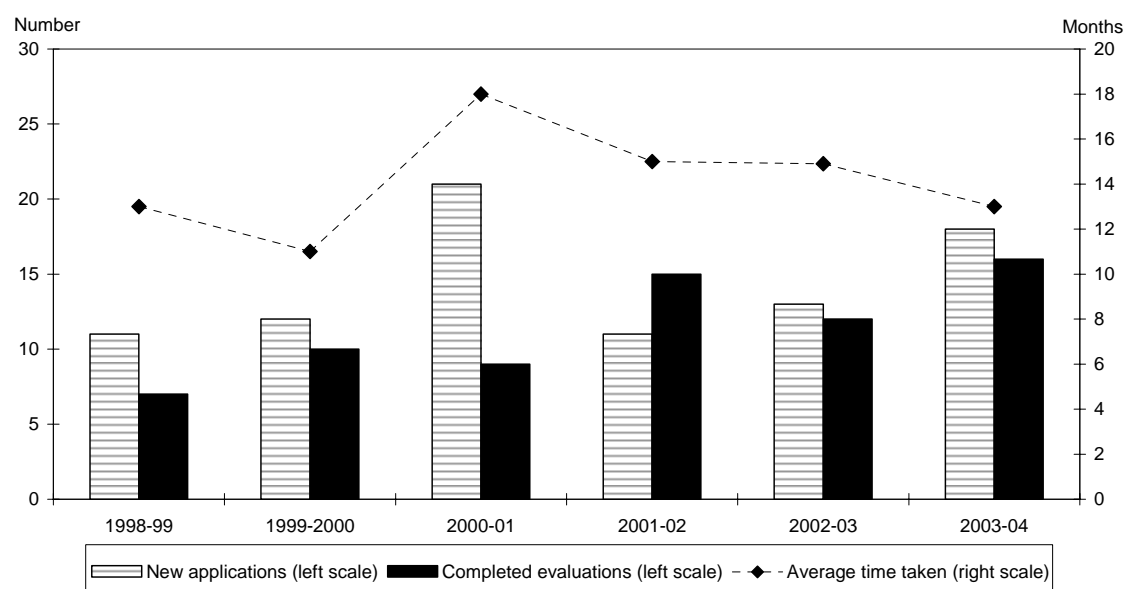
The time taken to complete HTA assessments (including Therapeutic Goods Administration (TGA) and MSAC processes) is of particular concern to device manufacturers as some of their products have relatively short life cycles (table 10.1).

On average, MSAC has completed around 11–12 evaluations per year and the average time taken to complete evaluations³ has varied between 11 and 18 months (figure 10.2). Although there has been some reduction in the average time taken to complete evaluations, from 18 months in 2000-01 to 13 months in 2003-04, the process appears to be quite lengthy. The MSAC assessment cycle comprises a number of stages. DoHA must first determine whether an application is eligible for

³ The time elapsed from submission of application (or reference) to final MSAC consideration (MSAC 2003).

MSAC review. In the case of an eligible application, MSAC contracts external evaluators and establishes an advisory panel. This requires MSAC to identify and contact experts in the field. An assessment report must also be prepared.

Figure 10.2 Indicators of MSAC processes, 1998-99 to 2003-04^{a, b}



^a Completed evaluations are those which have received Ministerial endorsement. ^b For 2003-04, the number of final assessment reports endorsed at MSAC meetings has been estimated.

Data sources: DoHA (2004g; 2003b; 2002a; 2001a); MSAC (2004a).

In total, the number of applications and references received by MSAC exceeds the number of completed evaluations. This is because some applications or references have been deemed ineligible for review and some evaluations are currently in progress. Completion rates are likely to be affected by the financial resources that MSAC is able to commit to conducting assessments. It is possible that the frustrations reported by participants about the MSAC process may have discouraged some parties from making applications.

Many of the new procedures examined by MSAC are specialised and complex, and therefore time-consuming to evaluate. Further time is consumed when advisory panels require additional information from applicants. The Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32) commented that the lack of Australian-based clinical evidence also can delay MSAC approval of new equipment and techniques that might otherwise improve patient outcomes.

MSAC formulates its recommendations to the Minister based on the assessment report and any feedback from the applicant. DoHA then prepares a submission to the Minister combining MSAC's final assessment report and recommendations with

policy advice from the Department. The Commission does not have information on the average time taken from MSAC endorsement of completed evaluations to Ministerial consideration and, in the case of approved items, listing on the MBS.

FINDING 10.3

The MSAC assessment process appears lengthy, taking 13–15 months on average to complete evaluations. This may reflect the fact that MSAC assesses the safety as well as cost effectiveness of new medical procedures and some devices, and that it may need to commission further analysis if applications do not provide sufficient information.

Administrative and compliance costs

The TGA and MSAC processes both generate compliance costs for applicants. In 2003-04, the TGA received around \$12 million in user charges from the medical devices industry for evaluation services and annual fees for maintaining listings on the Australian Register of Therapeutic Goods (ARTG) (TGA, pers. comm., 23 May 2005). Applicants also expend resources in preparing submissions for the TGA and/or MSAC. While the TGA recovers its costs from industry, the Australian Government funds MSAC activities. Departmental appropriations for MSAC and the MBS-listing process are not separately identified in DoHA's financial statements (DoHA 2004g).

As noted above, participants appear to be more concerned about the cost of perceived time delays in terms of revenue forgone as new technologies await or undergo assessment.

Mutual recognition

The use of overseas clinical studies or official assessments can potentially fast-track the evaluation of medical procedures in the Australian HTA system, generating both time and resource savings.

MSAC acknowledges that overseas or international trials are usually the main source of information as the Australian population is often too small to conduct sufficiently robust trials in a reasonable timeframe (MSAC 2004b). In providing guidance to applicants, MSAC notes that potential sources of information include reviews by overseas regulatory authorities (for example, the United States Food and Drug Administration — FDA).

While the MSAC Guidelines do not require applicants to submit Australian-based clinical studies, applicants are asked to provide information on the relevance of overseas clinical studies to Australian patients and settings (MSAC 2004b). The Commission was told that HTA committees, in considering overseas clinical studies of surgical procedures, need to take account of differences in the skill levels and experience of surgeons in Australia and other countries.

In the case of economic evaluation, it would be more difficult to rely on overseas assessments for making recommendations regarding MBS listing. This is because countries can differ greatly in terms of prices, relative efficiency of healthcare systems, incentives and payments systems. Social values and preferences also vary internationally. The OECD (2005a) reported a lack of consistency in data collection, analysis and reporting which creates significant barriers in transferring cost-effectiveness results from one setting to another. A study for the European Commission argued that exchangeability of evidence-based information between countries would be enhanced by the harmonisation of HTA methodologies and standards of data compilation (Pammolli et al. 2005).

FINDING 10.4

An overseas economic assessment of medical procedures is unlikely to obviate the need for an economic evaluation that incorporates Australian factors and conditions. That said, it may be possible to use overseas clinical studies and experience — with appropriate adjustments — as a basis for preparing Australian economic evaluations.

10.3 Prostheses and devices

Technology assessment of prostheses and devices (such as artificial hips and knees, pacemakers and intraocular lenses) has developed along sectoral lines. There is a formal process for considering prostheses for reimbursement by private health funds, which is the focus of this section. There also are committees at the State or hospital level that consider prostheses for use in public hospital systems (chapter 8).

Schedule 5 listing arrangements

Until new arrangements were introduced in 2004-05, once a prosthesis had passed TGA requirements, the manufacturer or supplier could apply to have the item listed on Schedule 5 (the Prostheses Schedule) which formed the basis of the benefits paid

by private health insurers.⁴ The Schedule set out how benefits were determined, what benefits would be paid, and what to do if the health fund and other party could not agree on a fee or charge for an item.

The process for listing on the Schedule has undergone a number of changes over the past five years. Originally, the supplier submitted the device application (which included a proposed price) for consideration by DoHA. The device was assessed by DoHA against a set of departmental guidelines to decide whether to list the item. With some exceptions, DoHA usually accepted the proposed price for listing purposes (AHIA 2005). That is, the benefit levels were set equal to the prices proposed by the supplier for the listed items.

However, by the late 1990s, the Schedule had become large, unwieldy and increasingly difficult to manage for the Department, health funds and hospitals. Moreover, the prices stipulated in the Schedule were not necessarily reflective of market prices or prices of comparable items in other countries (DoHA 2000). These problems led to several initiatives including a departmental review of the Schedule in 2000, creation of a new committee, and the introduction of new pricing arrangements.

The Minister established the Private Health Industry Medical Devices Expert Committee (PHIMDEC) in 2001 to oversee Appendix C (Other Medical Devices) of the Schedule. PHIMDEC responded to applications from manufacturers or suppliers for items to be included on Appendix C by assessing whether they met the criteria for the list. The Department continued to assess applications for inclusion on Appendix A (Surgically Implanted Prostheses) and Appendix B (Human Tissues).

It is not known whether PHIMDEC or DoHA applied clinical and cost-effectiveness criteria in deciding whether to list an item. However, according to NSW Health (sub. 20), the level of evaluation and monitoring undertaken by PHIMDEC was not considered as robust as that conducted by other HTA mechanisms.

Prostheses pricing was also deregulated in 2001. The Australian Government ceased to set the benefit payable by health funds for prostheses or other medical devices listed on Schedule 5. The benefit levels for items were to be negotiated and agreed between the health fund and the supplier, hospital or agent. The aim was to allow market forces to determine benefit levels (DoHA 2002a). A key principle underlying the reform was that health funds would cover the items listed on the Schedule on a 'no gap' basis (that is, the benefit level would be set equal to the item price).

⁴ The first surgically implanted prostheses list was established in 1985 following an agreement between the Australian Government and the medical profession (DoHA 2000).

As discussed in chapter 2, following the changes in 2001 there was rapid growth in prostheses costs. As DoHA (sub. PR56) noted, there were few incentives for ensuring value for money. There was little evidence-based assessment of effectiveness and cost effectiveness for prostheses (HoR 2004) — and pricing was left to individual health funds and suppliers. Following a review of the regulatory arrangements pertaining to the private health insurance industry in 2002-03, the Australian Government announced a range of measures, including proposed changes to prostheses listing and funding arrangements.

New listing arrangements

The new arrangements include administrative changes and amendments to the *National Health Act 1953* (Cwlth). The new arrangements are to be reviewed two years after full implementation.

Legislative changes

The National Health Amendment (Prostheses) Act was passed by Parliament in March 2005 to change listing arrangements for prostheses. The legislation requires health funds to offer a ‘no gap’ and ‘gap permitted’ range of prostheses for every in-hospital procedure on the MBS for which they provide cover. The Minister is required to determine in writing:

- no gap prostheses and the benefit amount for each item; and
- gap permitted prostheses and the minimum and maximum benefits for each item.

Health funds will still be able to choose to provide cover for prostheses that are not listed in the Ministerial determinations, for example, more expensive prostheses relating to MBS procedures and prostheses not related to MBS procedures.

New committees

Several new committees have been established to undertake different functions under the new listing process.

The Prostheses and Devices Committee (PDC), a non-statutory advisory committee, has been created to advise the Minister on the listing and benefit levels of prostheses and medical devices. The PDC will assess devices primarily for relative clinical efficacy based on the available evidence and data. It also will categorise devices into appropriate MBS procedures and manage the Prostheses Schedule (DoHA 2004f). Members of the PDC are appointed from health fund, hospital,

clinical, supplier and consumer groups. The PDC commenced operation in 2004 and its activities are supported by a secretariat within DoHA.

Clinical Advisory Groups (CAGs) — comprising mainly clinical specialists — provide advice to the PDC primarily on the relative clinical efficacy of prostheses and devices. Based on this advice, CAGs also recommend the grouping of like products that provide the same or similar health outcomes (DoHA 2005f). The relative clinical efficacy information will be used by the PDC to establish price ranges and by the Benefit Negotiation Group (BNG) to establish best prices for different categories of items grouped by clinical efficacy. CAGs have examined items from six major identified prostheses categories (that is, hips, knees, cardiac stents, pacemakers, defibrillators, and intraocular lens). A further six categories will be examined in 2005 (DoHA, sub. 34).

Where practicable, CAGs also may provide information to the PDC on cost effectiveness. According to DoHA (sub. PR56), the CAG for cardiac prostheses considered cost-effectiveness data that were submitted. However, such data were not available for consideration by the CAGs on hips, knees and intraocular lenses. It appears that the wider application of cost-effectiveness assessment is constrained by the limited availability of comparative clinical and price data. Moreover, the PDC's terms of reference ask it to review evidence on prostheses and devices primarily using relative clinical efficacy rather than cost effectiveness (DoHA 2004f).

The BNG advises the PDC on the appropriate level of benefit for products. It will negotiate prices for prostheses and devices with manufacturers, suppliers and distributors, taking account of the available evidence on efficacy, efficiency, alternative devices and other factors. The benefit negotiated will not be greater than the threshold recommended by the PDC. The BNG may comprise negotiators appointed or contracted by the PDC (DoHA 2004f). DoHA (sub. PR56) argued that the centralised benefit negotiation aims to introduce competitive tension into the market.

Under the new prostheses arrangements, an aggrieved party (which could be a health fund, hospital, medical practitioner or supplier) may appeal recommendations of the PDC or BNG on procedural grounds only. Appeals will be considered and determined by the Secretary of DoHA or his or her delegate (DoHA 2004f). Parties also may appeal to the Administrative Appeals Tribunal.

The new Prostheses Schedule

The Prostheses Schedule will list products within their clinical groups — that is, according to their comparative clinical efficacy or comparative clinical design

attributes — without separating gap and no gap items. The minimum and maximum benefits will be listed against each product, enabling the gap payable (if any) to be identified (DoHA, sub. PR56).

It is a requirement to include at least one no gap clinically-appropriate and clinically-effective product available for every in-hospital MBS procedure. Those products listed with a gap do not have proven additional clinical or design attributes that would justify a higher benefit than the no gap benefit.

The first Schedule under the new arrangements will be released in August 2005 but will take effect in October 2005 to allow hospitals and health funds time to develop administrative systems associated with the reforms, and to provide clinicians with time to undertake procedures already scheduled without affecting existing patients' gap payments (DoHA, sub. PR56).

Industry views

Although industry (including health funds, suppliers and hospitals) contributed to the development of the new arrangements, some participants expressed concern about whether the reforms would address all existing problems.

The MIAA (sub. 17) contended that there is potential for redundant reviews of new technologies by overlapping bodies. It expects that the reforms will increase overall costs of administration and compliance to at least double that of previous arrangements, adding to the overall cost of prostheses and delaying the availability of new technologies to private patients. The MIAA also claimed that the reforms may lead to a reduction in clinical choice and greater clinician involvement in patients' financial circumstances.

Some participants questioned whether the reforms will promote cost effectiveness. For example, Dr Stan Goldstein stated that:

The potential for new devices ... and prostheses to be introduced with minimal evaluation of efficacy and cost effectiveness, even by existing organisations ... or the newly formed Prostheses and Devices Committee, requires attention. (sub. 5, p. 7)

In addition, BUPA Australia (sub. 28) indicated that a continuing problem will be the lack of consideration given to clinical or cost effectiveness at the individual patient level. It argued for the development and use of decision support systems that will allow doctors to make clinical recommendations applicable to each circumstance, based on the best evidence and clinical guidelines as interpreted by a consensus of experts.

Indeed, under its terms of reference, the PDC will review evidence on new, emerging and existing prostheses and devices primarily using the criterion of relative clinical efficacy rather than cost effectiveness (DoHA 2004f). DoHA (sub. PR56) recognised that the evidence used to assess prostheses in the early stages of the new arrangements may not be as rigorous as that used by PBAC and MSAC, but it indicated that the new arrangements aim to establish a base from which cost-effectiveness assessment can be applied in the future.

The new assessment process for prostheses is an improvement on previous arrangements whereby items were listed for reimbursement with little or no evaluation. While the current focus is on relative clinical efficacy rather than cost effectiveness, the application of cost-effectiveness assessment is hampered by the lack of comparative clinical and price information.

FINDING 10.5

Prior to the introduction of the Prostheses Act, medical devices and prostheses were subject to little, if any, assessment or re-assessment of their clinical or cost effectiveness.

Unlike PBAC and MSAC, a major focus of the new Prostheses and Devices Committee will be relative clinical efficacy rather than cost effectiveness. There appears to be greater scope for prostheses and devices to be assessed for cost effectiveness, bearing in mind that evaluation methods may need to differ from those applying to pharmaceuticals and medical procedures.

10.4 Information and communications technology

It has been estimated that total spending on health ICT systems in Australia accounts for about 1–3 per cent of total healthcare costs — equivalent to expenditure of around \$1–2 billion annually. Some estimates suggest that spending on health ICT will need to double to around 4–5 per cent of total healthcare costs, which is about the level being spent in the United States and United Kingdom (appendix K).

In recent years, the Australian Government, and the States and Territories, have placed greater priority on upgrading ICT systems for health and medical services. It has been estimated that about \$1.3 billion will be invested in new health information systems from 2004-05 to 2009-10 (Reinecke 2004). There are a large number of ICT initiatives currently in progress at the national and State levels. Being based primarily on ICT, these projects are not subject to assessment by the TGA, MSAC or PDC.

A major ICT project at the national level is *HealthConnect* — a joint initiative between the Australian Government and the State and Territory Governments. This project aims to establish a network of electronic health records to improve the flow of information across the healthcare system through the electronic collection, storage and exchange of consumer health information. *HealthConnect* also incorporates *MediConnect* which is a medication records system. The implementation of *HealthConnect* is being managed by a program office within DoHA in consultation with the States and Territories and other key stakeholders. This initiative is discussed in more detail in appendix K.

As there is no independent body at the national level with the express purpose of evaluating ICT systems in the healthcare sector, some evaluation activities have been incorporated within the *HealthConnect* project. The main evaluation methods have included the use of studies and trials (box 10.1).

However, the evaluation studies and trials have been deficient in a number of respects. The consultants' reports examined only a narrow range of benefits and did not adequately demonstrate how *HealthConnect* would generate the claimed benefits. Several reviews of the *HealthConnect* system have observed that the restricted scale and complexity of the trials and field tests limited the rigour of evaluations, and that evaluation activity needed to focus on the most important issues (*HealthConnect* Program Office 2005a).

Overall, the approach taken in assessing the costs and benefits of *HealthConnect* has been disjointed. As a general principle, to evaluate the feasibility of a project or program, the likely costs and benefits need to be considered together and prior to making a decision on how or whether to proceed. Moreover, it appears that some governance and legal issues have not been adequately addressed prior to the implementation of *HealthConnect*,⁵ while its scope has also become far less ambitious. In contrast to the approaches adopted in the United States and United Kingdom, it does not involve building an entire electronic health environment (Dearne 2005c). The fact that so many unresolved issues remain after seven years of research and development suggests that there have been gaps in the planning and evaluation of the project and/or how these have been acted upon — for example, why some issues which are fundamental to implementation, such as standards and database design, and whether the adopted opt-in model is likely to be more or less cost effective than an 'opt-out' approach, were not addressed earlier.

⁵ The Office of the Federal Privacy Commissioner (2004) expressed concern that the roll-out of *HealthConnect* could precede the establishment of governance mechanisms. Another report identified a range of legal issues that need to be considered ahead of implementation of *HealthConnect* on a larger scale (*HealthConnect* Program Office 2005b).

Numerous health ICT initiatives are also underway at the State and Territory level. For example, the Victorian Government launched HealthSMART in 2003 which is a strategy to modernise ICT in Victoria's public healthcare system (VDHS, sub. 24). Most State and Territory spending on health ICT has been directed at clinical information systems, patient administration systems and electronic health records in public hospital systems (BCG 2004).

As detailed in appendix K, despite the large investment already committed, many of these ICT initiatives have been beset by various problems and have not yet provided solutions for the issues they are seeking to address. The difficulties confronting State Government hospital initiatives have included, among other things, the failure to realise benefits, concerns with tendering processes, significant cost over-runs, and delays in implementation. Many hospitals have primitive ICT systems compared with other businesses of similar size. Another key issue is the lack of interoperability of ICT systems within and between hospitals, as well as constraints in linking medical specialists into the system. Reinecke (2005) noted that there is inadequate interaction between hospitals and the primary care sector. The slow progress at the State and Territory level has generated frustration and prompted moves to implement some solutions at local levels (appendix K).

Some recent reports suggest that evaluation of health ICT projects in the public sector generally has been quite poor. The Boston Consulting Group (BCG 2004) found that, of around 360 current and planned health ICT projects identified in the public sector, fewer than half had scoped a business case — with only a handful of those identifying quantifiable, clinical or outcomes-based benefits to be achieved in a certain timeframe. The Centre for Health Informatics (2002) surveyed health ICT systems largely in the primary care and hospital sectors, finding that 17 per cent had no formal evaluation and nearly 60 per cent had only undertaken a case study or some form of qualitative analysis.

With so many ICT projects underway at the national and State levels, the Australian Health Information Council reported stakeholder concerns that these activities are often uncoordinated and suffer from diffuse accountability and decision making. In response to these concerns, the National E-Health Transition Authority (NEHTA) was established in 2004 to drive forward national priorities for information management and ICT in the health sector.⁶ The agreed national priorities focus on the critical standards and infrastructure required to support connectivity and interoperability of electronic health information systems. The role of NEHTA is discussed in more detail in appendix K.

⁶ The Australian, State and Territory governments committed \$9.5 million to the work of NEHTA in 2004-05 (DoHA, sub. 34). The governments recently agreed to provide a further \$18.2 million to fund NEHTA's core activities over the three years from 2005-06 (appendix K).

Box 10.1 **HealthConnect — studies and trials**

Scoping and feasibility studies

A number of studies were undertaken during the first research and development phase (2001–2003) of the *HealthConnect* project. These looked at a range of issues, including value, technical feasibility, preferred implementation model, role of the private sector, privacy, governance arrangements and cost. The *Interim Research Report* concluded that the *HealthConnect* concept could work and be of value and integrated into the day-to-day practices of healthcare providers (*HealthConnect* Program Office 2003a).

While the *Interim Research Report* in 2003 found value in the *HealthConnect* concept, research on the benefits was less than complete at that time:

While significant research into the likely costs, design and implementation options and related issues for *HealthConnect* has been undertaken, work on the benefits and their realisation has been less detailed and has not been consolidated to date. (DMR Consulting 2004, p. 14)

Consequently, the *HealthConnect* Program Office commissioned reports from consultants for a more detailed assessment of potential benefits and their realisation (DMR Consulting 2004 and Fujitsu 2004a).

Field test and trials

As part of the second research and development phase (2003–2005) of *HealthConnect*, trials are being used to test the effectiveness of the health information network in real settings. They are intended to assess the value, feasibility and acceptability of *HealthConnect*. Trials have been operating in Tasmania (completed in November 2004) and the Northern Territory since 2002 and in North Queensland since 2003. Further *HealthConnect* trials will commence in South Brisbane and New South Wales in 2005 (appendix K).

MediConnect was field tested in Launceston and Ballarat in 2002–2004. However, the initiative was hampered by technical and other difficulties. DoHA (2004g) reported that participation by doctors, pharmacies, hospitals and consumers was lower than initial targets due to delays in the development of pharmacy software in Launceston and slow uptake of the program by general practitioners in Ballarat. The media also reported that the Pharmacy Guild of Australia had lodged a patent application claiming ownership of key aspects of the medication record sharing system (Dearne 2005e). Following the field tests, *MediConnect* functions are to be incorporated into *HealthConnect*.

In early 2004, the Australian Government announced funding for the commencement of the national implementation of *HealthConnect*. This shifted the focus of activity from research and development towards planning for national implementation.

Despite significant investment in health information and communications technology (ICT) projects at the State/Territory and national levels, and the potentially substantial benefits that appropriate use of ICT offers, these activities largely have been uncoordinated — for example, as evidenced by major interoperability problems between different sectors of healthcare. Moreover, the level and quality of project evaluation generally have been poor. ICT in healthcare represents a significant opportunity but also a significant challenge. It is far from clear that current and past approaches will ensure a good return for the substantial investments being made.

10.5 Post-assessment processes

After medical procedures have been added to the MBS, and devices (including prostheses) have been added to the ARTG and Prostheses Schedule, they may be subject to some form of monitoring and review.

Monitoring

As stated in chapter 8, there are more than 4500 individual items listed on the MBS and supplementary schedules (DoHA 2004g). Although DoHA has primary responsibility for managing the MBS, the Health Insurance Commission (HIC) monitors and analyses MBS items to identify trends in specific item usage, broad types of service, costs and future audit topics (HIC 2003). As part of its reporting functions, the HIC examines the number, average cost and expenditure of medical services including general practitioner attendances, specialist attendances, obstetrics, anaesthetics, pathology tests, diagnostic imaging and optometry. The HIC regularly transmits this information to DoHA, which uses it to develop and review health policy relating to Medicare.

Similarly, there are many items to potentially monitor and review on the ARTG and Prostheses Schedule. For example, in relation to devices, there were around 27 500 items on the ARTG at 30 June 2004 (TGA, pers., comm., 23 May 2005) and the number of items listed for reimbursement on the Prostheses Schedule (currently around 9000 items) has expanded significantly since its establishment in 1985 (HoR 2004). This reflects increasing numbers of new products, product variations and relatively few deletions from the Schedule.

The Private Health Insurance Administration Council (PHIAC) monitors and publishes aggregate data on medical benefits paid by health funds for medical services provided in hospital. It also monitors trends in the use and costs of medical services including prostheses services (PHIAC 2005a). Individual health funds conduct their own monitoring, for example, the Hospitals Contribution Fund publishes statistics on various hospital admissions and the associated costs by type of admission (HCF 2004a).

Apart from use and costs, monitoring mechanisms can collect important clinical information. Registries have been established for diseases, medical procedures and prostheses. For instance, the National Coronary Angioplasty Register collects data from cardiac catheterisation units around Australia on coronary angioplasty procedures, indications, associated complications, lesion location, success rates and adjunctive techniques such as stenting (ABS 2002c).

Another example is the National Joint Replacement Registry which monitors the performance of prosthetic items. It collects data on patient details, the implants in their joints, the procedures adopted and the survival of the prostheses (appendix E). According to the Australian Orthopaedic Association, a registry is an effective method of determining which prostheses and surgical techniques are most successful for given demographic and diagnostic sub-groups (AOA NJRR 2004b). The registry can provide useful information to surgeons on the relative effectiveness of different prostheses and treatments.

Monitoring can play a role in determining whether a new procedure or device is clinically and cost effective. For instance, RANZCR (sub. 18, p. 2) noted that for some new technologies, ‘chicken and egg’ situations can develop where funding is needed to generate evidence of efficacy. The MIAA stated that:

Interim funding should be more widely permitted under circumstances where there is uncertainty on cost effectiveness due to lack of data. This enables clinicians to become proficient at using the technology over time, resulting in an increased ability to measure the health outcomes. (sub. 17, p. 141)

Along similar lines, the Centre for Health Economics Research and Evaluation (sub. 9) argued that consideration should be given to providing MSAC and PBAC with more policy options to overcome uncertainty in the results of cost-effectiveness analysis of new technologies.

Where MSAC has identified a medical technology which shows promise of cost effectiveness, it may consider recommending interim funding to enable the collection of further clinical and economic data. This approach can result in faster access to new medical procedures while additional evidence on cost effectiveness is being gathered.

Review

Although the MBS contains a large number of medical procedures that are commonly used in clinical practice, many have never been subjected to cost-effectiveness assessment by HTA bodies. ACT Health stated that:

... a substantial number of old technologies that were introduced before the development of the current regulatory mechanisms have never been appropriately assessed. In effect, these technologies have been ‘grandfathered in’ and should be reviewed to determine whether they should continue to receive approval. (sub. 11, p. 2)

While MSAC examines new medical procedures, a range of committees reviews existing MBS items. The Medical Benefits Consultative Committee is an informal advisory committee which reviews particular services or groups of services on the General Medical Services Table of the MBS and considers appropriate fee levels. The Pathology Services Table Committee’s primary role is to advise the Minister on the need for changes to the structure and content of the Pathology Services Table of the MBS, including the level of fees (DoHA 2004e). Similar roles are undertaken by the four diagnostic imaging Memoranda of Understanding (MoU) Management Committees.⁷

These committees may review particular procedures identified as problematic, but this may not involve a systematic re-assessment of the available evidence on clinical and cost effectiveness. DoHA (sub. PR56) indicated that such reviews can result in amendments to service descriptions in the MBS or deletion of items if procedures are no longer applicable or have been superseded by new technologies. In the latter case, new procedures would be referred to MSAC.

As noted in section 10.2, MSAC can re-assess existing MBS procedures but its ability to do so has been constrained by a lack of resources and by the type of references it has received. Some participants criticised the fact that assessments of new procedures have taken precedence over re-assessments of existing MBS items. For example, the ADIA stated that:

It seems incongruous that the efficacy of perceived, relatively new technology such as MRI and new applications for CT will continue to be subject to close scrutiny yet the great bulk of established services will not. (sub. 12, app. 1, p. 3)

ACT Health (sub. 11) also reported that Australia has strong gate-keeping processes for new technologies, but there are insufficient processes for the regular review of approved technologies.

⁷ These include the Radiology Management Committee, Cardiac Imaging Management Committee, Nuclear Imaging Consultative and Economics Committee, and Obstetric and Gynaecological Ultrasound Management Committee.

There have been *ad hoc* reviews of the Prostheses Schedule. For instance, DoHA undertook a review in 2000 to ensure that all items contained in it adhered to departmental guidelines. Those items that did not meet the guidelines were removed from the list (DoHA 2000). However, it appears unlikely that any previous reviews used clinical or cost effectiveness as criteria for categorising or rationalising the Schedule. Under the new prostheses arrangements, CAGs are reviewing a number of prostheses categories (section 10.3).

FINDING 10.7

Once listed on the MBS, medical procedures are not subject to systematic re-assessment of their clinical or cost effectiveness. While MSAC can undertake such re-assessments, its ability to do so is limited by its resources and by the types of reference it receives.

Appropriate monitoring and review processes could help to improve the overall cost effectiveness of medical technologies on the MBS and Prostheses Schedule. Such processes could facilitate the conditional introduction of new procedures and devices where evidence of cost effectiveness only becomes available over time.

11 Future advances in medical technology

The terms of reference (c) for this study ask the Commission to ‘as far as practicable, identify the likely impact of advances in medical technology on healthcare expenditure over the next five to ten years, and identify the areas of significant potential growth’.

According to Fuchs (1998, p. 2), ‘most experts believe that “technology” is the driving force behind the long-term growth of health care expenditures’. The Commission’s recent work on the *Economic Implications of an Ageing Australia* (PC 2005a) found that most of the growth in health expenditure over the last 20 years or so was due to factors such as greater demand for health services, in combination with the adoption of new technologies. Modelling estimates prepared as part of this study confirm that technology has played an important role in driving total real healthcare expenditure growth over the period 1992-93 and 2002-03. Moreover, there is some evidence that this role is becoming increasingly important (chapter 3).

It is reasonable to expect that technology will continue to play a key role in influencing future healthcare expenditure. The *Intergenerational Report 2002-03* (CoA 2002), stated that non-demographic factors (such as new medicines and increased use of diagnostic procedures) were likely to have the greatest impact on future health spending in Australia — a view broadly supported by modelling work subsequently undertaken by the Department of Health and Ageing (DoHA, sub. 34).

This chapter attempts to shed some light on the nature of likely developments in medical technologies and how they may affect healthcare expenditure over the next five to ten years and beyond. The chapter also summarises the Commission’s work in estimating expenditure impacts of selected likely future individual technologies. Further details on the assumptions and methodology used to estimate expenditure impacts are in technical paper 3.

11.1 Background

At any one time, there can be thousands of health technologies undergoing development — for example, GlaxoSmithKline Australia (sub. 21) alone has almost 150 new products in development. Many of these technologies will fail to progress through all stages of research, development, clinical trial and regulatory approval to be used for treating patients. Some advances appear to have great potential but never become commercially available, others may be unanticipated or seem to offer little potential, yet ultimately have a significant effect on healthcare outcomes. To complicate things further, some commentators over-emphasise the potential benefits, feasibility and proximity to market of some technologies under development, while others exaggerate the risks and fail to appreciate how quickly some technological advances can start to have a real impact on health outcomes.

As a result, it is difficult to identify likely medical advances and to predict the timing of their release onto the market, let alone estimate their implications for health expenditure. Net expenditure effects will depend on factors such as:

- whether the medical advance will increase or decrease the per unit cost of a particular procedure or treatment;
- how the number of procedures undertaken will change as a result of the technology development; and
- whether the advance will change the location of treatment, for example from an inpatient hospital setting to an outpatient basis.

In light of these provisos, this chapter outlines some key areas of medical technology currently under development globally that appear likely to have a significant impact on healthcare in Australia over the next five to ten years or beyond. However, it is more than likely that some unforeseen technological developments will arise and that these or other developments will not meet their initial promise.

A broad theme emerging across medical advances is the potential revolutionary influence of genomics. Many expect the continued study of genomics to provide a whole new set of tools and approaches for tackling disease, such as the development of ‘biological’ medicines and treatments (to complement or substitute for existing ‘chemically-based’ medicines) and eventually increased targeting or ‘personalisation’ of medicine:

The impact of the Human Genome Project is expected to revolutionize medical practice and biologic research well into the 21st century. (Weissleder and Mahmood 2001, p. 319)

Currently, and increasingly in future, the following key factors will also influence medical technology developments and healthcare expenditures:

- ageing — Australia's population is ageing which will increase calls on the healthcare system for services such as cardiac intervention, aged care and home healthcare;
- ageing will increase the need for treatment of chronic diseases such as osteoarthritis, which may imply high healthcare expenditure because of the long duration of treatment (some diseases once considered relatively short-term acute conditions are also becoming longer term chronic conditions) (ACT Health, sub. 11);
- patients will likely be more demanding (and perhaps more proactive in managing their care) because they are better educated and health information is more readily accessible through avenues such as the media and the internet (which is increasingly available to more people);
- there may be more emphasis on prevention and early intervention to manage health, on the basis that prevention can produce better outcomes at less cost — for example, Australians are increasing their (out-of-pocket) expenditure on items like non-prescription medicines and alternative therapies suggesting attempts to prevent illness or to generally improve wellbeing (DoHA, sub. 34);
- a shifting emphasis towards a broader definition of health that includes notions of wellbeing (including a standard of health that will enable older residents to lead more active lives) as opposed to merely the absence of disease, may imply increased expenditure on so-called lifestyle drugs and technologies (to address conditions like baldness), as well as treatments for traditional medical conditions (IFF 2001);
- rapid developments in new technologies and their increasing complexity will place demands on regulatory arrangements to adapt. For example, the divide between medical devices and drugs will increasingly blur, as will the boundaries between diagnostic and treatment technologies (AHA, sub. 25; MIAA, sub. 17);
- greater use of risk assessment tools is likely to be facilitated by developments in molecular biology, genetics and molecular epidemiology. Multivariable risk analysis is already used to predict the risk of cardiovascular disease and is likely to be used in predicting other chronic conditions such as type 2 diabetes mellitus (DM) and diseases of ageing (Kannel et al. 2004; Tracy 2003);
- point of care or home-based testing is likely to increasingly substitute for clinical laboratory testing. Consumers are already able to undertake blood glucose and pregnancy testing at home, and self-monitoring of the effects of oral anticoagulation drugs is also likely in the future; and

-
- impediments or potential barriers, that may slow or prevent adoption of new technologies, could apply across several potential medical advances. For example, the ethical and moral implications of some of the medical advances will become increasingly important, and new skills training will be required as the roles of physicians and other medical personnel change.

It is difficult to summarise the likely effects of all these factors on healthcare expenditure. Moreover, it is inappropriate to consider only the potential expenditure effects of medical advances in isolation of their expected benefits, such as the monetary and non-monetary benefits the technologies deliver to patients and their families.

While some new technologies may be cost saving on a per unit basis, they can increase expenditure overall if they increase the range of conditions or the numbers of patients that can be treated, or if they fail to substitute for existing treatments or procedures (chapter 4). For example, coronary artery angioplasty could replace a far costlier procedure (coronary artery bypass grafting (CABG)) but as the procedure is more easily performed, hospital stay is shorter and morbidity is reduced, there has been a ‘boom’ in the number of angioplasties performed in the United States and yet only a small decrease in the rate of bypass grafting (Fett 2000 using American Heart Association 1996 and Hannan et al. 1994). It has been noted that ‘there is very limited evidence of the substitution of newer for older procedures’ (Hobbs et al. 2002, p. 133). In Australia, data from Victoria and Western Australia showed that an ‘exponential increase’ in angioplasty after 1991 was accompanied by an acceleration in the rates of CABG (rather than a decline) (Hobbs et al. 2002, p. 133). DoHA reinforced the point that new technologies can reduce unit costs but also increase the number of procedures performed:

In general, technology in the broadest sense has served to reduce the unit cost of specific outcomes but also to increase the range of outcomes which are achievable. Historically the latter has outpaced the former in health care. Reduction in unit cost is clearly illustrated by the reduced average time spent in hospital ... resulting from alternative models of care, better diagnostics, improved techniques such as keyhole surgery and better ambulatory care ... However many hospital episodes would not have occurred if there was not this technological advancement. For example same day endoscopies have become a major diagnostic and therapeutic procedure which results in hundreds of thousands of new hospital episodes. So while the average length of stay is decreasing, overall the total bed days has not changed greatly ... (sub. 34, pp. 17–18)

Another factor that may increase expenditure, with perhaps few benefits, occurs when new technologies are used beyond the indications tested in clinical trials. Similarly, overall expenditure would rise if a new technology delivers little additional benefit over an existing technology and is merely an ‘add-on’ rather than

a replacement or substitute for the existing technology. For instance, Professor Karen Facey (sub. 39, p. 1) observed:

Decisions about investment in technology are often difficult because they do not yield savings, but are often add-ons to current systems or a more expensive replacement to an old system ...

More generally, as technological advances continue to improve survival rates of patients with serious diseases like cardiovascular disease and cancer, there is a potential for increased expenditure as patients are treated for longer periods of time (VDHS, sub. 24).

On the other hand, some factors may have a downward influence on health expenditure overall. For instance, the costs of treating diseases such as DM, osteoporosis and heart disease can fall dramatically if increased consumer involvement in health decisions results in behavioural change or active management of the disease. In future, increasing consumer interest in wellbeing may help prevent, or reduce the severity of, diseases that have significant lifestyle causes such as smoking and alcohol.

Some medical advances, such as new drugs, may also offer opportunities to reduce healthcare costs in other parts of the health system by, for instance, reducing hospitalisations or aged care costs. One example is drugs that reduce rejection after organ transplantation (NHMRC, sub. 36). Another is:

... if one of the 28 treatments currently being developed for Alzheimer's Disease proves effective, as well as treating a major illness of an ageing population, it could save much money in other parts of the health system such as aged care costs. (Medicines Australia, sub. 30, p. 49)

However, the South Australian Government (sub. 35) suggested that the scope to achieve additional cost savings through reducing the length of hospital stay is expected to be lower than in the past because many procedures have already been shortened to day procedures.

The use of pharmaceuticals, or other less invasive treatments, in place of options such as surgery, may also generate benefits in terms of workforce participation and productivity.

It is also difficult to predict likely impacts on future net expenditure because the volume of treatments and the per unit cost of the new technology will likely change over time. For example, the question arises as to whether the costs of new advances will stay the same or fall over time as patents expire, newer competing technologies emerge, or as economies of scale are achieved (NATSEM, sub. 1).

11.2 Technology development process

Advances in medical technology can take many years to reach the marketplace. Hundreds of companies are involved, spending billions of dollars — for example, GlaxoSmithKline Australia (sub. 21) advised that it spends about A\$6.7 billion on research and development annually. Bringing new pharmaceuticals to patients requires, on average, 10–15 years of testing, clinical research and regulatory review (PhRMA 2004) (box 11.1).

Box 11.1 **Pharmaceutical development process**

Estimates of the costs and time required to develop new drugs vary. According to the US Food and Drug Administration, it takes an average 8.5 years and costs approximately US\$500 million (FDA 2002b). The Pharmaceutical Research and Manufacturers of America (PhRMA) estimates that 10–15 years are required and Medicines Australia (sub. 30) refers to one estimate that places the cost at about US\$800 million and other estimates as high as US\$1.7 billion. The development process involves three overlapping stages which are outlined below.

Stage 1: Research and Drug Discovery. Researchers identify a targeted mechanism of action for the drug. Several possible candidates are developed and tested to determine which chemical compounds have the greatest potential to have the desired action on the enzymes, cell cultures or other substances involved in the disease. At the end of this stage there are just a small number of lead compounds. At this point drugs are patented. This stage usually takes between two and five years. For every 20–40 drugs that have been tested at this stage, only one drug will enter pre-clinical development.

Stage 2: Pre-Clinical Development. The purpose of this phase is to assess the drug's fitness for human trials. This assessment includes using tissue cultures, animals or other means to test the drug's toxicity and whether there are any serious unwanted side-effects. Suitable formulations and doses of the drug are developed. Pre-clinical development takes around one year. Just 1 in 50 drugs that enter pre-clinical development will be approved for phase I human trials.

Stage 3: Clinical Development. This stage involves four phases. Progression to each new trial phase depends on a successful outcome at the previous phase. Clinical development usually takes between five and seven years to complete. Just 1 in 5 drugs that begin phase I trials will be approved for marketing.

Phase I — involves human testing on a small group (20–30) of volunteers to evaluate safety and to identify side-effects.

Phase II — the drug is trialled on a group of 100 to 300 patients with the targeted condition to test its safety further. This involves a trial of the drug's effectiveness in patients with the disease or condition that it is expected to treat.

(Continued next page)

Box 11.1 (continued)

Phase III — involves trials on a much larger scale (between 1000 and 3000 patients), and the testing is more rigorous. Patients are randomly chosen to be treated with the drug or a control substance, usually a placebo. This phase is used to assess the drug's safety, effectiveness, side-effects and to compare it to commonly used treatments.

Phase IV — clinical development does not stop once the drug is approved as this final phase involves surveillance of the drug for adverse events within the clinical setting.

In contrast to drugs, it appears that many medical devices do not have to be accompanied by such extensive clinical trial data. This is reflected in generally shorter development times for devices.

Sources: FDA (2002b); Medicines Australia (sub. 30); PhRMA (2001, quoted in Sweeny 2002b); Rang et al. (2003); Sweeny (2002b).

As a result of the lengthy process that must be followed before a pharmaceutical can be used to treat patients, the new drugs likely to affect healthcare expenditure within the next five to ten years would be those that:

- are already in the latter stages of the development/approval process (phase III trials) although not all of these drugs will receive regulatory approval; or
- are already on the market and currently used to treat patients but a new application or use of the technology is developed.

The Pharmaceutical Research and Manufacturers of America maintains a database of medicines in development. According to this database (as at November 2004), for seven conditions alone (those identified as National Health Priority Areas by the Australian Health Ministers Conference), there were about 550 medicines undergoing human trials or awaiting approval by the US Food and Drug Administration (FDA) (Medicines Australia, sub. 30) (table 11.1).

Many of these pharmaceuticals will fail in clinical trials and thus will never be widely used to treat patients. But some of these may be available to patients within the next five to ten years. Some estimates suggest that 1 in 5 medicines that begin clinical trials reach the market while other studies suggest that, in more recent years, only 1 in 9 reach the marketplace (Medicines Australia, sub. 30). Therefore, of the drugs listed in the table below, a maximum of about 100 could be expected to be used to treat patients in future.

Table 11.1 Pharmaceuticals in pipeline, by condition^a

November 2004

<i>Condition</i>	<i>Clinical trials</i>			<i>FDA application</i>	<i>Other</i>	<i>Total</i>
	<i>Phase I</i>	<i>Phase II</i>	<i>Phase III</i>			
Cancer	56	122	62	4	1	245
Arthritis	24	27	17	9	4	81
Cardiovascular	18	35	20	0	2	75
Diabetes	18	20	9	6	3	56
Mental health	9	16	12	6	3	46
Asthma	8	20	4	5	1	38
Injury prevention	1	0	3	0	0	4
Total	134	240	127	30	14	545

^aThere may be double counting of some drugs, for example, if they are in trial for more than one condition.

Source: Medicines Australia (sub. 30, p. 46).

Relative to pharmaceuticals, the development process for medical devices is shorter and product lifetimes are also often shorter (two to four years) (MIAA, sub. 17). In 2004, the US FDA approved or cleared thousands of devices used to diagnose or treat a wide range of conditions (Centre for Devices and Radiological Health 2004). In Australia, the development time for some devices is as short as four years and for others approximately eight years (MIAA, sub. 17). In contrast to the pharmaceutical industry which comprises many large multinational corporations, there are few large multinational corporations and many small to medium sized enterprises in the medical devices industry (MIAA, sub. 17). Although the products of research efforts are often sold to larger companies, a large percentage of new medical device development is initiated by smaller companies or even individuals, such as surgeons or academics (BBI 2003).

With so many players involved, it is a challenge to identify the key advances in devices that will affect healthcare expenditure in Australia over the next five to ten years. In addition, medical devices tend to undergo continual evolution, often in response to feedback from surgeons (MIAA, sub. 17).

Different types of technology also often compete to treat the same disease. For example, some pharmaceuticals being trialled for treatment of cardiovascular disease may face competition from devices. Some of these technologies will be successful, while others will not. The process of technology development is also dynamic — some technologies may be replaced relatively early by new, more effective technologies.

In December 2003, a nation-wide system for monitoring and alerting policy makers to medical developments on the horizon was established (box 11.2) (chapter 8). This system focuses primarily on devices, tests and procedures, rather than

pharmaceuticals. Other countries also have ‘horizon scanning’ units to alert policy makers to upcoming medical developments, in some cases including pharmaceuticals.

Box 11.2 Horizon scanning

In 2003, the Australia and New Zealand Horizon Scanning Network (ANZHSN) was established to provide governments with advance notice of significant new and emerging health technologies and to alert them to their potential safety, benefits and cost impacts before the technologies are introduced into the health system.

A key element of the ANZHSN is the National Horizon Scanning Unit (NHSU) which operates out of the Health Technology Assessment Unit (University of Adelaide). The NHSU identifies new technologies and/or technologies that are likely to emerge that may have a significant impact on the health system within three years.

The NHSU conducts activities for the Health Policy Advisory Committee on Technology (HealthPACT), which also considers scanning and health technology assessment undertaken by the Australian Safety and Efficacy Register of New Interventional Procedures — Surgical (ASERNIP-S). ASERNIP-S is a program of the Royal Australasian College of Surgeons that provides an early alert system to identify emerging surgical techniques and technologies.

HealthPACT is a member of EuroScan, an international collaboration of agencies that undertake horizon scanning. EuroScan members can access all horizon scanning reports prepared by these agencies (these are usually not publicly available).

Additional information about horizon scanning can be found in chapter 8.

Sources: NSW Health (sub. 20); VDHS (sub. 24).

11.3 Projected disease burden

Identifying which of the medical technologies in the pipeline are most likely to appear on the market within the next five to ten years only provides one input to estimating what the impact of those technologies may be on healthcare expenditure. Another key factor is the expected or projected disease burden — the number of people who will benefit from the technologies in future and their level of use of the new technologies. The future burden of disease depends largely on factors such as the age and gender make-up of the population and lifestyle factors. Overall expenditure will also depend on other factors such as income, the unit cost of care, insurance coverage, whether support care is available from family and friends and so on.

Population ageing — a worldwide trend, particularly for developed economies (PC 2005a) — is a key factor affecting healthcare expenditure. In Australia, population ageing has been evident for over a century and is expected to continue as a result of both improved life expectancy and reduced fertility rates over a long period of time. Indeed, recent ABS population projections indicate that while average ages are expected to increase every year over the next 40 years, the extent of ageing accelerates between now and 2012 (PC 2005a).

The incidence of some diseases, such as cancer and dementia, could be expected to increase as the population ages. For example, the number of cancer cases rose 34 per cent between 1991 and 2001 partly as a consequence of population ageing and, while expected to survive for longer periods, numbers of cancer patients are expected to continue to increase in future (Cancer Council Australia and Clinical Oncological Society of Australia, sub. 32). In addition, population ageing will likely result in an increased disease burden due to degenerative diseases such as neurological, sensory and musculoskeletal disorders. For example, the burden of dementia is particularly expected to increase significantly (VDHS 1999). However, some diseases have shown a declining rate of incidence. For example, there has been a significant fall in incidence and mortality from coronary heart disease over the last 40 years (Fett 2000).

Lifestyle factors will also affect the future disease burden. For instance, the prevalence of obesity, a key risk factor for type 2 DM, has been rising in Australia over recent time — almost 60 per cent of those aged 25 or over are obese or overweight, representing a doubling of rates in the last two decades (Cancer Council Australia and Clinical Oncological Society of Australia, sub. 32). DoHA (sub. 34) noted that the prevalence of DM has more than doubled over the last 20 years (technical paper 3).

Table 11.2 shows the medical conditions expected to be the leading causes of disease burden in Victoria over the next five to ten years (projections for Australia are expected to be released in the near future but, in the interim, these provide a guide for Australia's projected disease burden as similar patterns could be expected) (HSV 1999). Medical technology developments occur in response to anticipated demand, which in turn largely reflects the projected disease burden. The anticipated accelerated ageing of the population is expected to be the major driver of the projected disease burden over the next few decades. Thus technological advances affecting diseases of ageing could be expected to have the greatest impact on healthcare expenditure in Australia in the next five to ten years.

Table 11.2 Top 10 ranking of disease burden, major disease groups by gender

Victoria, 1996 and 2016

<i>Males</i>	<i>Rank 2016</i>	<i>Rank 1996</i>	<i>Females</i>	<i>Rank 2016</i>	<i>Rank 1996</i>
Cancer	1	2	Cancer	1	2
Cardiovascular diseases	2	1	Neurological and sense disorders	2	4
Mental disorders	3	3	Cardiovascular diseases	3	1
Neurological and sense disorders	4	4	Mental disorders	4	3
Diabetes mellitus	5	7	Chronic respiratory diseases	5	5
Chronic respiratory diseases	6	5	Musculoskeletal diseases	6	6
Digestive disorders	7	11	Diabetes mellitus	7	8
Musculoskeletal diseases	8	10	Digestive disorders	8	9
Unintentional injuries	9	6	Genitourinary disorders	9	10
Intentional injuries	10	8	Unintentional injuries	10	7

Source: HSV (1999), p. 91.

11.4 Likely advances in medical technology

The sections below describe some of the key current developments occurring in medical technology (IFF 2003). Some of these technologies may become available as mainstream treatments or procedures within five to ten years (some are already available to a few patients or for the treatment of selected conditions), but some will likely affect healthcare beyond this timeframe. In other cases, an unforeseen stumbling block may prevent the developments from reaching patients at all. Although, in practice, the boundaries between categories (such as drugs and devices, imaging or computing advances, diagnostic versus treatment technologies) and techniques (for example, nanotechnology, diagnostics, imaging and information technology) will increasingly become blurred, the technologies have been grouped into the broad categories listed below (IFF 2003):

- rational drug design;
- imaging and diagnostic advances;
- bioengineered and artificial organs and joints;
- minimally invasive surgery, robotic-assisted surgery and image-guided surgery;
- new vaccines;
- blood substitutes;
- genetic testing, gene therapy and pharmacogenomics;

-
- stem cell therapies;
 - xenotransplantation;
 - nanotechnologies and nanomedicine; and
 - information and communications technology (ICT) developments.

Rational drug design

In the past, most drugs have been discovered through random trial and error — a slow and inefficient process (IFF 2003). The hope for rational drug design is that the use of advances in computer modelling, along with genetic information about the structure of potential drug targets, may make it possible to design optimal drugs (Goldman et al. 2004). If successful, these methods would allow researchers to investigate many more drug candidates, thus potentially generating many more new treatments:

It has been estimated that successful drug therapy currently is directed at fewer than 500 targets. Considering that the human genome contains some 30 000 genes, it is possible that its study could lead to at least 3000 to 5000 potential new targets for therapy. (WHO 2002, p. 69)

According to the Institute for the Future (IFF 2001, p. 9):

In the future, computer-based drug discovery and clinical trials conducted almost entirely via computer models will be the norm, not the exception.

The hope is that rational drug design and other design techniques may help companies reduce their drug discovery and development times and allow them to terminate research on unpromising drug candidates sooner (TCSDD 2005). This would be expected to reduce the costs of bringing a drug to market. In addition, to the extent that pharmaceuticals can substitute for hospital treatment, rational drug design might have a downward influence on future expenditure. For example, anti-coagulant and anti-platelet drugs have eliminated the need for surgery for many patients prone to heart attack and stroke (DoHA, sub. 34). And, the IFF (2001) considered that pharmaceuticals will increasingly substitute for other treatments, such as operations.

However, counteracting this possible downward influence, attempts to design drugs for more complex diseases could cause the costs to rise. For example, the FDA gave marketing approval to a rationally designed, molecular-targeted drug to treat leukaemia (Glivec/Gleevec) in 2001 (Capdeville et al. 2002) but the drug is expensive (about US\$28 000 per year) (Atkins and Gershell 2002).

Other categories of (high cost) pharmaceuticals on the horizon that are expected to delay mortality for some diseases (thereby increasing demand for these and other treatments and raising expenditure) include vascular endothelial growth factor drugs for cardiovascular disease and monoclonal antibody drugs for cancer (IFF 2001). The Tufts Center for the Study of Drug Development (TCSDD 2005) considered that oncology monoclonal antibodies would increasingly go into clinical trial following the success of some recent launches. For example, final trials are underway for a monoclonal antibody that would treat osteoporosis through injections twice a year in place of patients taking pills weekly (Langreth 2005). If it were to prove successful, this treatment would clearly bring significant benefits by preventing the complications of osteoporosis, but at high cost given the long-term nature of the treatment.

One implication of rational drug design may be that, if drugs are able to replace other treatments, future expenditure on pharmaceuticals as a proportion of all healthcare expenditure may continue to rise rapidly (IFF 2001).

Imaging and diagnostic advances

Imaging techniques (such as X-rays, computed tomography (CT), positron emission tomography (PET) and magnetic resonance imaging (MRI)) provide information on the state and functioning of tissues, bones and organs by means of a visual display. Some imaging techniques can be used for both diagnostic purposes and treatment. As a result of developments in information technologies, physics and chemistry, and in genetics and molecular biology, future developments in imaging technology are expected to include (IFF 2003):

- advances in directing the energy sources (such as X-ray, ultrasound, magnets and electron beams used to produce the images) more narrowly so that less damage occurs to adjacent tissue;
- improvements in contrast media (used to distinguish organs through variations in lightness and darkness of the images) and the resolution of detectors which will produce clearer images;
- computing advances that enable 3D rather than 2D images for improved information;
- technologies to display the images are becoming larger, of improved resolution and with better contrast;
- magnets, and therefore, scanners in MRI are becoming smaller with lower capital and operating costs offering potential for small units to be dedicated to orthopaedic, neurological and mammography applications;

-
- with respect to stenting, infrared imaging may enable assessment of factors leading to restenosis;
 - in future, PET scanning is expected to become cheaper, faster and therefore more widely available as a technique for rapidly detecting cancer that has spread or that has recurred;
 - a new class of imaging technologies for more accurate diagnosis and improved management and treatment of patients— a fusion of PET and CT — to merge anatomical and biological information all into one device, procedure and image is under development (fusion of PET and MRI is also being investigated though the main focus is on PET and CT) (DoHA, sub. PR56; Phelps 2002);
 - *in vivo* molecular imaging will enable healthcare experts to assess the effects of many drugs, and eventually gene therapies, by determining whether these treatments reach their target sites and whether they are working; and
 - functional imaging — imaging that provides information about how tissues or organs are operating (as opposed to information only about their structure) — is expected to reduce many invasive diagnostic procedures such as surgical biopsy. Future applications of functional imaging could be used to study disease and how the body responds to treatment.

Potential advances in imaging techniques are expected to improve the efficacy and efficiency of diagnosis and treatment (particularly as the distinction between techniques traditionally used for diagnosis and techniques for delivering treatment continue to blur). It is expected that the range of diseases that can be detected using imaging techniques will continue to expand. For example, improvements in MRI have already expanded its application to the heart, other organs and the foetus (Goldman et al. 2004). Advances in miniaturisation of imaging devices will improve portability, ‘if not lower cost’. Improvements in displaying images are also expected to lower the costs of producing more detailed images and in less time. And practitioners will increasingly use imaging techniques to monitor progress of treatments (Goldman et al. 2004).

Imaging techniques provide for non-invasive diagnosis of conditions. In future, there may be a reduced need for surgery to examine the structure and function of organs, or even to perform certain procedures, as imaging technologies will be increasingly employed in the place of surgery (IFF 2003).

Imaging advances will enable earlier diagnosis of conditions such as cancer, heart disease and Alzheimer’s Disease (AD) by enabling scanning devices like PET scanners, to view molecules (known as ‘probes’) attached to cells that indicate the presence of these diseases (MIAA, sub. 17). This activity is high cost and could be expected to increase healthcare expenditure though it may bring about offsetting

savings if early detection and treatment is more cost effective than treatment of a condition at a more advanced stage.

Developments in diagnostic tools for colon cancer and lung cancer are designed to diagnose the disease more accurately, at an earlier stage and using less intrusive methods. For colon cancer, prospective developments include wireless capsule endoscopy and 3D virtual colonoscopy, while computer-aided tomography will be available in future to identify very small nodules in the lung as they become cancerous (MIAA, sub. 17).

According to the Cancer Society Australia and the Clinical Oncological Society of Australia, radiotherapy (as a treatment for cancer) will also be subject to significant advances:

Radiotherapy is a cost-effective and highly technical form of cancer treatment, which will be subject to significant advances in medical technology over the next 10 years. Developments such as the emergence of Intensity Modulation Radiation Therapy, currently being trialled in Australia, and proton radiotherapy, unavailable here but used in the US and Europe, may have a major effect on the cost and effectiveness of treating cancer. (sub. 32, p. 23)

Intensity Modulated Radiation Therapy (IMRT), which is likely to become more prevalent in the next five to ten years, allows more radiation to be targeted to tumour sites, while also limiting harm to adjacent healthy tissue (Faculty of Radiation Oncology, RANZCR, sub. 18). If successful, these types of techniques could reduce hospital stays and morbidity.

It cannot always be assumed that imaging improvements will automatically lead to corresponding improvements in treatment. In some cases, the ability to diagnose a condition precisely through imaging advances may ‘run ahead’ of improvements in techniques to treat the condition.

Where they are successful in reducing the need for surgery or the length of hospital stays, imaging advances would be expected to reduce hospital costs per separation. However, the capital and operating costs of the imaging technologies themselves can be high. In addition, these technologies tend to be used as complements to existing imaging techniques rather than substitutes for them (IFF 2003), further increasing expenditure. However, over time, as the technologies are improved, costs may fall. For example, Phelps (2002, pp. 335–36) observed that over the last 20 years PET imaging technology has improved, ‘several hundred fold’, resulting in better image quality and reduced imaging time but the cost of the device has also fallen from US\$2 million to between US\$800 000 and US\$1.5 million.

The extent to which future advances in diagnostics and imaging impact on health expenditure will also vary amongst new technologies. For example, the Royal

College of Pathologists of Australasia cited a past technological advance in the diagnosis of breast cancer to note that:

... technological advances may in fact increase rather than decrease the manpower required ... whereas breast cancer was once diagnosed using only a couple of slides, it is not uncommon now for an anatomical pathologist to review more than 50 slides in order to make a comprehensive diagnosis that will enable the patient to be given appropriately tailored treatment. (sub. PR52, p. 1)

Bioengineered and artificial organs and joints

Bioengineered organs, using new biomaterials, represent an option for producing organs that will not be rejected by their recipients. Biomaterials have been used to improve artificial joints, and there has been progress in creating more complex organs, such as artificial pancreata (to treat DM), and artificial hearts (to treat heart failure) (Weksler 2002). These organs could be used as a bridge to transplantation, thus reducing mortality while patients await organ transplants (MIAA, sub. 17).

The Medical Industry Association of Australia (MIAA, sub. 17) considered that initial results of clinical trials of integrated implanted glucose sensors and implanted insulin pumps (and sensors with integrated external pumps) suggest that these artificial pancreata will be available to patients within five to ten years.

For heart conditions, left ventricular assist devices (LVADs) have been used as a bridge to transplant (though could not be used indefinitely) since the late 1980s and LVADs that could be used for permanent implant are now on the horizon (VDHS, sub. 24). In the United States, the economic feasibility of expanding indications for LVADs has been questioned as it has been estimated that 60 000 people could potentially benefit from them (Goldman et al. 2004 using Rose et al. 1999). Weksler (2002, p. 20) also recently noted that ‘the size of the chronic heart failure population could ... render them a sizeable budget item’.

For the management of back pain, artificial spinal disks (already used in Europe) may replace spinal fusions. These are expected to cost more per unit than fusion but disability during recovery is reduced (MIAA, sub. 17). With respect to knee and hip joint replacements, prostheses may eventually be constructed out of cartilage and bone (appendix E).

Tissue engineering has been occurring for over a decade to produce epidermal tissue to replace the skin of burn victims and future applications could involve regeneration and replacement of complex tissues and organs (Goldman et al. 2004).

Minimally invasive surgery, robotic-assisted surgery and image-guided surgery

Current examples of minimally invasive surgery include laparoscopic (or keyhole) surgery and coronary angioplasty. Future advances in coronary angioplasty procedures could see further falls in the need for open operations for CABG (IFF 2003). Braidotti (2005) has reported on a company that is attempting to develop a fully biodegradable stent using a polymer technology that would keep the vessel open then be re-absorbed and degraded once natural healing occurs (appendix H).

Improvements in imaging, as a result of improvements in information technology (information storage and graphics), are increasing the scope to use image-guided surgery — a minimally invasive surgical technique (IFF 2003). Applications include image-guided brain surgery through small openings in the skull. These advances allow scope for surgeons to operate remotely using robotics and 3D computer images (IFF 2003).

A relatively new way of performing minimally invasive surgery is through robotic-assisted surgery (box 11.3) but, according to the Victorian Department of Human Services (sub. 24), the equipment is expensive to acquire and maintain and the surgery takes longer. However, some of these costs may be offset by reduced stay in hospital after the operation and less pain and discomfort for patients (VDHS, sub. 24).

Improvements in computing, medical imaging and robotics will also likely increase the applications of computer-aided surgery (CAS). For example, CAS is an accepted method for neurosurgery but is still relatively new for orthopaedics, such as knee replacement surgery. CAS can improve a surgeon's precision through the use of real-time maps of the patient's anatomy which allow the surgeon to make adjustments during the procedure if required. Improved precision results in improved outcomes which would be expected to reduce the initial hospital stay, the need for physiotherapy and revision surgery. The technique also offers scope to reduce the need for pre- and post-operative X-rays and CT scans (MIAA, sub. 17).

Box 11.3 **Robotic-assisted surgery**

Robotic-assisted surgery is a minimally invasive (requiring small incisions) technique whereby the surgeon operates on a patient by controlling the movement of tiny robotic 'arms and hands' to perform surgery. The surgeon controls operation of the robot through hand movements made while watching a magnified display of the surgery site.

Currently, robotic-assisted surgery is available in two hospitals in Australia (one private and one public). In 2003, the Epworth Hospital in Melbourne was the first hospital in Australia to introduce a robotic system, and in 2004 it established the Australian Institute for Robotic Surgery. The second system was purchased by Royal Adelaide Hospital (with funds provided by the Pickard Foundation) late last year.

In Australia, robotic-assisted surgery is initially being used for cardiac and prostate surgeries though it has a wide range of potential applications. Robotic-assisted surgery is considered a significant surgical advance with the following potential benefits:

- reduced trauma to the body;
- shorter hospital stays;
- reduced post-operative complications, such as infection;
- reduced post-operative pain; and
- lower blood loss (and therefore transfusion).

ASERNIP-S conducted a 'technology overview' of a robotic system in August 2004. It noted that while robotic surgery offered some advantages over conventional laparoscopic or open surgery, it had substantial set-up and maintenance costs (including hardware and software updates) and was subject to a significant learning curve for surgeons. ASERNIP-S (2004, p. 2) also noted the 'paucity of studies comparing robotic surgery with conventional surgery'.

Sources: ASERNIP-S (2004); Cropper (2005); Royal Adelaide Hospital (2004); VDHS (sub. 24).

The increasing use of minimally invasive techniques in areas such as neurosurgery and cardiology could thus see a reduction in recovery times as well as reduced complications arising from surgery, with significant benefits for patients and potential offsetting savings in the health system. For instance, wound infection associated with open surgery has fallen with developments in minimally invasive surgery (MIAA, sub. 17). Goldman et al. considered:

These trends toward surgery that is minimally invasive and robotically performed are improving the outcome of surgical procedures while decreasing complications, hospital stays, recovery time, and costs. Driving these advances ... is the fact that in most types of surgery, the morbidity that results is largely the result of the procedures required to gain access to the affected area, rather than the procedure that is finally performed on the target organ. (2004, p. 12)

A more rapid return to work (or other activities) is also possible, producing gains in individual welfare as well as productivity gains.

However, as procedures become less invasive and, therefore, less risky, the number of candidates suitable for treatment will likely expand (for example, surgery may become an option for the very aged or frail who would otherwise not have been able to deal with the trauma of open surgery) with potentially significant implications for expenditure. Indeed, DoHA (sub. 34, p. 18) observed:

Savings in unit cost of delivering services within a hospital are difficult to harvest. The introduction of new technology changes the pattern of expenditure in complex ways ... The introduction of new imaging techniques for example, has reduced the requirement for initial exploratory operation and supported the use of laparoscopic (or 'keyhole') surgery. The new technique is clearly beneficial from the patient's perspective, and a cost saving is realised in terms of operating room time spared. However net savings are difficult to quantify since the new imaging equipment has purchase and maintenance costs, the time saved by the surgeon with that patient will generally be used to treat others who still remain on the waiting list, and as services continue to become less invasive latent demand is likely to emerge.

Given that they represent a new way of performing surgery, a potential impediment to the adoption of these surgeries is skills shortages. Also, minimally invasive techniques are best suited to high volume procedures (that is, those frequently performed) as it allows surgeons a greater opportunity to learn the techniques involved (Goldman et al. 2004).

New vaccines

In the past, vaccines have primarily been used to prevent acute diseases and infections. But in future (and recently in some cases) vaccines could be used to prevent and treat non-infectious diseases by, for example, targeting tumours (IFF 2003). According to Davis (2004, p. 17), 'the first vaccines ... to prevent cancer could be on the market within a few years'.

Several cancers are linked to infections, for example, cervical cancer is linked to the papilloma virus and stomach cancer is linked to the *Helicobacter pylori* virus (Terada 2002). One avenue for preventing these cancers involves developing vaccines for their underlying cause (other cancer vaccines work by strengthening the body's immune response). If these vaccines prove successful, they could produce significant benefits in terms of preventing cancers. Several pharmaceutical companies are working on developing a vaccine for preventing cervical cancer and one expects to file a vaccine with the FDA in 2005.

Another vaccine, developed to cure some cases of psoriasis, works by reducing the attack of lymphocytes against the patient's own skin cells thereby improving the patient's health and replacing the need for long-term pharmaceutical treatment (Fett 2000). This technology may eventually be applied to other auto-immune conditions, such as rheumatoid arthritis (Fett 2000).

Clinical trials, including some phase III trials, are underway for several vaccines aimed at treating colorectal, breast, lung, renal cell and prostate cancer, lymphoma, and melanoma (Goldman et al. 2004). Vaccines to prevent diseases like DM, AD and atherosclerosis may also be possible in the near future (IFF 2001).

Potential impediments to the development of new vaccines might include the danger of infecting patients, rather than curing them (IFF 2003), or public fears that vaccines are unsafe. Development times for vaccines are also lengthy as patients are observed for several years after they have received the vaccine. Vaccines may also pose a challenge for health technology assessment (HTA) processes — as new types of vaccines are expected to primarily deliver benefits in the longer-term, a question arises as to what is the appropriate discount rate to apply to these benefits (chapter 9). Access issues also arise, for example, such as whether a vaccine for cervical cancer should be provided to all women or only a subset of women according to risk-based criteria.

Blood substitutes

Blood shortages and high costs are driving the search for substitutes (Australian Institute of Medical Scientists, sub. 3). A blood substitute would address the problem of blood shortages and eliminate the need for testing blood for infectious diseases. Artificial blood would also likely be a universal source, that is, compatible for all blood types and would have a longer shelf life than natural blood (Goldman et al. 2004). At 2003, several companies had blood substitutes in clinical trials and IFF (2003) predicted availability of a blood substitute by 2010.

Artificial blood would have application in transfusions, cardiac bypass procedures and renal dialysis (IFF 2003) and would offer significant benefits. However, DoHA (sub. 34, p. 12) noted that adoption of blood products can pose particular challenges for HTA processes:

Cost-effectiveness studies for new technologies in the blood sector also present particular challenges ... the safety, adequacy, security and consumer confidence of the blood supply, are often considered of greater importance than subsequent cost outlays, demonstrated by the frequent adoption of the precautionary principle in relation to national blood policy decision-making. In the blood sector, it is not unusual for governments to agree to take preventative action in the face of scientific uncertainty ...

According to Goldman et al. (2004) using IFF (2000), the challenge for the developers of blood substitutes is to create a product that can perform all the functions of natural blood including oxygenating tissues and fighting infection.

Genetic testing, gene therapy and pharmacogenomics

The sequencing of the human genome (through the Human Genome Project) has raised expectations of major advances in the prevention and treatment of disease — it ‘could give rise to an amazing number of medical breakthroughs’ (Goldman et al. 2004, p. 5). This section outlines some of the different types of gene-based technologies and discusses key issues associated with their potential application.

Genetic testing

Genetic testing is currently used to predict or detect a range of rare and common conditions. It is also used for pre-natal tests for conditions like Down Syndrome. In Australia, testing for cancer-causing genes is estimated to account for approximately one-third of the total workload of clinical geneticists and genetic counsellors (DoHA, sub. PR56). For example, government and private laboratories offer genetic testing for determining either the underlying causes of breast cancer or to identify family members who may develop breast cancer (appendix L; DoHA, sub. PR56). In addition, a private company in Australia also offers DNA tests for conditions such as cancers, heart diseases and memory loss (Cancer Council Australia and Clinical Oncological Society of Australia, sub. 32).

The use of genetic testing is expected to expand in the future to allow individuals increasingly to identify their susceptibility to other more complex diseases (in which environmental and lifestyle factors may also play a part) such as cancer, DM and heart disease (IFF 2003). According to the Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32, p. 2), genetic screening is expected to ‘start having a major impact on the prevention and early detection of cancer within 10 years’. In the United States, Goldman et al. (2004, p. 5) consider that ‘predictive tests will be available for more than ten common conditions, including some types of cancer’ by 2010.

Providing it is accurate in its predictive capacity, information gleaned from genetic tests could be used for preventative strategies and earlier interventions. DoHA also noted that even where treatment or cure is not currently available, the tests:

... may provide patients with many options they would not otherwise have the opportunity to consider. (sub. PR56, p. 17)

However, it is possible to overstate the predictive ability of these tests. For example, the IFF cautions that:

... most common chronic diseases, such as heart disease, most cancers, and Alzheimer's, have a complicated and variable genetic component plus superimposed environmental and behavioural contributing factors. The sheer complexity of these diseases will make accurate prediction impossible from genetic information alone. Still, public interest and the resulting demand for new solutions will drive science to try and solve many health problems such as these. (2001, p. 18)

Genetic testing could also result in more effective use of pharmaceuticals and fewer side effects as trial and error in prescribing drugs is removed and genetic information could help guide cost-effective treatment choices (IFF 2001) (see 'pharmacogenomics' below).

However, genetic testing may provide few benefits, if any, and could generate significant costs in terms of distress to patients, if the tests were poor at accurately predicting future likelihood of disease and/or if there were no effective treatment available for the predicted disease.

Gene therapy

Gene therapy involves correcting defective genes that are responsible for disease by replacing the genes, repairing them or by changing them. In contrast to traditional pharmaceutical treatments, which are chemical compounds, gene therapy aims to use biological agents — namely DNA and RNA — to treat disease (GTRAP 2005). Various methods for delivering genetic material to the right cells are being investigated. These techniques are experimental but could potentially reduce disease prevalence by effectively preventing disease from developing or even curing the disease.

Gene technology is expected to have an increasing impact on the treatment of cancer (Cancer Council Australia and Clinical Oncological Society of Australia, sub. 32). Clinical trials are already underway to test gene therapy treatments for some types of cancer (Goldman et al. 2004). Queensland Health (sub. PR43) predicted that the first uses of gene therapy are likely to emerge in:

- killing cancerous cells more effectively and increasing effectiveness of conventional cancer drugs; and
- preventing and treating cancers by boosting patients' immune systems to recognise and destroy tumour cells.

Gene therapy has also been trialled to treat Severe Combined Immune Deficiency (SCID) and haemophilia. However, a French SCID trial has been halted twice due

to reports of trial participants developing leukaemia (Centre for Genetics Education 2004b), while haemophilia trials have also been terminated for either safety, logistical or economic reasons (Brettler 2005).

If development succeeds, gene therapy would represent a revolution in medicine because therapy could be aimed at correcting the cause of the disease, rather than treating the symptoms, and because the technology can potentially be applied to a wide range of diseases and targets (Weissleder and Mahmood 2001).

Pharmacogenomics

The sequencing of the human genome is also making it possible to identify which drug is best for a particular individual and to design drugs for specific sub-populations through pharmacogenomics — the use of molecular biology techniques to identify and study genes relevant to drug therapy (Shenfield et al. 2002).¹ Pharmacogenomics is expected to enable the creation of drugs eventually that ‘are personalized for an individual at the genetic level’ (IFF 2001, p. 9). Thus some drugs will be prescribed to narrowly defined groups of patients:

Forecasters expect that by 2020, the discipline of pharmacogenomics will commonly predict drug responses, and gene-based designer drugs will have been introduced for the treatment of cancer and other diseases. (Goldman et al. 2004, p. 5)

Improved targeting of medicine through the application of pharmacogenomics is expected to improve safety and effectiveness. Apart from providing benefits to patients, enhanced effectiveness and tolerance of medicines should result in fewer adverse effects and serious complications with potential offsetting savings in other parts of the health system. In addition, according to DoHA (sub. PR56) pharmacogenomics also has the capacity to improve healthcare delivery by better predicting adverse events and improving prescribing efficacy.

An early application of pharmacogenomics has been the development of *trastumuzab* (trade name Herceptin) for treatment of a particular type of breast cancer (Centre for Genetics Education 2004c). Herceptin targets only those cells that display an excess of the protein produced by the HER2 gene, slowing or stopping their growth (appendix I).

¹ In this report, the terms ‘pharmacogenomics’ and ‘pharmacogenetics’ are used interchangeably. Strictly speaking, ‘pharmacogenetics’ is a subset of ‘pharmacogenomics’ and refers to the genetic basis for differences in individual responses to drugs, while ‘pharmacogenomics’ is the use of molecular biology techniques to identify and study genes relevant to drug therapy (Shenfield et al. 2002). Given that individually targeted drug therapy is likely to be very expensive, the future of pharmacogenetics is likely to involve the development of drugs that work well with certain population groups, rather than just for individuals (Centre for Genetics Education 2004c).

Issues associated with the implementation of gene-based technologies

While gene-based technologies have the potential to deliver large benefits such as improved accuracy of diagnosis and increased efficacy of drug prescribing, there are a number of issues associated with their implementation. These issues are summarised below.

Timing

There is considerable debate about when some of the benefits of gene-based technologies might be realised. For example, a presentation at an OECD workshop (Baker 2002, p. 88) considers gene therapy a ‘relatively young discipline’ while the IFF predicted that it will have a high impact on healthcare in the future but that this may not occur until after 2010 (IFF 2003). Amongst comments received from participants, DoHA (sub. PR56, p. 19) considered that gene technology, especially as a method for diagnosing disease, ‘will most likely be an area of growth in the coming decade’. The Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32, p. 18) stated that:

... even the most conservative scientists and clinicians would agree that genetics will have a significant impact on medical services within the next 10 years.

Some commentators believe that the wait for more targeted drugs will be much shorter — ‘some experts say it could be as little as four years before it emerges as a clinical tool for a range of illnesses ... [including] asthma’ (Skatssoon 2005). Melzer et al. (2003) also reported that while the introduction of pharmacogenetic products is likely to be gradual, a majority of researchers in the field believed that it would have an impact on care of more than 15 per cent of patients within 15 years.

Potential impacts on healthcare expenditure

With gene-based technologies currently in their early stages of development and application, their impact on healthcare expenditure is difficult to predict. DoHA (sub. PR56) considered that gene-based technologies may result in initial increases in healthcare expenditure, but that these costs could be mitigated by:

... resulting improvements in Australian health and consequent downstream healthcare savings. (sub. PR56, p. 14)

The IFF (2001, p. 22) noted that, although ‘less expensive than invasive treatments’, genetic testing and counselling can be expensive. Similarly, DoHA (sub. 34, p. 11) observed that gene technologies may ‘permit highly expensive individual genetic

screening linked to personalised vaccination programs’ and the Australian Association of Pathology Practices considered that:

... current/recent medical practice has been directed at ‘batch’ therapy — i.e. all oncology treatments for a specific cancer are very similar. However, with the introduction of the ‘omics’ (proteomics, genomics), medical therapies have become individualised, hence leading to a potential for marked increase in costing. (sub. 4, p. 7)

Developments in genetic testing may also result in the opening of new markets, with demand for more tests and more treatments for more people as illness profiles are identified through genetic testing:

Genomics will open markets for diagnostic testing, preventative medicines, follow-up treatments and even support services such as lifestyle counselling. (PWC 1999, p. 19)

Education and support programs will also be required as anxiety and depression would likely increase if patients become aware of the diseases that may afflict them in future, particularly if those diseases are currently untreatable. There is already a large network of genetic support groups in Australia to assist people to understand and adjust to the diagnosis of a genetic condition (Centre for Genetics Education 2004a; DoHA, sub. PR56)

However, in the future, the unit cost of a genetic test may fall. The Australian Institute of Medical Scientists expressed hope that:

... costs per test ... are reduced with the application of newer micro-array and similar technologies, which offer improvement over previous extremely manual testing procedures. (sub. 3, p. 4)

In addition, if genetic testing were to result in more prevention of disease, rather than treatment at a later stage, this could potentially reduce healthcare expenditures (OECD 2005a), particularly if the information prompts individuals to reduce the risk of acquiring the disease by, for example, engaging in relatively low cost lifestyle changes. For example, DoHA noted that in familial cancer testing:

... the ability of the individual to undertake preventative measures could distinctly improve future quality of life, and minimise the need for more expensive treatment at a later stage. (sub. PR56, p. 14)

In regard to the potential expenditure impact of pharmacogenomics, DoHA (sub. PR56, p. 15) considered it ‘almost impossible’ to predict the impact of this advance on healthcare expenditure and that the impact would vary greatly between treatments.

There may be reduced expenditure if a particular drug is no longer prescribed for people in which the medicine has little or no effect (Allen Consulting Group 2004 in GlaxoSmithKline Australia, sub. 21).

Furthermore, the costs of developing some drugs may also fall. Smaller clinical trials (in the hundreds of patients instead of thousands of patients) would be possible as patients who share genetic factors can be grouped for testing a drug's clinical efficacy (Weksler 2002). Smaller clinical trials might allow drugs to reach the market more quickly and could reduce risks to participants as high-risk patients could be excluded. However, it may also be difficult to recruit sufficient numbers of patients for clinical trials given that they need to share genetic characteristics.

However, despite possible savings in drug development costs, the South Australian Government (sub. 35) observed that targeting of treatments would likely be high cost due to the need for genetic testing to pre-determine likely effectiveness of the targeted therapies. The National Centre for Social and Economic Modelling (sub. 1, p. 9) also considered that emerging targeted therapies are associated with very high costs:

... the new biotechnology-based therapies — if listed on the PBS — have the potential to increase considerably the already high growth rates of PBS expenditures.

Apart from noting that these drugs could be 'increasingly expensive', the IFF (2001, p. 10) observed that, for its target population, these drugs could effectively have a monopoly with associated pricing power. In addition, as the therapies are targeted, costs might need to be recovered from a smaller population of users (South Australian Government, sub. 35) with implications for patient access to these potentially beneficial treatments. These drugs may also pose challenges for current HTA processes which require evidence of efficacy based on extensive clinical trials involving large numbers of patients. DoHA also commented that the 'incremental benefits from such therapies would have to be very high to justify their cost' (sub. PR56, p. 21).

Ethical and privacy issues

There are serious ethical and privacy concerns that may impede the development of gene-based technologies. Fears about issues such as whether these technologies will be used to enhance specific attributes in individuals (IFF 2003) or whether genetic screening could be used to screen people for employment, insurance policies or access to government services need to be addressed (ALRC and AHEC 2003):

If consumers are not willing to share personal information, the ability to match disease profiles with a product and thereby deliver personalized medicine will be difficult, if not impossible. (IFF 2001, p. 33)

Methods to ensure that such important information is not misused will be required to garner public support for gene-based technologies. Perhaps more so than traditional medicine, gene-based therapies raise issues about how health information

is collected, shared and stored. Public confusion about the merits or potential shortcomings of gene-based technologies (for instance, as has occurred in some countries with respect to genetically modified foods) could limit or slow their development significantly (IFF 2001).

In Australia, the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (2003) have reported on the ethical, legal and social implications of gene-based technologies. In response to this report, the Australian Government has established a Human Genetics Advisory Committee (DoHA, sub. PR56). Other recommendations of the report are still being considered by the Australian Government (DoHA, sub. PR56).

Patent issues

Another potential issue associated with gene-based technologies is concern over the patenting of genes. To recoup investments in research and development, companies have sought to patent certain genes and gene sequences. However, concern has been expressed over the potential impact of this practice on healthcare costs and experimental research (ALRC 2004). The ALRC (2004) has also recently examined these issues and recommended a number of changes to the patent system to accommodate emerging scientific breakthroughs. The Australian Government has yet to respond to the ALRC's report (DoHA, sub. PR56).

Stem cell therapies

Unlike most cells in the body, which have a 'specialised' (for example, skin or bone) function, stem cells can potentially become many different types of tissues (Melton 2004). This has raised hopes that stem cells may offer a means in future to cure many illnesses by potentially regenerating or replacing organs and tissues. Indeed, stem cell research that involves implanting stem cells into the brains of patients with Parkinson's Disease to attempt to regenerate the neurons controlling movement is underway (Goldman et al. 2004). Early human trials have also begun for the treatment of spinal cord injury, and trials are underway or planned for cardiology applications (Melton 2004). Other research into cures for AD, cancer, DM and stroke is occurring and an Australian researcher recently announced that he would launch studies into cystic fibrosis, Huntington's Disease and muscular dystrophy (Simpson and Dunn 2005).

According to the IFF (2003), stem cell therapies could potentially be used to grow tissues for 'patching' faulty or diseased organs (such as hearts damaged by cardiovascular disease or pancreatic function destroyed by DM) even within five

years, but attempts to create complete organs, such as hearts, livers or kidneys, are more distant. In Australia, Simpson and Dunn (2005) note that research to enable stem cells to be used to grow spare replacement tissues (through a technique called nuclear transfer) would be possible only if changes are made to the law banning therapeutic cloning. Therapeutic cloning is one of the issues being considered in the current independent review of laws covering human cloning and embryonic research. The review is due to report to the Council of Australian Governments in December 2005 (Bishop 2005).

Human embryos and adult bone marrow are sources of stem cells (Melton 2004). Some stem cell research is focused on exploiting adult stem cells as they are more readily accessible. Other research efforts have concentrated on embryonic stem cells on the grounds that these can potentially become any tissue in the body and thus have been considered the most versatile (Coghlan 2004). However, some recent research in Australia suggests that adult stem cells taken from the nose can potentially develop into many different cell types, suggesting that adult cells may be more versatile than originally thought (Smith 2005).

Stem cell therapies could potentially expand treatment options for many diseases resulting, for example, in a large increase in organ replacement surgery. If the technology were to prove successful in humans, it would bring major benefits in terms of improving patients' lives, but would also be associated with major expenditure implications: 'the magnitude is huge, really huge' (IFF 2003, p. 132).

Some scientists consider that stem cell research is progressing too quickly:

... stem cell science is still in its infancy: we know little about which cells can develop into which tissues, under which conditions. (Melton 2004, p. 40)

And:

... while millions of pounds a year are being ploughed into the field, research is at a very early stage. There is wide disagreement about which cell surface markers identify the different stem cell types, and which tissues they can develop into. (Coghlan 2004, p. 37)

The FDA has also been cautious about letting human trials proceed (Melton 2004).

Apart from the state of scientific knowledge, strong legal, ethical and religious objections (such as opposition to the collection of stem cells, particularly embryonic stem cells) are other serious impediments to the development of stem cell therapies. For example, in Australia, scientists could only use excess *in vitro* fertilisation embryos created before 5 April 2002 for research, but this ban recently expired. In addition, if recent Australian research (and anticipated trials) eventually make it possible to obtain stem cells relatively easily from an adult patient (such as through

the nose) and to grow them in the laboratory for re-introduction into the *same* patient, this may address some of the current ethical objections to stem cell therapies and would also be expected to avoid the risks and costs that otherwise arise when the patient's body rejects introduced (foreign) cells (Smith 2005).

Xenotransplantation

Xenotransplantation refers to the transplant of cells, tissues or organs (such as kidneys, livers and hearts) across species — current research efforts focus on the pig (Goldman et al. 2004). In theory, if successful, xenotransplantation could provide a greatly increased supply of organs for transplantation to treat both chronic conditions, like DM or Parkinson's Disease, or to replace malfunctioning tissues/organs as a result of organ failure (for instance renal failure).

Organ xenotransplantation

Initially, organ xenotransplants would likely be used for several months while the patient awaits a human organ but, according to the IFF (2003), they may be offered as permanent transplants within approximately 10 years. The feasibility of organ transplants has been enhanced by the fact that xenotransplants of nervous tissue are already being used to treat Parkinson's Disease (Goldman et al. 2004 using IFF 2000).

If successful, organ xenotransplantation could have a large beneficial impact on the health status of many individuals given the long waiting lists for suitable donor organs, particularly as the list of organs suitable for transplantation has grown. As a result, potential application of the technology, if successful, could have significant implications for healthcare expenditure. For example, a study by Goldman et al. (2004) estimated the cost of heart xenotransplantation at potentially US\$50 000 to US\$100 000 per patient.

Cell xenotransplantation

Another possible use of xenotransplantation is treatment of chronic conditions such as DM with cell xenotransplants (IFF 2003). Clinical trials on animals have reported successful results from the transplantation of pig islets (specialised cell groups in the pancreas) to treat type 1 DM (Elliott et al. 2005). Living Cell Technologies (sub. 44) reported that human trials of cell transplants for treatment of type 1 DM are due to begin overseas in early 2006.

Potential impediments

Potential impediments to widespread adoption of xenotransplantation include concerns about transmitting diseases between species, ethical issues and concerns about equitable access to the technique (IFF 2003). A method for removing the need for lifelong immunosuppressive therapy would also need to be identified (Goldman et al. 2004). For example, type 1 DM sufferers have been shown to be reluctant to undergo cell xenotransplantation after being told immunosuppression therapy increases the risk of infection or cancers (Deschamps et al. 2005). There is some evidence that researchers and companies are working to overcome these impediments. For example, Living Cell Technologies (sub. PR44) drew attention to a number of advantages in its approach to cell xenotransplantation including:

- the use of animal cells that are not genetically modified;
- the absence of the use of toxic immune suppressive drugs; and
- use of high health status pigs as source animals.

The scientific capability to perform organ xenotransplants successfully may also be some time away. For example, experts surveyed by Goldman et al. (2004) considered the probability that organ xenotransplants would be available within 10 or even 20 years as very low (less than 5 per cent). Few attempts at organ xenotransplantation into humans have been made (and recipients' survival has been extended by only a matter of days) thus much research would need to occur before clinical trials can be conducted (Goldman et al. 2004).

Furthermore, the National Health and Medical Research Council (NHMRC 2005b) has recently made a number of decisions with respect to organ and cell xenotransplantation which could delay the development of this technology in Australia, including:

- a ban on clinical trials of animal-to-human whole organ transplants for five years; and
- a ban on clinical trials using animal cellular therapies for five years.

Nanotechnologies and nanomedicine

Nanotechnologies involve the production and application of materials (nanowires, nanotubes and nanoparticles) at a tiny — nanometre (equal to one-billionth of a metre) — scale. This allows users to exploit the different properties (such as changed strength or heat or electrical conductivity) that materials have at the nano scale (RS and RSA 2004).

Nanotechnologies can be applied to just about any field. For example, they have been used for years on computer chips. Apart from healthcare, they also have applications in the chemicals, textiles, transportation and energy sectors. In healthcare, tiny devices are being developed to deliver drugs directly to the site of the body in need. This development could result in more effective delivery of the dosages required, and protect the drug from degradation (Nowak 2005). Such technologies might eventually have application in treating cancer by delivering chemotherapy direct to tumours (Nowak 2005).

The MIAA (sub. 17) considered that developments involving the convergence of nanotechnology, information technology and biotechnology would offer potential to repair damaged hearts and to cure type 1 DM and that nanotechnology could be used to kill cancer cells through heat treatment.

Nanotechnologies may also have application in medical devices such as joint replacements and heart valves. The materials currently used to make medical implants sometimes wear out during the patient's lifetime. In future, nanoceramics, such as zirconia, may represent bio-compatible, lightweight, strong and hardwearing alternatives to current materials used in implants (RS and RSA 2004) offering alternatives for replacing, restoring or improving the function of tissues and organs.

In addition, nanotechnologies may have potential to enhance diagnostic and therapeutic techniques by producing images at the cellular level at a much higher resolution than MRI and by reducing the size, but improving the accuracy, of sensors. They also offer potential as tools for monitoring patients' health (RS and RSA 2004).

Some commentators consider that some applications of nanomedicine will be available in the near future — about five years (Smith 2004). In the United States, some medical products containing nanoparticles are already on the market but many other medical applications of nanotechnologies, such as for targeting the delivery of drugs to specific sites in the body or for gene therapy, are likely to occur over the longer term (over 20 years) (RS and RSA 2004).

The potential toxicity and health and safety implications of nanoparticles are currently unclear (HSE 2004). Some applications of nanotechnologies have raised similar ethical concerns as gene therapies and other developments. The potential for tiny devices to monitor health could bring significant benefits but may also raise privacy issues and concerns about potential misuse of monitoring functions (RS and RSA 2004).

ICT developments

Several submissions commented that there remains significant scope in the health system to take greater advantage of the ICT developments that have significantly changed many other industries. For example:

... health has been a slow adopter of ICT primarily due to chronic under-investment and the complexity of many of the information systems and their implementation. (VDHS, sub. 24, p. 27)

And:

A matter of ongoing concern [in the context of cancer control] ... is the paucity, compatibility, and integration of information systems. There have been some productive developments in this area, e.g. the NSW Radiotherapy Information Strategy, but this is limited in its application. (Faculty of Radiation Oncology, RANZCR, sub. 18, p. 3)

Dr Trevor Kerr (sub. 16, p. 3) also considered that the healthcare industry has not made sufficient investments in information technology for performing activities such as ‘storing, processing and analysing patient histories, drug regimens, claims and billing’.

Many hospitals have in comparison with businesses of comparable size, incredibly antiquated ICT systems, with consequent implications on areas such as administrative cost control, reporting, logistics and inventory management.

Although, in some cases, implementation or trials are already underway, the following areas could benefit further from ICT developments in the future (DoHA, sub. 34; IFF 2003):

- greater automation of processes such as maintenance of medical records (IFF 2003);
- improved data analysis and storage could result in an improved understanding of the nation’s disease profile, facilitating the design of preventative programs to improve healthcare planning and delivery (IFF 2003);
- continuing reduction of the costs of communication between healthcare providers and between patients and healthcare providers;
- more communication between suppliers, other healthcare providers, regulators and patients will likely occur through the internet. Patients are also expected to use the internet increasingly to source information about their disease or condition, the treatment and self-care options available, and to access support groups;

- cancer diagnosis and predisposition profiling could dramatically improve from the development of large scale computational bioinformatics aimed at further analysing DNA. This, in turn, could lead to reduced healthcare expenditure in the future (AAPP, sub. PR59); and
- telehealth and telemedicine links will continue to expand offering new ways of managing patients and monitoring their health status (IFF 2003).

In future, ICT applications could enable more patients to substitute trips to their doctor or to medical facilities with communication through ‘telehealth’ and ‘telemedicine’ links, while improving communication of medical data between home and the hospital or care facility (Pompidou 2002). There are already some telehealth/telemedicine networks established in Australia (box 11.4).

Box 11.4 Telemedicine in practice — an example

In Katoomba hospital, doctors are able to use a Virtual Critical Care Unit (ViCCU™) to communicate with specialist doctors at the Nepean Hospital in Penrith, 50 kilometres away. The ViCCU™ allows the doctors in Penrith to see the patient through a camera that provides the clarity of digital television.

The ViCCU™ — a high-speed internet-based network — provides Katoomba doctors with virtual access to Penrith doctors 24 hours a day. Previously, consultations with Penrith doctors could only occur by telephone.

Some of the benefits of the ViCCU™ are that better decisions are made about whether, and where, a patient should be transferred and, if the patient is transferred, staff at the receiving hospital are better prepared for the patient's arrival. Improving decisions about patient transfers is important because it saves lives and money.

The ViCCU™ and the high-speed network were built by the Centre for Networking Technologies for the Information Economy (CeNTIE), a joint initiative of the Department of Communication, Information Technology and the Arts and the CSIRO Information and Communications Technology Centre. The ViCCU™ is just one of the projects that CeNTIE has been working on during the past three years. For example, another application is a networked virtual surgical training centre which allows students to operate on a virtual body under the guidance of experienced surgeons who may not even be in the same room.

CeNTIE has spent \$44 million over three years developing the national high-speed network and the applications that run on it.

Source: Sears (2005).

Telehealth and telemedicine links, as well as other ICT developments (such as electronic health records, remote monitoring of patients and increased use of the internet as a source of communication and information) that are currently being

trialled or increasingly implemented across Australia are discussed further in appendix K.

In the short term, the costs of establishing ICT systems or links and of training staff can be very high (AAPP, sub. 4; Dr Trevor Kerr, sub. 16) but, generally, ICT developments are expected eventually to deliver cost savings such as reduced administration costs, time savings, lower transportation costs for remote patients and less ‘doubling-up’ of pathology and radiology tests.

Improved patient care as a result of fewer errors, reduced adverse events and side-effects from drug interactions, and better access to care for remote patients is expected to be an important outcome of future ICT developments.

The Australian Healthcare Association (sub. 25, pp. 3–4) summarised the cost savings that could accrue from improved information management systems:

... [ICT] are promoted as having the potential to be cost reducing. An example is the potential for electronic medication management. It is estimated that 2-3% of Australia's 5.9 million hospital admissions are related to problems with medicines. This accounts for a fifth of all mistakes in the health care system in Australia, costing public hospitals \$380 million a year ... Electronic medication management systems, by giving doctors immediate information about potentially dangerous interactions with other drugs and potential allergic reactions, have the capacity to significantly reduce the error rate and thus the costs, as well as improving outcomes. They also create a more efficient system for the interaction between physicians, nurses, pharmacists and other health-care providers. US studies have shown that, when an electronic medication management system is implemented, the rate of adverse drug reactions is reduced by 40.9% and prescription errors by 99.4%. The systems can also be used to order X-rays, pathology, special diets and other services for patients.

Potential impediments to technological advances in the areas of data storage, retrieval and the linkage of health records focus on the need to address privacy and confidentiality issues. To ensure that data can be used by as many parts of the healthcare system as possible, the rollout of ICT improvements will also require consistency in record-keeping between providers so that data can be easily and efficiently transferred between medical professionals and to avoid duplication in designing basic elements of data storage and retrieval systems.

A possible scenario for future medical advances

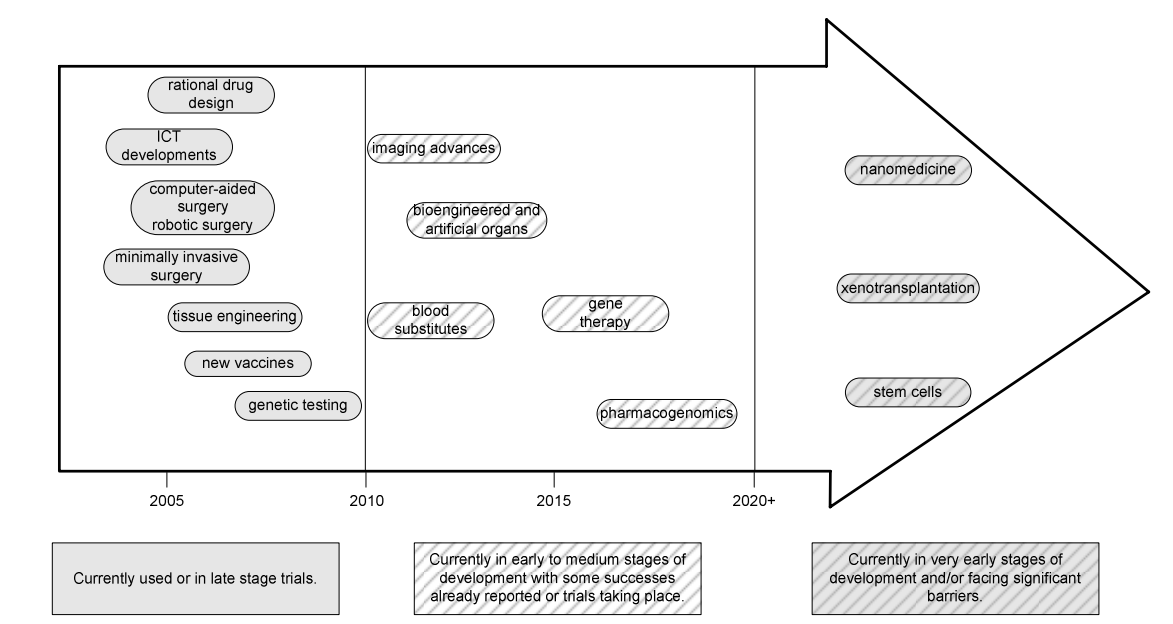
Based on the analysis presented above, one possible scenario for when advances in medical technology may become available to patients is presented in figure 11.1. The figure is divided into time periods, with the placement of the technologies in different time periods reflecting:

A possible scenario for future medical advances

Based on the analysis presented above, one possible scenario for when advances in medical technology may become available to patients is presented in figure 11.1. The figure is divided into time periods, with the placement of the technologies in different time periods reflecting:

- their current status of development. For example, robotic-assisted surgery and genetic testing are already being used and thus are expected to be more widely used in the next five years, whereas nanomedicine and stem cells are still in very early stages of development; and
- the likelihood that the development of the technology could be impeded by issues such as ethical and privacy concerns. Stem cells, xenotransplantation and gene-based technologies face at least one of these impediments.

Figure 11.1 **Medical advances — possible future developments?**



11.5 Illustrative expenditure impacts of some future advances in medical technology

This section summarises the Commission's work on estimating the expenditure impacts of some likely future technologies on selected treatments for the disease categories of cardiovascular disease, cancer, DM and neurological disease. As the estimates are only intended to be an illustrative guide to possible impacts of future advances, quantitative estimates are not presented in this section. Rather, only the likely direction of impacts— expenditure increasing or decreasing — is presented.

-
- lack of direct comparability between disease prevalence, incidence and cost data; and
 - the need to make general assumptions about unit costs, volumes, offsetting cost savings and health inflation.

A ‘technology-specific’ rather than an aggregate or ‘residual’ approach has been used to estimate future expenditure impacts. According to Mohr et al. (2001) the key advantages of the technology-specific approach are that:

- it treats technologies at an identifiable, descriptive level, rather than as a residual; and
- analysis can be tailored to accommodate unique aspects of medical advances, such as their impact on quality of life.

In estimating net future expenditure impacts, it is assumed that the selected advances in medical technology will occur by 2015-16 (ten years into the future). To assist in determining whether a new technology is expenditure increasing or decreasing, a comparison is made between estimates of:

- net expenditure in 2015-16 using a new technology for treatment of a condition within a disease category; and
- net expenditure in 2015-16 using a current technology for treatment of a condition within a disease category.

Estimates are derived for the following four advances in medical technology:

- insulin sensitisation drugs for prevention of type 2 DM;
- implantable atrial defibrillators for control of atrial fibrillation and stroke prevention;
- robotic-assisted surgery for prostate cancer; and
- a vaccine for treatment of established AD.

These technologies have been selected from a study by Goldman et al. (2004) aimed at predicting future advances in medical technology in the United States. The selected technologies encompass a broad range of medical interventions — pharmaceuticals, devices, surgical procedures and vaccines — across different disease groups. Reasons for selecting these technologies include:

- the technology is currently in advanced clinical trials or is already widely used overseas and therefore has a reasonably high likelihood of being introduced widely in Australia over the next ten years; and

-
- the technology is considered at least a partial substitute for an existing technology, allowing for comparison of estimated net expenditure impacts of current and future technologies.

Insulin sensitisation drugs for the prevention of type 2 DM

Insulin sensitisation drugs for prevention of type 2 DM among the obese population are a likely future advance in medical technology. Key benefits from this advance could include a reduction in morbidity and mortality associated with type 2 DM. Offsetting cost savings could also be achieved through a reduction in healthcare expenditure for treatment of this condition.

Recent research has examined the use of a drug from the thiazolidinedione class as a preventative treatment for type 2 DM (Goldman et al. 2004). Currently, two drugs from this class are used for secondary treatment of type 2 DM. At this point in time, there is limited data from human trials to suggest that prolonged treatment with a thiazolidinedione can prevent the development of type 2 DM in high-risk persons (Goldman et al. 2004). However, for the purposes of illustrating likely future expenditure impacts from treatment of type 2 DM, it is assumed that one drug from the thiazolidinedione class is widely prescribed in Australia by 2015-16 with the aim of preventing type 2 DM among the obese population.

Details of assumptions regarding unit cost, volume and offsetting cost impacts of a type 2 DM drug are presented in technical paper 3. In summary, these assumptions are:

- the unit cost of a type 2 DM prevention drug is relatively more expensive than other existing oral blood glucose lowering drugs;
- there is a significant expansion in the number of persons taking oral blood glucose lowering drugs, as the drug is used for prevention and not only treatment of type 2 DM; and
- offsetting cost savings are achieved from a corresponding reduction in the prevalence of type 2 DM among the obese population. These cost savings offset approximately one-quarter of the cost of a type 2 DM drug.

The analysis suggests that a type 2 DM prevention drug would be likely to significantly increase health expenditure in Australia. Therefore, widespread introduction would likely depend on whether the intervention is considered beneficial and cost effective compared with other treatments such as lifestyle modification and surgery for the severely obese.

Implantable atrial defibrillators for control of atrial fibrillation and stroke prevention

Implantable atrial defibrillators (IADs) are a promising new treatment for atrial fibrillation (AF), a heart condition where the pathway of the normal electrical stimulation to the atria is abnormal. AF is associated with increased hospitalisations, heart failure, acute myocardial infarction and an increased risk of stroke (Santini and Ricci 2003). Current treatments for AF include antiarrhythmic drugs and external defibrillation in hospital. Anticoagulant drugs are also commonly prescribed to reduce the risk of stroke. Key benefits of IADs include improved quality of life and decreased symptoms (Goldman et al. 2004).

There are currently a number of safety and tolerability concerns over IADs. However, further research aimed at minimising pain associated with IADs is expected in the future. For the purposes of illustrating future expenditure impacts of treatment of cardiovascular disease, it is assumed that IADs are widely available to Australian sufferers of AF by 2015-16 with the aim of managing AF and reducing the incidence of stroke.

Details of assumptions regarding unit cost, volume and offsetting cost impacts of using IADs to treat AF are presented in technical paper 3. In summary, these assumptions are:

- unit costs of IADs are comparable with the existing cost of implantable cardioverter defibrillators used to treat ventricular fibrillation;
- IADs are available to all patients diagnosed with AF in 2015-16; and
- offsetting cost savings are achieved from a corresponding reduction in the incidence of stroke. These cost savings offset approximately one-tenth of the cost of IADs.

The analysis suggests that IADs would be likely to increase health expenditure in Australia significantly, largely due to the high unit cost of IADs relative to existing AF treatments and the large eligible population.

However, the high potential costs of such an intervention may make feasibility problematic. It may also be the case that IADs are themselves replaced over the next 20 years by catheter-based ablation techniques aimed at stopping the initiation or maintenance of AF (Goldman et al. 2004).

Robotic-assisted surgery for prostate cancer

Robotic-assisted surgery represents the latest advancement in surgical treatment of prostate cancer. In the US, approximately 10 per cent of radical prostatectomy

procedures are robot-assisted (Binder et al. 2004). Technical paper 3 outlines a number of other factors that also suggest that this type of surgery will become widely available over the next ten years in Australia.

Robotic prostatectomy (RP) is considered a substitute for open radical prostatectomy and laparoscopic radical prostatectomy (El-Hakim and Tewari 2004). Open radical prostatectomy is the most common prostatectomy technique performed in Australia and involves the removal of the whole of the prostate gland through a cut in the abdomen (Andrology Australia 2003). RP essentially involves performing laparoscopic surgery with the aid of robotic technology (El-Hakim and Tewari 2004). Potential benefits of RP include more precise removal of the cancer and better preservation of sexual function and urinary control (El-Hakim and Tewari 2004).

Details of assumptions regarding unit cost, volume and offsetting cost impacts of RP for treatment of prostate cancer are presented in technical paper 3. In summary, these assumptions are:

- the total cost of an RP procedure is assumed to be up to 25 per cent higher than conventional open radical prostatectomy (Lotan et al. 2004);
- the potential benefits of RP (as noted above and in box 11.3) contribute to an increase in the growth rate of radical prostatectomy; and
- offsetting cost savings are achieved through a reduction in hospital stay.

In summary, RP would likely increase health expenditure in Australia, although to a significantly smaller degree than a type 2 DM prevention drug or IADs. However, it may also be the case that key drivers of cost for RP will decrease in future, for example, the cost of the robot may decrease and operating room times may decrease as surgical teams become more familiar with the technology. Other benefits such as improvement in post-operative quality of life and a faster return to work may also make RP a cost-effective option (Morgan et al. 2005).

Vaccine for treatment of established AD

A vaccine for established AD is a possible future breakthrough. AD is characterised pathologically by the development of plaques of beta-amyloid in brain cells (Goldman et al. 2004). AD is the most common cause of dementia disorders and is currently incurable (Access Economics 2003a).

Currently, the cholinesterase inhibitors are the class of drugs approved for use in Australia to improve cognitive function in sufferers of AD. In addition to these drugs, a number of other drugs based on the amyloid hypothesis are currently being

trialled. One of the most promising streams of research in this area has been development of a 'vaccine' to clear amyloid once it has been deposited (Goldman et al. 2004). The likely effect of such a vaccine would not be to cure AD, but to decrease the rate of progression by between 20 and 50 per cent (Goldman et al. 2004). The key benefit of this vaccine would be an improvement in cognitive function and thus an improvement in quality of life.

A recent human trial of an AD vaccine was terminated early after 5 per cent of patients developed inflammation of the brain. However, some positive results from this trial have also been reported, including a significant reduction in cognitive decline (Hock et al. 2003). Current research is focused on refining the vaccine to avoid side effects.

To illustrate the potential effects of future technology on treatment of neurological diseases, it is assumed that human trials into an AD vaccine continue and that the vaccine is demonstrated to be successful in slowing the progression of AD by 20 per cent by 2015-16 (Goldman et al. 2004). The analysis also suggests that an AD vaccine is likely to result in an increase in health expenditure relative to continuing with existing treatment.

However, it may be that the vaccine will have a high probability of acceptance in Australia if it can demonstrate benefits over cholinesterase inhibitors such as improvements in quality of life.

Summing up selected future expenditure impacts

Table 11.3 summarises the qualitative estimated future net expenditure impacts of the selected advances in medical technologies. To varying degrees, all four selected technologies are predicted to be expenditure increasing. These outcomes are consistent with Mohr et al. (2001) and Goldman et al. (2004), who both found that new medical advances they examined would have an upward impact on healthcare expenditure.

Table 11.3 Estimated net expenditure impacts of selected advances in medical technology

<i>Technology</i>	<i>Disease category</i>	<i>Per patient costs</i>			<i>Volume</i>	<i>Net expenditure impact</i>
		Unit cost	Substitute/ complement/ add on	Costs elsewhere		
Insulin sensitisation drugs for prevention of type 2 DM	Diabetes	↑	Partial substitute	↓	↑	↑
IADs for control of AF and stroke prevention	Cardiovascular disease	↑	Substitute/ add on	↓	↑	↑
Robotic-assisted surgery for prostate cancer	Cancer	↑	Substitute	↓	↑	↑
Vaccine for treatment of established Alzheimer's disease	Neurological disease	↑	Substitute	na	↑	↑

na Not available.

Based on the assumptions outlined in technical paper 3, all four advances in medical technology examined would appear likely to increase health expenditure in the future. Because the results depend heavily on assumptions regarding volumes, unit costs, offsetting cost savings and health inflation, they serve only as illustrations of possible expenditure impacts of future technological advances. Importantly, these technologies also have the potential to deliver significant benefits, which have not been evaluated in this expenditure analysis.

11.6 Conclusions

Population ageing and rising patient expectations, combined with medical advances, hold the prospect of increasing healthcare expenditure in the future. This chapter has outlined only some aspects of what the future of healthcare might bring and has, by no means, covered all the new technologies currently in the pipeline.

While predicting the future is fraught with difficulties, it seems likely that new medical technologies will deliver major benefits to the community by incorporating better understanding of the molecular biology and genetic basis of disease and by merging advances in fields like imaging and information technologies.

The expenditure impacts of these uncertain developments are less clear depending on factors such as exactly which technologies will become available and when, who will access them, how the technologies will be used, to what extent the technologies will be more effective than those currently available and whether the technologies will expand the range of conditions that are treatable. However, the four technologies examined in this chapter are all projected to be expenditure increasing, an outcome generally related to their high unit costs and potentially wide application.

This chapter has highlighted the possible effects that some medical advances may have on medical practice, community benefits and healthcare expenditure in the future, assuming other important influences, such as lifestyle decisions (for example, steady declines in smoking), public health campaigns (for example, bans on smoking in public places), HTA processes and incentives contained in the health system overall, remain unchanged.

FINDING 11.1

New medical technologies in the pipeline have the potential to revolutionise the practice of medicine over the next 10 to 20 years. Significant benefits to the community could be delivered through the development of biological and targeted treatments, convergence of different types of technologies and application of new technologies to treat chronic diseases.

FINDING 11.2

New medical technologies in the pipeline are likely to have high unit costs and potentially wide application. When combined with significant demand pressures arising from higher incomes, an ageing population and increasing community expectations, these technologies have the potential to significantly increase health expenditure by governments, insurers and the wider community.

FINDING 11.3

ICT developments have significant capacity to improve health outcomes in their own right, or by providing architecture for the development and diffusion of other medical technologies and more efficient and safer delivery of health services through greater connectivity. Realising this potential will require better upfront assessment, planning, coordination and more investment.

12 Conclusions and future policy challenges

This chapter briefly draws together key conclusions and outlines future policy challenges arising from likely advances in medical technology.

12.1 Conclusions

That advances in medical technology can induce increased spending is not necessarily a problem — the critical issue is whether increased spending brings benefits that exceed the additional costs.

In other markets, increased spending can be presumed to signify increased benefits and net community benefits overall, but normal market tests do not generally apply in the market for healthcare and medical technology. In particular, decisions to use advances in medical technology are often divorced from the requirement to pay for them. Thus, patients and their doctors have incentives to use technologies even if they are perceived to provide only negligible health benefits, and without much focus on the cost. On the other hand, governments and institutions that fund technology typically face incentives to control spending. Sometimes ‘rationing’ of access to new technologies is based on assessment of community-wide costs and benefits, but frequently it is not.

The weight of evidence suggests that advances in medical technology over the past ten years, in the aggregate, have been a (possibly the) major driver of increased private and government health expenditure. Importantly, however, the impact of the supply of advances in medical technology on health expenditure cannot be considered in isolation from demand and policy influences. It is the interaction of supply and demand factors that determines the ultimate level of spending and technology use. Rising incomes and population growth, community expectations, subsidised consumer prices, growth in private health insurance membership coupled with ‘no-gap’ arrangements and, to a lesser extent, past increases in the average age of the population, have also been important drivers of technology use over the past ten years.

Analysis of individual technology impacts likewise suggests that many if not most individual new technologies have increased expenditure. For some, the expenditure impact has been unambiguous because they have higher unit costs, complement or add to the existing mix of technologies, or treat an entirely new disease. Others have reduced unit treatment costs or have generated offsetting savings elsewhere in the health system, but at the same time have facilitated significant increases in the volume of treatment.

Although the benefits of many advances in medical technology are demonstrable and substantial, it is not possible to say *precisely* what impact advances in medical technology have had on the overall cost effectiveness of the health system. On the whole, these advances arguably have often provided value for money, although the estimated cost effectiveness of individual technologies, where such measures are available, varies widely. For some, the net benefits have been negative, or very incremental or are as yet unknown.

Indeed, it is virtually impossible to conclude that a particular technology will *always* be cost effective or, for that matter, not cost effective — this will depend on how and by whom the technology is used in practice and the cost effectiveness of alternative treatments.

There is some evidence that some technologies are not being used as cost effectively as they might. In some cases, this is because they are supplied to patients at low risk levels or are used inappropriately, in others, because they are being under-used by some patient groups with apparent clinical need. There is also evidence that some technologies diffuse into practice without a full assessment and, thus, with little known about their cost effectiveness. In some cases, side effects have emerged, diminishing benefits. The cost effectiveness of others may come to be surpassed by newer technologies yet they remain in wide use.

Health technology assessment (HTA) has a critical role to play in promoting cost effective use of new medical technologies. While existing HTA processes play an invaluable role in assessing the cost effectiveness of many new pharmaceuticals, procedures and some devices, there appear to be numerous opportunities for improvement, including:

- There is considerable scope for a more coordinated and systematic approach to HTA across the public and private sectors and across levels of government, as well as more systematic reviews of efficacy and cost effectiveness of new technologies once they are in use. (Post-release monitoring and reviews can allow conditional introduction of new technologies and may be particularly suited to new medical procedures and devices (for which cost-effectiveness assessment is not well-developed), as well as new targeted biological drugs.)

-
- There is room for greater national coordination of the development of clinical guidelines, based on cost-effectiveness assessment, to inform decisions by clinicians or, indeed, their patients.
 - There seems to be potential for greater use of overseas efficacy, effectiveness and, to some degree, cost-effectiveness analysis and related clinical guidelines. This seems particularly relevant considering the relatively small size of the Australian health budget in a global context and bearing in mind that most medical technology is imported.
 - There would appear to be grounds for greater procedural transparency and community involvement in HTA processes and their underlying objectives both to assist with assessing the inherently subjective benefits of technologies and to foster greater acceptance of individual technology funding decisions.
 - There would appear to be significant risks if current and foreshadowed substantial expenditure on information and communications technology initiatives (including *HealthConnect*) is not subject to appropriate cost–benefit evaluation.

These are general, indicative findings. A comprehensive review of HTA arrangements would be required to formulate recommendations that take all costs and benefits into account, and is beyond the scope of this study. In particular, a system-wide review looking at duplication and overlap and opportunities for greater efficiency would seem to have merit. In some areas, changes are already underway.

Importantly, the limitations and costs of HTA itself, as well as the potential benefits, have to be considered. Extending complete assessment to every technology regardless of the cost (including not only the substantial administrative and compliance costs but also the potentially large costs of delaying the introduction of beneficial technology to the Australian community) would not be desirable.

It is especially important that HTA is used to encourage optimal purchasing and use of technology, not simply to restrain expenditure pressure posed by new technologies. The primary objective of HTA should be to promote community wellbeing, not to achieve narrow government budget objectives. Greater community involvement in HTA processes could assist in this regard.

12.2 Future policy challenges

What can be described as revolutionary advances in medical technology are in the pipeline, emanating largely from the study of the human genome. Medical technology research and development increasingly are being aimed at diseases of

ageing (for example, cancers, dementia, arthritis) and diseases associated with lifestyle (for example, smoking and obesity-related diseases such as cardiovascular illnesses and diabetes). Some of these developments could facilitate the prevention of disease while others might transform life threatening illnesses (such as cancers) into manageable chronic conditions. Many advances — whether preventative, diagnostic or treatment — are expected to provide significant benefits to the Australian community, but will do so at significant cost.

Future technological advances, interacting with (and encouraged by) growing demands for health services driven especially by an anticipated rapid increase in the average age of the population, as well as income growth and strong community expectations that new technologies should be accessible to all, will make for a potent mix. They will place increasing pressures on health systems posing challenges for governments, private insurers and the community generally. They are also likely to heighten risks of differential access to advances in medical technology (between private and public patients, advantaged and disadvantaged socioeconomic groups and Indigenous and non-Indigenous populations).

These increased spending pressures underscore the need for more systematic technology assessment to facilitate equitable, evidence and needs based access. Addressing existing gaps and improving HTA processes could identify, facilitate access to and use of, beneficial technologies, especially compared with alternative rationing mechanisms that are not evidence based. More comprehensive and systematic HTA is likely to entail more resources (including investment in necessary skills), but has the potential to generate large pay-offs over time.

However, technology is only one input in healthcare and health technology assessment is not a panacea. Concerns about technology use often reflect broader structural, incentive and resourcing problems in Australia's healthcare system. For instance, under a regime of continued universal access to most health care, where incentives to use technology are divorced from the need to pay for it, advances in medical technology will perpetuate tensions between community expectations and demands and budgetary priorities.

So although better evidence of the relative cost effectiveness of technologies has the potential to facilitate improved health outcomes by informing purchasing and funding decisions by governments, hospitals, medical practitioners and individuals, appropriate *use* of technology ultimately will depend on the incentives facing consumers, clinicians and those funding purchases of technology, as well as the availability of medical professionals and other inputs. If, for example, public hospitals, continue to be driven by short-term budget constraints, they may have little incentive to purchase more broadly cost-effective technologies, which reduce costs elsewhere in the health system or which have long-term pay-offs for the

community. If the supply of medical professionals is constrained, so too will be access to new technologies.

In the Commission's view, there is a pressing need to explore what overall level of subsidised access to healthcare and the technology it embodies, the community considers is appropriate, and the institutional and incentive structures that will deliver it efficiently and equitably. *Inter alia*, this means addressing the issue of what basic services a universal healthcare system should cover in future.

APPENDIXES

A Public consultation

As part of the study process, the Commission received 62 submissions (table A.1), visited or otherwise discussed the issues involved with a number of individuals and organisations (table A.2) and held a roundtable discussion with a number of key medical industry bodies (table A.3). The Commission thanks all those who have contributed to the study to date.

Table A.1 List of submissions

<i>Individual or organisation^a</i>	<i>Submission number</i>
National Centre for Social and Economic Modelling	1
Centre for Health Economics, Monash University	2
Australian Institute of Medical Scientists	3
Australian Association of Pathology Practices Inc.	4, PR 59
Dr Stan Goldstein	5
Boston Scientific Australia & New Zealand*	6
Andrea Hayward	7
Australian Society of Anaesthetists Ltd	8
Centre for Health Economics Research and Evaluation, University of Technology Sydney	9
Dr Michael Loughnan	10
ACT Health	11, PR 61
Australian Diagnostic Imaging Association	12
Pharmacy Guild of Australia, The	13
Australian Health Service Alliance*	14
N. Stenning & Co. Pty Ltd	15
Dr Trevor Kerr	16
Medical Industry Association Australia Inc.*	17, 40, PR 54
Faculty of Radiation Oncology, Royal Australian and New Zealand College of Radiologists	18
Healthcare Worker Safety Special Interest Group of the Medical Industry Association Australia Inc.	19
NSW Health	20
GlaxoSmithKline Australia	21
BreastScreen Victoria Inc	22
AstraZeneca Pty Ltd	23
Victorian Department of Human Services	24, PR 46
Australian Healthcare Association	25
Australian Nursing Federation	26
Royal Australian and New Zealand College of Radiologists, The*	27

(Continued next page)

Table A.1 (continued)

<i>Individual or organisation^a</i>	<i>Submission number</i>
BUPA Australia	28
Medtronic Australasia Pty Ltd*	29
Medicines Australia	30, PR 62
Fair Go Mate Pty Ltd*	31
Cancer Council Australia / Clinical Oncological Society of Australia	32
Enku Kebede-Francis	33, PR 45
Department of Health and Ageing	34, PR 56
South Australian Government	35
National Health and Medical Research Council	36
Wyeth Australia Pty Limited*	37, PR 57
Johnson & Johnson Medical Pty Ltd*	38
Professor Karen Facey	39
Institute of Medical and Veterinary Science	41
Dr Geoff McDonald and Mr Steven Tipper	PR 42
Queensland Health	PR 43
Living Cell Technologies	PR 44
Dr Yolande Lucire	PR 47
Health Services Development, Institute of Advanced Studies, Charles Darwin University	PR 48
Australian Electrical & Electronic Manufacturers' Association (AEEMA)	PR 49
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-s)	PR 50
Australian and New Zealand Society of Blood Transfusion	PR 51
Royal College of Pathologists	PR 52
University of Queensland, University of NSW and University of Oxford	PR 53
Dr Jeff Brownscombe	PR 55
National Association of People Living with HIV/AIDS	PR 58
Dr Thomas Faunce	PR 60

^a An asterisk (*) indicates that the submission contains confidential material not available to the public.

Table A.2 List of visits

<i>Individual or organisation</i>
AEEMA
Alcon Australia
Amgen Australia
ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures)
Australian Electrical and Electronic Manufacturers' Association, The
Australian Health Insurance Association
Australian Healthcare Association
Australian Institute of Health and Welfare
Australian Nuclear Science and Technology Organisation, The
Aventis

(Continued next page)

Table A.2 (continued)

Individual or organisation

Baker Heart Research Institute
BUPA Australia
Centre for Health Economics Research and Evaluation, University of Technology Sydney
Consumer Health Forum and Cochrane Collaboration
CSIRO Preventative Health Flagship
Department of Finance and Administration
Department of Health and Ageing
Department of Human Services
Department of Industry, Tourism and Resources
Department of Prime Minister and Cabinet
Guidant
Department of the Treasury
Dr Stan Goldstein
Eli Lilly Australia
GlaxoSmithKline (GSK)
HealthConnect, Department of Health and Ageing
Health Insurance Commission
Health Technology Assessment Unit, Department of Public Health, University of Adelaide
Institute of Actuaries of Australia
John Curtin School of Medical Research
Johnson & Johnson Medical Pty Ltd
Macquarie Bank
Medibank Private
Medical Industry Association of Australia
Medical Services Advisory Committee
Medicines Australia
Medtronic Australasia
National Centre of Epidemiology and Population Health
National E-Health Transition Authority
National Health and Medical Research Council
Office of Aboriginal and Torres Strait Islander Health
Pfizer Australia
Pharmaceutical Benefits Branch, Department of Health and Ageing
Private Health Insurance Branch, Department of Health and Ageing
Professor Hugh Taylor, Centre for Eye Research Australia
Professor John McNeil, Department of Epidemiology and Preventive Medicine, Monash University
Professor John Zalcberg, Peter MacCallum Cancer Institute
Roche Diagnostics
Royal Australasian College of Physicians, The
Secretariat to the Medical Services Advisory Committee
Secretariat to the Pharmaceutical Benefits Advisory Committee (PBAC)
St Jude Medical
St Vincent's Hospital
Stryker Pacific
Therapeutic Goods Administration

(Continued next page)

Table A.2 (continued)

Individual or organisation

Walter and Eliza Hall Institute of Medical Research, The
Wyeth

Table A.3 **List of roundtable attendees**

Individual or organisation

Australian Institute of Medical Scientists
Baker Heart Research Institute
Cancer Council of Australia
Clinical Oncological Society of Australia
Department of Health and Ageing
Institute of Medical and Veterinary Science
Medical Services Advisory Committee
Medicines Australia
Merck, Sharp and Dohme
National Heart Foundation
NSW Department of Health
Professor Guy Maddern
Professor Stephen Graves
St Jude Medical
Victorian Department of Human Services

B Measuring health and economic outcomes

The terms of reference require the Commission to investigate the net impact of advances in overall and individual health technologies on economic, social and health outcomes. This requires identifying possible outcome measures and which are appropriate for the task at hand. This appendix provides more detailed and technical information relating to some of the indicators and measurement issues outlined in chapter 5. In doing so, it also covers some issues relevant to chapters 7–10. Specifically, it discusses:

- a framework for considering the relevant impacts in economic evaluations (section B.1);
- data issues relating to single-dimension health outcome indicators (section B.2);
- incorporating quality of life (QoL) considerations, through health-related quality of life (HRQoL) instruments (section B.3);
- combining length and quality of life through summary measures, including the quality-adjusted life-year (QALY) and disability-adjusted life-year (DALY) (section B.4);
- issues in measuring and isolating economic benefits and costs (section B.5); and
- other general measurement issues — discounting, the use of marginal and average outcomes, and valuing outcomes in healthcare (section B.6).

B.1 A framework for economic evaluation

From a public policy perspective, economic evaluation of the overall impact to the community of advances in medical technology should encompass all costs and benefits — to individuals, organisations and others in the community; tangible and intangible. Luce et al. (1996), in the report of the US Public Health Service Panel on Cost Effectiveness in Health and Medicine, commented that:

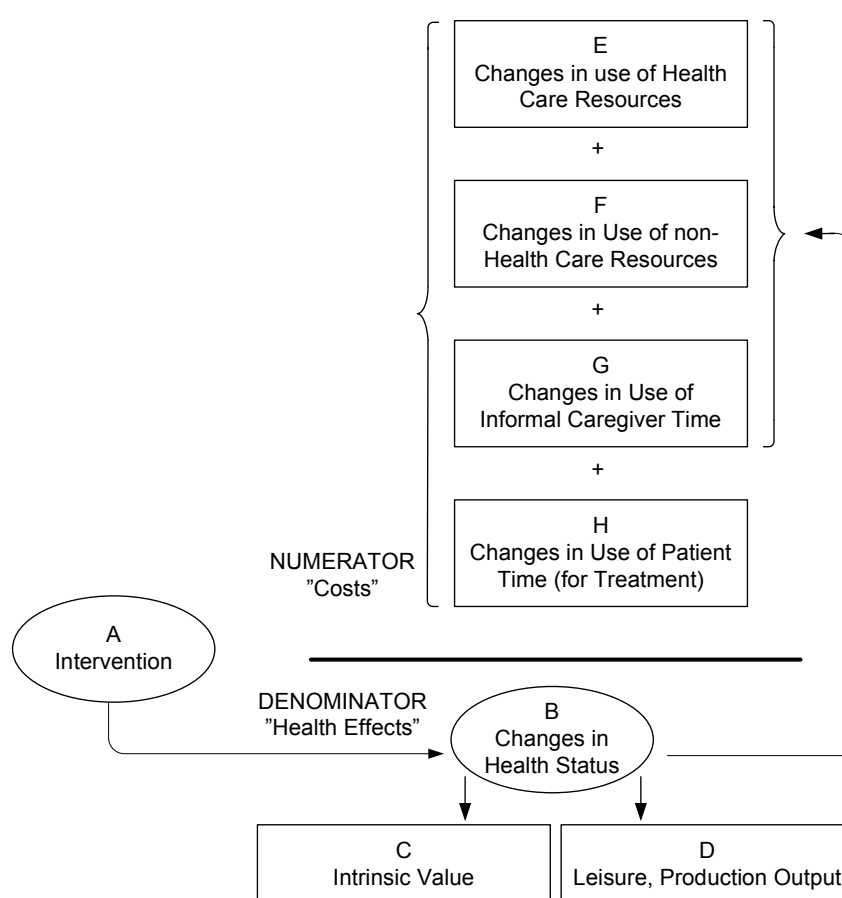
... an ideal cost-effectiveness analysis begins by identifying all the consequences of adopting one intervention or another, including use of resources ... and the effects of the intervention on health status. (p. 178)

Identifying and delineating the costs and benefits is not easy. Luce et al. (1996) illustrated one possible approach (figure B.1), showing the potentially wide-ranging impacts that are relevant to economic analysis, such as cost-effectiveness analysis (CEA).

- Some impacts relate to the intervention itself — including the effect on the use of resources (including time) within the health system, such as doctors and hospitals (E); in non-healthcare sectors (F); and by carers who may give assistance (G); as well as by the patients themselves (H).
- Other impacts result from the effect of the intervention on patient health. Changes in an individual's health status (B) resulting from an intervention (A) will change that person's utility directly — health has an intrinsic value (C) — as well as changing the amount or type of work done and the way leisure time is used (D) (Luce et al. 1996). Changes in the patient's health status may also lead to flow-on effects for the use of resources in the healthcare and other sectors, as well as of carers.

Figure B.1 Economic impacts of medical interventions

A possible way to consider costs and benefits in CEA



Source: Luce et al. (1996), p. 177.

The conclusions of Gold et al. (1996), in the report of the US Public Health Service Panel on Cost Effectiveness in Health and Medicine, provide an indication of how these benefits and costs ideally should be treated in CEA:

Regardless of the instrument chosen ... health outcomes should be 'health-related' and not include all the possible effects of an intervention. Nonhealth effects, such as financial consequences that do not flow directly from changes in health status, should be captured in the numerator of the CEA. For example, the cost of time spent traveling to or waiting in the doctor's office should be measured as a cost. However, financial consequences that are directly caused by changes in health status are best reflected in the weights assigned to the health states. For example, patients with arthritis who are unable to work with their hands would reflect their loss of productivity — and, hence, income — in the weights they assign to the pain and loss of dexterity caused by their condition. To the extent that these financial losses are borne by persons other than the patient they would have to be counted separately among the costs. (p. 110)

The issues surrounding which are, or should be, considered costs or benefits in CEA are discussed in more detail in section B.5. At this stage, the most salient point is that economic impacts are a broad concept, not merely incorporating factors that are financial or production-related. Thus, the distinctions between social, economic and health outcomes in this report are influenced more by the terms of reference than by general economic theory. Furthermore, the framework of figure B.1 helps to highlight potential risks of doublecounting benefits, which is an ongoing issue in CEA (section B.5).

B.2 Single-dimension health outcome measures: data issues

Mathers et al. (1999) noted that aggregating individual data to generate population-level statistics is the simplest and most widely used way to produce population health measures. Some of the most commonly cited measures include mortality rates, life expectancy, and disease incidence and prevalence (box B.1). The coverage and quality of data relating to these measures in Australia are generally good, although there are some gaps. Even where comprehensive data are available, all measures have limitations as indicators of health status.

Mortality rates

According to Mathers et al. (1999), Australia has a virtually complete registration of deaths and good information on cause of death. There are gaps, however, in relation to Indigenous deaths (SCRGSP 2005). This suggests that the accuracy of mortality-related information is generally likely to be high, enabling fairly accurate pictures of overall rates, as well as

rates by disease and some population groups.

Box B.1 Single-dimension indicators of population health — examples

Mortality rates are calculated as the number of deaths in a specified period as a proportion of the population. They are generally quoted in terms of deaths per thousand people, and can also be estimated by cause of death and across different groups in society. Age standardisation, to account for differences in the age distribution of the population, is required to allow meaningful comparisons of mortality rates across time and population groups. The probability of death between specified ages can also be used to measure mortality risk, and to compare these outcomes across countries, jurisdictions and so on.

Life expectancy statistics provide an indication of how long a person can be expected to live, measured at a particular age (often birth). They are estimated using mortality data and can be measured in two ways. Period life expectancy uses current mortality patterns across all age groups in the population, and is the most often quoted life expectancy measure. The alternative, cohort life expectancy, uses projected trends in mortality rates to estimate the average life expectancies likely to be achieved by people currently alive. Where mortality rates are declining over time, the estimated life expectancy is higher with the cohort measure. Another life expectancy measure is 'early adult death', which is the probability of a person dying before a specified age.

As well as providing information about the expected longevity of the current population, life expectancy measures can be used to compare outcomes across groups in society. The extent to which this is possible varies. For example, gaps in Indigenous mortality data affect the accuracy of their estimated life expectancies.

Disease incidence and prevalence. The incidence of disease refers to the number of new cases of a condition that are diagnosed in the population during a specified time period. Prevalence refers to the number of cases of a condition in the population at a particular point in time. Both can be expressed as a proportion of the number of people in the population. In general, there is a positive relationship between the two, an increase in the incidence of a condition generating an increase in its prevalence.

When assessing the impact of advances in medical technology on outcomes, the impact on incidence is more relevant for acute medical conditions, and the impact on prevalence more appropriate for chronic conditions or where an extension in survival is involved. Both offer an incomplete picture of the impact of disease on quality of life, however, to the extent that they do not account for the severity of conditions.

Sources: DoHA (2002b); Mathers et al. (1999); SCRGSP (2005); VDHS (1999).

The limitations of mortality rates as measures of health outcomes and for assessing the impact of advances in medical technology include:

- they do not account for QoL;
- because they depend on probability of diagnosis as well as on survival rates, if diagnostic techniques improve, mortality rates for a particular condition could increase

or remain unchanged, even if technology has increased survival rates (Lichtenberg 2004b);

- there can be very long and variable lags between the time of an intervention and its effect on mortality rates (SCRGSP 2005); and
- timeliness of available data — the most recent Australian statistics are for 2003.

Life expectancy

Because the calculation of life expectancy depends on mortality rates (the expected length of a life is inversely related to mortality rates at that time (AIHW 2005c)), issues relating to mortality rates also affect life expectancy estimates.

Disease incidence and prevalence

The quality of incidence and prevalence data in Australia varies. Data are relatively complete for some diseases, but unavailable or severely limited for others.

Gaps appear most significant for incidence data. Although available for some conditions from disease registers or epidemiological studies, only prevalence data are available for most (VDHS 2004). In this situation, computer programs are used to model incidence and duration from estimates of prevalence, remission, case fatality (unavailable in most cases) and background mortality. Where remission or case fatality rates are unknown, these also need to be estimated.

Mathers et al. (1999) highlighted other problems relating to both prevalence and incidence data. These included:

- inconsistencies between reported incidence, prevalence and mortality rates for some conditions;
- the fact that only self-reported data from population surveys are available for the prevalence of some conditions, with inconsistencies between these and the estimates obtained from epidemiological studies; and
- the lack of recent information for some conditions.

B.3 Incorporating quality of life

None of the single-dimension indicators outlined in section B.1 accounts explicitly for QoL — people's emotional, social and physical wellbeing, and ability to undertake daily tasks. Yet QoL is a significant aspect of the overall wellbeing of the population and is,

therefore, an important consideration in assessing the impacts of advances in medical technology. Measuring QoL is, however, complex and inevitably involves a high degree of subjectivity. What, for example, is important? Is it equally important to everyone? How can we measure it?

This section outlines measures that have developed to incorporate, and issues that arise in incorporating, health-related QoL (HRQoL) — the subset of QoL that can be affected by health status. Hawthorne et al. (2002) noted the two could be considered identical concepts, but the environment in which a person lives and socioeconomic status are not usually included in HRQoL.

This section does not provide an exhaustive discussion of the issues, instead aiming to highlight the most salient aspects from the perspective of CEA. It does this by discussing various questionnaire-based measures that attempt to measure the HRQoL of the population or subset of the population — so-called HRQoL instruments. Interest in, and use of, these instruments is growing, a trend attributed to the increasing importance of chronic relative to infectious diseases, developments in technology that can save and prolong lives, and an increasing awareness of limited healthcare resources (Hawthorne et al. 2002). As well as being useful in their own right, some of these instruments can be used in the calculation of summary health outcome measures (section B.3).

At a general level, all HRQoL instruments involve posing a series of questions (called ‘items’) about various ‘dimensions’ (also referred to as domains, facets or elements) — such as physical, psychological and social wellbeing, and day-to-day functioning — that are seen as essential to wellbeing. The strength of the respondent’s experience in relation to each item can be defined by the use of ‘levels’ (such as ‘very good’, ‘good’, or ‘poor’). From this, a health profile or single index score can be calculated (Brazier et al. 1999). The instruments differ, however, in terms of exactly what they include and how they are applied.

Different approaches to measuring HRQoL

HRQoL instruments can be disease-specific, focusing on aspects of QoL that are most relevant to the condition in question, or generic. Generic measures have the advantage of more readily allowing comparisons across a range of conditions and interventions. On the other hand, as Gold et al. (1996) commented, they can lack sensitivity to differences in health status that may be important for, or specific to, certain conditions or interventions. Which type of instrument is more appropriate depends on the purpose of the analysis.

In addition, some instruments — preference-based instruments — attempt to attach values

(‘utilities’) to different health states, while others — psychometric (nonpreference-based) instruments (box B.2) — do not.

Box B.2 **Nonpreference-based QoL instruments — examples**

Medical Outcomes Trust 36-item short form health survey (SF-36). A generic instrument used in general population surveys and clinical trials, it covers eight dimensions (physical functioning (these questions relate to specific limitations, such as climbing a flight of stairs), role — functioning, bodily pain, general health, vitality, social functioning, role — emotional, mental health) and 36 items, with the levels varying for different questions. It results in a profile for each dimension, as well as two summary measures, one for physical and one for mental health, each incorporating four of the dimensions. Weighting was avoided by using items with equivalent relationships to their dimensions. Shorter versions (SF-12 and SF-8, which uses one item per dimension) have also been developed but are best used with larger samples. A preference-based six-dimension version, SF6D, has also been developed.

Nottingham Health Profile. A generic instrument used to evaluate perceived distress across populations. It has six dimensions (physical, mobility, pain, social isolation, emotional reactions, energy and sleep) and 38 items. Scores are presented as a profile, not an overall score, with weights derived from patients and non-patients.

World Health Organization’s Quality of Life (WHOQoL) Instrument. Designed to be an internationally-applicable and cross-culturally comparable QoL instrument, it consists of six dimensions (physical health, psychological health, level of independence, social relationships, environment, spiritual), with a total of 96 items, as well as an ‘overall quality of life and general health’ item. A five-point response scale is used to rate the intensity, frequency, capacity or evaluation of each item. No procedure yet exists to combine the dimension scores into a single index.

Sources: ACPMH (2003a, 2003b); ATC (2004); Cai and Kalb (2005); Hawthorne et al. (2002; 2003); Marosszeky (2003); Ware (2002).

With psychometric instruments, scores are assigned to each component of the health state — the total being derived by simply adding the questionnaire responses without weighting them by the relative importance or preference attached to the health states. This approach effectively assumes that the number of items in each dimension is a sufficient reflection of the relative importance of the various dimensions (Gold et al. 1996).

Psychometric instruments can be useful, and are used in clinical settings, because they take a broader view of health outcomes than do clinically-focused measures, such as the extent of reduction in cholesterol or blood pressure (Dolan 2000). They thereby provide an overall picture of the impact of interventions on people’s ability to function (Donald 2003).

They also have a number of weaknesses, including the subjectivity of reporting perceived ability and the fact that they cannot incorporate mortality (HOAP 2005d). Gold et al. (1996) also noted that they may not accurately reflect how different types of pain (that affect different aspects of function, for example) differentially affect a person's life experience. They commented:

... simply summing up numerical weightings across questions on a health assessment scale does not guarantee that changes in scores will coincide with changes in health status that are seen as better or worse off by patients or by the general public. (p. 98)

It is unlikely that people attach equal weight to all components of a health state yet resource allocation decisions must reflect the value attached to different outcomes. Therefore, using these instruments in economic analyses, and specifically CEA, is seen as inappropriate (Gold et al. 1996; HOAP 2005d).

In contrast, although also imperfect and not directly incorporating mortality, preference-based instruments result in scores that allow morbidity and mortality to be combined in a single weighted summary measure, enabling benefits to be expressed in terms of years of life produced, adjusted for quality (HOAP 2005c). Indeed, many of these instruments were developed specifically for this purpose. Utility estimates could also be derived from non-utility measures, with the use of a suitable algorithm (Medicines Australia, sub. 30).

Assigning preferences to health states

Preference-based instruments that describe many dimensions of health, assign scores to each response, and attach utility-based weights to these to combine them in a single index (usually ranging from 0 to 1) are referred to as multi-attribute utility (MAU) instruments. The weights used are not linked to any particular condition, disease or disability but are based on individuals' values for their own health state (patient weights) or the state of others as described to them (community weights) (Gold et al. 2002). They are 'utility weights' if derived using a scaling technique to elicit health state preferences (box B.3). The utilities derived with these techniques range in value from 0 to 1, with higher numbers representing better HRQoL (Petrou 2003). These can then be used as preference weights for QALYs (section B.3).

Aspects of the standard gamble (SG), time tradeoff (TTO) and person tradeoff (PTO) techniques — which, unlike the rating scale (RS) and magnitude estimation (ME), account explicitly for uncertainty — have been said to resemble situations in health services.

- The PTO seeks information similar to that needed to make policy decisions (Kaplan 1996).

Box B.3 Deriving HRQoL value/utility weights

Utility — the value or strength of preference attached to an object (in this case, specific health state/s compared to each other or death) — can be measured in various ways.

- **Rating scale (RS)** (visual analogue scale). Commonly used to assess an individual's health, it has many variants but typically presents respondents with a vertical or horizontal line calibrated between 0 and 100, where the end points (best and worst state) are unambiguously defined (usually as 'full health' and 'death'). Respondents place the health state/s being evaluated somewhere between these points, with the distance on the scale representing the strength of feeling. Seldom used by economists because of ambiguity in interpreting results and doubts as to whether it allows preferences to be aggregated.
- **Magnitude estimation (ME)**. Respondents are asked to provide the ratio of undesirability of pairs of health states — for example, is one health state two, three or more times worse than the other state? If state *A* is *x* times worse than state *B*, then the undesirability/disutility of state *A* is *x* times as great as state *B*. By asking a series of questions, all states can be related to each other on the undesirability scale. Ratings across respondents are standardised and aggregated using the geometric mean. Not widely used to value condition-specific health states.
- **Standard gamble (SG)**. Consists of a choice between (usually) a lifetime in the health state of interest and a gamble between normal health (full life) and death. The probability of full life is varied until the respondent is indifferent between the gamble and certainty of life in the inferior health state. The probability of the favourable outcome at this point is taken as the index of preference strength (utility). Variants of this technique try to accommodate different situations (such as valuing mild or temporary states where respondents would be unwilling to consider death as an alternative). Widely applied for generic and condition-specific measures.
- **Time tradeoff (TTO)**. Respondents specify the proportion of a given number of remaining years of life (usually ten) that they would be prepared to give up to avoid living in the health state being measured. If a person with a life expectancy of ten years with a given condition would give up two (20 per cent) of these years to be in normal health, then the utility score is 0.8 (ie 1.0–0.2; '1' being normal health). Developed specifically to value health states as an alternative to SG, it is widely used for both population-level surveys and to value condition-specific health states.
- **Person tradeoff (PTO)**. Originally known as the equivalence technique, it involves respondents making a choice in a context not involving themselves, and is seen as a way to estimate the social value of different health states. Respondents consider two programs. The first returns a defined number of patients (*x*) from imminent death to the health state being evaluated. The second returns a variable number, *N*, patients from imminent death to full health. *N* is varied until the two programs appear equally attractive. The utility of the health state equals *N/x* at this point, implying the undesirability or desirability of the second program is *N/x* times as great as that of the first. A series of such questions allows all conditions to be related to each other on the undesirability scale. Not widely used to evaluate health states.

Sources: Brazier et al. (1999); Hawthorne et al. (2002); Kaplan (1996).

-
- The SG has been likened to a decision about a treatment that could result in death but significantly improve life if successful (Mathers et al. 1999).
 - The TTO has been likened to a patient with a chronic condition for which treatment will improve but shorten life (Mathers et al. 1999). Another perceived benefit of the TTO is that it directly measures the number of years equivalent to a given time in a health state — that is, it collapses quantity and quality of life considerations into a single measure (Dolan 2000; Gold et al. 1996).

Others have suggested, however, that the SG does not in fact resemble the real world, where people face multiple potential options but where the stark choice between certain death or health is not typical (Dolan 2000; Gold et al. 1996). This type of ‘gamble’ is seen to be particularly unrepresentative of the treatment of chronic diseases, such as arthritis, for which no intervention either will cure the disease or is likely to result in immediate death. Meanwhile, it has been suggested that the TTO actually ‘confounds’ health state and time preferences, not allowing for the fact that time preferences may be upward biased (Gold et al. 1996), and assuming (unrealistically) that the perception of illness severity is independent of the time spent in that state (Petrou 2003). Unlike the SG, TTO valuations are also affected by discounting (Dolan 2000).

Other issues relevant to all techniques in practice include the following.

- Administrative ease/complexity, and whether respondents understand what is required and can accurately reflect their preferences in their responses (so-called ‘cognitive burden’).
 - The RS, for example, is seen to be relatively inexpensive to use and easy to understand, while the TTO and SG, based on probability assumptions, are seen as more difficult concepts to understand (Kaplan 1996; Petrou 2003).
- Variations in valuations for the same or similar health states across techniques and groups, and depending on how the survey is conducted and health states presented/described to respondents.
 - The RS, for example, consistently (though not always) produces lower values than do the SG or TTO (Gold et al. 1996; Kaplan 1996; Petrou 2003; Tengs and Wallace 2000).
 - Patients tend to provide higher ratings for particular health states than do non-patients, while health professionals tend to assign lower ratings than does the general public (Kaplan 1996; Petrou 2003; Tengs and Wallace 2000).
 - Respondents in experiments have reversed previously revealed preferences when the same information is presented differently, or have refused to ‘trade’ across

health states when one is seen as particularly bad (Kaplan 1996). ‘Framing’ bias is seen as a particular issue for the SG (Petroou 2003).

Which technique is the best to use has not been settled either theoretically or empirically and no true gold standard exists (Dolan 2000; Gold et al. 1996). Methods based on economic theory, such as the SG and TTO (the former based on expected utility theory, the latter on decision theory) are often preferred by economists because they are more closely linked to the theoretical foundations of CEA. To the extent, however, that their underlying assumptions are violated in practice, they lose much of their apparent superiority (Dolan 2000).

Using preference-based instruments — some issues

Many preference-based HRQoL instruments have been developed over the years (box B.4) but their use is more contentious than is the use of simpler health outcome measures (Segal and Richardson 1994). Issues of contention include the appropriateness of generic versus condition-specific instruments; extent to which instruments accurately capture the aspects of health that are important to QoL; and inclusion of different dimensions in different instruments, resulting in sometimes very different pictures of health status (Gold et al. 2002; Hawthorne et al. 2003).

With respect to the latter concern, instruments vary widely in the specificity of health states and dimensions included, with no two having identical dimensions (Gold et al. 1996; Tengs and Wallace 2000). Some of these differences can be particularly important from the perspective of CEA and their use in QALYs (section B.3). Many instruments, for example, exclude mood or emotional function, which Gold et al. (1996, p. 109) noted can ‘markedly distort the interpretation of the effects’ of some treatments. Exclusion of mood and psychological dimensions also limits the ability to use them to compare treatment outcomes for mental illness.

In addition, some measures only consider ‘beneath the skin’ concepts — that is, they do not include social dimensions (social interaction or role function) in their description of health. Others are more broadly based and include the ability to perform activities such as going to work or school (Gold et al. 1996). Gold et al. (1996) argued that:

A system that provides inadequate or absent information regarding a domain that is important to the condition under investigation will be unable to provide sensitive information about changes in the condition; it will not be a valid measure of effect. (p. 121)

In contrast, Kaplan (1996, p. 33) commented that even if instruments have different dimensions, ‘they may still be tapping the same constructs’ — mental health may, for example, be represented in questions about role functioning.

A further constraint on using these instruments for QALYs and cost-effectiveness comparisons relates to the already-noted problems with scaling techniques used to elicit preferences, and diversity in how these weights are collected (Gold et al. 1996). Gold et al. (1996) noted that lack of a standard valuation measure creates problems for standardising CEA across conditions and illnesses, with Kaplan (1996) highlighting the impact different values can have on decisions (section B.3).

Box B.4 Preference-based utility instruments — examples

15D. Comprises 15 dimensions (mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual function), each having one item and five levels. Respondents indicate their level of health on each dimension. This instrument can be used as a profile or single index measure, with health state values estimated by a simple additive formula: the value of each dimension multiplied by preference weights. The weights were elicited from the adult Finnish population using the RS and ME techniques.

Assessment of Quality of Life Index (AQoL). A generic HRQoL MAU instrument, it is the only one that uses Australian weights. It consists of five dimensions (illness, independent living, social relationships, physical senses, psychological wellbeing), each having three items. The overall instrument score (between 100 and 0) is derived using a multiplicative model, using TTO weights that were elicited from a sample of respondents from Victoria. The illness dimension was not used in utility calculations. Designed for economic evaluations, it can also be used as a psychometric instrument.

EQ-5D. Originally known as EuroQoL, and designed for cross-European comparisons of QoL, this consists of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each of which has three ordinal health levels (‘no problem’, ‘some/moderate problem’, or ‘extreme problem’). Respondents choose the level that best describes their current experience. A unique health state is defined by an additive formula combining one level from each dimension. The utility weights were obtained from a representative sample of the UK population (US weights have also been derived), using the TTO. Utilities are computed using a regression model.

Health and Activity Limitation Index (HALex). A generic health measure developed for a US health initiative, it estimates utilities by combining scores from two attributes — self-perceived general health, and activity (disability and role functions) — based on questions from the National Health Interview Survey. There are six levels in the activity questions, ranging from ‘not limited’ to ‘unable to perform activities of daily living’ (the extent of limitation defined relative to what is appropriate for a person of that age); and five levels for self-perceived health, ranging from ‘excellent’ to ‘poor’.

(Continued next page)

Box B.4 (continued)

Health Utilities Index (HUI). Developed in Canada for clinical and population studies, there are three versions of the HUI. Each includes a health status classification system, a preference-based MAU function, data collection questionnaires, and algorithms for deriving HUI variables from questionnaire responses. They use multiplicative models to combine utilities. Utility scores reflect community preferences, and are based on expected utility theory, with extensions accommodating multiple attributes. The second and third versions focus on capacity rather than actual performance.

Quality of Wellbeing (QWB). Developed in the United States, this combines preference-weighted measures of functioning (assessed in three dimensions: mobility, physical activity and social activity), and 27 symptoms (reflecting the fact that symptoms affect QoL, even if they do not affect functioning). Respondents report actual activity rather than a perception of what could have been performed. The overall score is calculated using an additive formula and RS weights. It has been used in population studies and clinical trials, and to evaluate interventions for medical and surgical conditions.

Rosser-Kind (Disability/Distress) Index. Developed in the 1970s as a measure of hospital performance, this index has two dimensions (disability and distress, with eight and four levels respectively). Weights have been developed with the ME, RS and TTO techniques, each giving different values. Now seldom used because of limited sensitivity in detecting differences in health status.

Sources: Asada and Ohkusa (2002); Brazier et al. (1999); Gold et al. (1996); Hawthorne et al. (2002 and 2003); HOAP (2005a; b and e).

Given the theoretical and empirical issues that surround these measures, Hawthorne et al. (2003, p. i) advised ‘caution should be exercised in treating any of the instrument results as representing a utility score which truly represents a trade-off between life and health related quality of life’. Despite this, Segal and Richardson (1994, p. 20) commented that the measures produced by these instruments ‘provide a workable approach to the measurement and comparison of dissimilar outcomes’. Similarly, Dolan (2000, p. 1754) commented that violation of some theoretical assumptions does not of itself mean that an approach should be abandoned. Rather, because most assumptions are only ‘satisfied approximately’, a judgement needs to be made about ‘the extent to which the loss of realism ... [is] compensated for by their greater tractability’.

B.4 Combining quality and quantity of life

Although HRQoL instruments are useful as descriptive systems of health status, like single dimension measures, they focus on just one, albeit important, aspect of life — ‘quality’.

Summary measures of population health, on the other hand, combine mortality *and* morbidity information into a single index number. There are two broad classes of summary measure (Mathers et al. 1999).

- **Health expectancies** extend the concept of life expectancy by estimating the number of years that a person could expect to live in a defined health state.
- **Health gaps** measure the difference between a population's actual health status and some 'ideal' or reference status. They can extend the notion of mortality gaps — which measure the gap in years between age at death and a 'standard' age before which death is considered premature (potential life years lost) — to include time lived in imperfect health.

Various summary health measures have been developed over the years (box B.5), each with strengths and weaknesses relating to theoretical underpinnings/underlying assumptions, quality of the inputs used, and/or empirical validity. The most commonly cited measures are QALYs and DALYs. The importance of both is growing but their uptake has varied across entities (Gold et al. 2002).

Box B.5 **Summary health outcome measures — examples**

Standard definitions of (and terminology relating to) summary health measures do not exist. They have varied over time and across studies, with some terms used interchangeably. The following examples aim to reflect more common current use of the terms.

Health-adjusted life-expectancy (HALE). Generic term for health expectancy measures that estimate a single index number indicating the expectation of equivalent years of good health. They are calculated for an exhaustive set of health states, defined in terms of severity of disability, with good health assigned a weight of 1, and non-zero weights to at least some states.

Disability-adjusted life-expectancy (DALE). A form of HALE that can provide an indication of the proportion of total life expectancy at birth that is lost due to disability. The World Health Organization publishes DALE estimates for 191 countries.

Disability-free life-expectancy (DFLE). Uses dichotomous health state weights (1 to states with no disability — above or below a specific threshold — and 0 to states above a certain threshold) to estimate expected years in good health (that is, without disability). It, thus, does not place any positive value on years lived with disability.

Active life expectancy (ALE). Like DFLE, ALE uses dichotomous health state weights to decompose life expectancy into estimates of time lived in 'active' and 'inactive' health states. Can be used in absolute terms (number of years expected to be spent in an active state), or relative terms (active years as a proportion of total life expectancy).

(Continued next page)

Box B.5 (continued)

Quality-adjusted life-year (QALY). Combines quality of life and survival into a single index number by weighting the time spent in each health state by an associated quality/utility weight between 0 (death) and 1 (full health). States deemed worse than death can have negative values. One QALY can be thought of as a year of healthy life.

The term QALY is also sometimes used as a generic term to describe the class of measures that adjust life years for quality of life.

Healthy year equivalent (HYE). A form of QALY which involves valuing health *profiles*, not discrete states, that vary in the sequence and duration of health states. Distinguished by the use of (two-stage) SG to evaluate all, not one, of the years lived in a health state — respondents must state the number of years of perfect health considered equivalent to a particular profile. Designed to avoid the perceived restrictive assumptions of QALYs, HYE place fewer restrictions on individual preferences, but there is debate about whether and under what restrictions they are a more valid index of utility. It also can be demanding to use — a large number of profiles, each requiring preference measurement, may be possible, and cognitive demand on respondents is high.

Disability-adjusted life-year (DALY). The DALY, adopted by the World Health Organization as a standard of reporting and comparing population health, combines a measure of time lived with (years lost to) disability, and time lost due to premature mortality. One DALY can be thought of as a lost year of healthy life. It represents the total *burden of disease* — the gap between a population's health and a hypothetical ideal (living to old age free of disease and disability). Total disease burden is calculated as the sum of DALYs across diseases.

Sources: Brazier et al. (1999); Cairns (1996); Dolan (2000); Gold et al. (1996; 2002); Hawthorne et al. (2003); Mathers (2002); Mathers et al. (1999); Viney and Savage (2003).

QALYs

The most widely-used measure of health-related utility, QALYs were developed in the late 1960s by economists, operations researchers and psychologists, mainly for use in CEA — to allow comparisons across different health conditions and interventions. (When the cost-effectiveness ratio is calculated using QALYs, it is referred to as cost-utility analysis.) QALYs can be calculated for a particular patient or subpopulation, and to examine specific segments of life (such as following treatment) (box B.6). Condition-specific QALYs could be developed but it would be difficult to ensure their comparability across conditions (Cairns 1996).

QALYs have been used to assess the cost effectiveness of particular interventions, as well as to construct QALY 'league tables' that rank different interventions by their cost per QALY. In Australia, submissions to the Pharmaceutical Benefits Advisory Committee do

not need to express outcomes in QALYs, but the Department of Health and Ageing (DoHA 2002b, p. 6) suggested that ‘this form of analysis should be considered whenever it is appropriate to the proposed drug’. It also noted that few trials have yet measured drug therapy impacts on QALYs, and that surrogate outcome indicators will be needed for most economic evaluations.

Box B.6 QALYs — numerical examples

Following the life path of an individual

The following example, taken from Gold et al. (2002, p. 125), illustrates the calculation of QALYs, by following the life path of a woman with a life expectancy at birth of 79 years (discounting is not applied so as not to complicate the example).

- Her first 40 years of life are spent in excellent health, with a HRQoL weight of 0.95 (1 is rarely used in practice because many assume that it is inappropriate to view anyone as ever being in perfect health).
- Between ages 40 and 60 (20 years), she experiences some non-specific wear and tear, decreasing her HRQoL to 0.9.
- Between ages 60 and 70 (10 years), other symptoms decrease her HRQoL to 0.8.
- At age 70, her health further declines, with her HRQoL falling to 0.7 until her death 12 years later at age 82.
- This life path gives her 72.4 QALYs (ie $40 \times 0.95 + 20 \times 0.9 + 10 \times 0.8 + 12 \times 0.7$).

If she had a successful replacement of an arthritic hip at age 60, avoiding the fall in HRQoL until the age of 70, she would have gained one extra QALY (ie $10 \times (0.9 - 0.8)$), for a total of 73.4 QALYs. A bad outcome from her hip replacement may have resulted in a fall in HRQoL to 0.7, persisting until her death, reducing the number of QALYs by one (ie $10 \times (0.8 - 0.7)$), because an extra 10 years would be spent in a health state with a value of 0.7). Alternatively, if she died at 60 because of the surgery, she would have lived 56 QALYs (ie $40 \times 0.95 + 20 \times 0.9$, the QALYs accumulated to that point).

Aggregating QALYs across the population

Aggregation of QALYs is made relatively straightforward by two underlying premises. First, that a QALY gain to a young person is equivalent to a QALY gain to an older person and, second, that a gain of 0.50 QALYs for one person is equivalent to gains of 0.25 QALYs for two people. Thus, if an intervention extends the life of one person by one year at an existing QALY level of 0.50, and produces a health improvement in another equal to 0.25 QALY for one year, it produces 0.75 QALYs in total health benefits. (Wang 1998)

Part of the increasing appeal of QALYs lies in the fact that, by combining quality and quantity of life in one indicator, they provide a common metric to compare outcomes across interventions and conditions.

Their use as inputs to CEA is not without problems, however. At a theoretical level, healthcare evaluation technically does not require QALYs to be an index of utility but they tend to be viewed as such (Savage and Viney 2003). This requires them to meet several restrictions, not all of which are accepted as reflecting reality (box B.7). Nonetheless, according to Garber et al. (1996, pp. 30–1), QALYs do meet the theoretical requirement that ‘the measure of health benefit to an individual should reflect the gain in expected utility to that individual’. They commented further that, although it appears restrictive, the QALY is a close approximation to a broader set of plausible utility functions.

Box B.7 QALYs — underlying assumptions

For QALYs to be an index of utility, they require an accurate description of the health outcomes associated with a condition/intervention, and a method for eliciting and ordering preferences for the outcomes. As well as conforming to the Von Neumann–Morgenstern axioms of expected utility theory, several other restrictions are needed. These are that the value of the health state is constant and unrelated to the duration of the state, when it occurs, or where it occurs relative to other states. Most QALY applications also assume decision makers are risk neutral — that is, that they are indifferent among various survival curves that have the same life expectancy.

Some have queried the use of the QALY for economic evaluation because of the restrictiveness of its underlying assumptions and doubts as to real world applicability. It is likely, for example, that the value of a health state depends on the time spent in that state, and on a patient’s prognosis. It has also been suggested that the lost quality of life associated with a condition may depend on whether the person was already in good health (the disutility of health changes may be subject to diminishing returns).

Sources: Brazier et al. (1999); Gold et al. (1996; 2002); Savage and Viney (2003); UK DH (2004).

Prieto and Sacristán (2003) pointed to technical arithmetic issues that arise in the calculation of QALYs because one component of their multiplicative model (life years) has a true zero, whereas the utility component has an arbitrary zero for death. They argued that this ‘jeopardises the meaning and interpretation of QALYs’ (Prieto and Sacristán 2003, p. 1).

Moreover, an underlying premise of QALYs is that all QALY gains are equal — regardless of who, or how many people, gain them or when in life they occur. Although this makes aggregation straightforward (box B.6), it may not be realistic. For example, preference might in practice be given to those in poorer health states, or to interventions that improve the quality of life of many people rather than save the lives of a few (even if the number of QALYs gained through the two interventions is equal) (Gold et al. 1996; McGregor 2003). Gold et al. (1996, p. 8) argued that this aggregation problem arises because ‘the numerical sums are equal but we do not in fact value them equally’, and that

the assumption that all QALYs are of equal value is less likely to apply the more heterogeneous is the population.

At a practical level, although their general nature allows QALYs to be used to compare a range of conditions and interventions, the extent to which this includes comparing interventions with *very* different health outcomes — such as those for schizophrenia and heart disease — is unclear (Gold et al. 1996; McGregor 2003).

Further issues using QALYs in practice relate to the HRQoL instruments and scaling techniques that underlie the quality component of their calculation. The issues that surround the use of these techniques and instruments (section B.2) also affect the quality of QALY estimates, as well as their comparability across studies.

The utility weights used to calculate QALYs have been obtained from various HRQoL instruments, including the HUI, QWB, EQ-5D and HALex (box B.5), and using a variety of scaling techniques (section B.2). It is because these measures relate to health states, not specific conditions, that it is theoretically possible to describe and value combinations of illnesses using QALYs (Gold et al. 2002).

However, different measures and techniques can produce widely varying value estimates (section B.2), and these differences may not be unimportant. Kaplan (1996), for example, illustrated the potential impact of a seemingly small difference in values. If the estimated difference in the effect of a drug and a placebo is 0.05 on one scale and 0.02 on another, then the benefit would have to last 20 years in the first case and 50 years in the second to produce one QALY. Tengs and Wallace (2000) also noted that QALY weights estimated on different scales are not directly comparable, while relative rankings can also be affected by whether incremental or average effectiveness has been measured (section B.5).

In addition, the population ‘average’ response used to define QALY weights/values is derived from individual survey responses, which are inherently subjective. Valuations may vary across individuals due to differences in age, education, risk aversion or time preference (UK DH 2004). As Wang (1998) observed:

QALY values are therefore reflective of the population on which they are defined, and are not meant to be viewed as fundamental or immutable characteristics.

Despite these issues, and the alternative measures that have developed, Prieto and Sacristán (2003, p. 3) commented that nothing has ‘so far succeeded in displacing the intuitively attractive QALY’. Partly, this may reflect the view of Garber et al. (1996, p. 31) that ‘QALYs may still offer a close enough approximation to health-related utility to justify their use in cost-effectiveness analysis’.

What this does mean, however, is that caution is needed in using and interpreting QALYs,

particularly their use in ‘league tables’. Use of a modified approach (the threshold approach) has been suggested as a way to assess the ‘value for money’ of interventions (Malek 2001). This would involve construction of a matrix that categorises cost per QALY values ‘according to the strength of evidence underlying them’ (Malek 2001, p. 5) — that is, according to the quality of the studies from which they were taken.

DALYs

The DALY was developed in the 1990s, through a collaborative effort between the World Bank and World Health Organization. It was explicitly designed to provide disease and injury-specific estimates of burden that were additive across disease categories (Mathers 1999). By providing a measure of the global burden of premature death, disease and injury, it was to provide information to support health policy and priority setting (resource allocation) (Gold et al. 2002; Mathers et al. 1999).

The HRQoL weights used to calculate DALYs (box B.8) are attached to specific diseases, not health states, drawing on the International Classification of Impairments, Disabilities and Handicaps, and range in value from 0 for a state of good or ideal health to 1 for death and states equivalent to death (box B.9). The weights for the Global Burden of Disease (GBD) project were developed through a PTO-based deliberative process involving 22 ‘indicator’ health conditions and a series of focus groups with health experts. The results of this process were then used to estimate the burden of disease for all major disease groups (Mathers et al. 1999). The DALY also allows for non-uniform age weights, the GBD project weighting a year of healthy life lived at younger and older ages lower than those for other ages.

Proponents of the DALY argue that it provides a better way to measure the health burden of specific diseases than do health expectancies, such as QALYs. Mathers (1999, p. 1) argued that this is because they provide:

... a straightforward partitioning of total burden by an exhaustive set of disease and injury categories, and are additive across disease categories, whereas potential gains in health expectancy are not additive ... [and provide] ... a more sensitive measure of changes in burden than gains in health expectancies through disease elimination.

On the other hand, several criticisms and concerns have been associated with the framework. Some of these relate to the five key social preferences/values underlying the DALY calculation (box B.10).

Box B.8 Calculating DALYs

DALYs are calculated as the sum of years of life lost due to premature mortality (YLL) in the population and years lost due to disability (non-fatal health conditions) (YLD).

$$\text{DALY} = \text{YLL} + \text{YLD}$$

where:

$\text{YLL} = N \times L$, N = number of deaths at a specific age, L = life expectancy (generally period life expectancy (section B.1)) at that age of death; and

$\text{YLD} = I \times \text{DW} \times L$, I = incidence of non-fatal condition, DW = disability weight (between 0 for perfect health and 1 for death), L = average duration of condition until remission or death (in years).

When discounting is applied, the formulas become:

$$\text{YLL} = 1/r (1 - e^{-rL}); \text{ and}$$

$$\text{YLD} = [I \times \text{DW} \times L(1 - e^{-rL})] / r, \text{ where } r \text{ is the discount rate.}$$

YLD, which requires estimation of condition incidence and modelling of disease progression, is the most problematic to estimate. Meaningful estimates require a clear definition of the condition (in terms of case or episode, and severity level or disease stage), and that the disability weight and population incidence (or prevalence) data relate to the same definition.

It is because YLL measures the incident stream of lost years of life due to death that incidence tends to be used to calculate YLD, although a prevalence perspective can also be used. By focusing on the number of cases of a condition regardless of the time of onset, a prevalence-based YLD provides a measure of 'current' disease burden. In contrast, the incidence approach estimates the disability flowing from new cases of conditions, some of which may occur in the future. It has been suggested, therefore, that the two approaches could play different roles in economic analysis — the latter providing better information to evaluate preventative technologies, with prevalence possibly better suited to evaluating alternative options to alleviate current disease.

Sources: Gold et al. (2002); Mathers et al. (1999); VDHS (1999); WHO (2000); Zhao et al. (2004).

For example, although age weights are intended to capture the greater social responsibility in early and mid-adult life for the very young and old, some have argued that they are inequitable, arbitrary, do not reflect social values, and add complexity to the analysis without significantly changing overall burden estimates and rankings (Homedes 2000). Other issues have related to its appropriateness as a health outcome measure in CEA; its focus on overall, not marginal, burdens; and the fact that it does not reflect the different abilities of people to cope with functional limitations.

The National Centre for Social and Economic Modelling (NATSEM) noted problems using burden of disease measures to assess pharmaceuticals in particular:

While more general use of the ‘burden of disease’ measure represents a significant advance on what had been attempted previously, in its current form ... [it] is not well suited to assessment of the benefits of many pharmaceuticals. This is because a high proportion of pharmaceuticals neither save lives nor reduce the number of years lived with disability. Obvious examples are the pain killers, drugs that bring about prevention of disease, drugs that improve the quality of life of Australians generally and the drugs that keep people ‘operational’ (ie at work, or allow them to function independently). (sub. 1, p. 14)

Box B.9 DALYs — a numerical example

As with the QALY example in box B.6, the following is taken from Gold et al. (2002, p. 127) to illustrate the calculation of DALYs, by following the life path of a woman with a life expectancy at birth of 79 years (discounting is not applied so as not to complicate the example). Assume an ideal life expectancy at birth of 82.5, and an ideal life expectancy for someone at age 60 of 84.83 years.

- Until the age of 60, she would be considered fully healthy, her disability weighted 0.
- The onset of osteoarthritis would result in a disability decrement of 0.158 if untreated, and 0.108 if treated. This counts as if lasting the whole of her remaining life expectancy (ie 24.83 years); giving an implied loss in DALYs of 3.9 years (24.83×0.158) if untreated or 2.68 years (24.83×0.108) if treated.
- The decrement to health due to the onset of diabetes would be included by adding to the arthritis decrement: the full weight of the decrement stemming from the diabetes scores (0.012 to 0.078); and the decrease in actual life expectancy (ie the loss of life years relative to the ideal) due to the diabetes and its complications.
- If she died at age 60 because of the hip replacement surgery, she would have lost 22.5 DALYs (ie 82.5 (the ideal life expectancy at birth of a female) - 60).

Box B.10 DALYs — five key social preferences/values

- The appropriate ‘standard’ life expectancy on which to compare years of life lost (duration of time lost due to death at each age).
- The valuation of years of life lost through death compared with those lived with poor health/disability (disability weights).
- The value of years lost at different ages (age weights).
- The value of life and health gained now compared with later (time preference, discount rate).
- The degree to which people are equal (that is, whether two people gaining ten years is equivalent to one gaining 20 years).

Sources: Gold et al. (2002); Homedes (2000); Mathers (1999); Mathers et al. (1999).

Moreover, comorbidities, which are likely to increase in importance as the population ages, are not incorporated into the measure (although Mathers et al. (1999) attempted to do this for Australia). This means, for example, that a therapy that creates unwanted side effects cannot be captured in the DALY framework (Gold et al. 2002).

QALYs and DALYs compared

QALYs and DALYs can be seen as complementary concepts (box B.11) and have some broad similarities — both involve describing health, developing values or weights, and combining values for different states or conditions with estimates of life expectancy, for example.

Box B.11 QALYs and DALYs as complementary concepts

Take an example of deafness. Suppose that the ‘utility’ of deafness is 0.67. Then the ‘disutility’ of deafness is 0.33 (ie $1 - 0.67$). Ignoring age weighting and discounting, and assuming a life expectancy of 80 years, a deaf man who lived 50 years represents:

- 33.4 QALYs gained (ie 0.67×50); and
- 46.6 DALYs lost (ie $0.33 \times 50 + 30 \times 1$, that is years lost due to disability plus years of life lost relative to the ideal).

Source: Amensen and Nord (1999).

They differ, however, in how they do this and present population health from different perspectives (table B.1). The impact of this was illustrated by the simple numerical examples provided in boxes B.6 and B.9 above.

Moreover, in practice, they produce different disease-burden estimates and rank order of illnesses. One study (cited in Gold et al. 2002) found the DALY system recorded a decrement due to asthma of 0.06, while the QALY-linked QWB measured a 0.32 loss from full health. As discussed above, inconsistencies can also result from different QALY-associated HRQoL measures. However, the differences are compounded in comparisons of DALYs and QALYs due to the different methods they use to calculate life expectancies (Gold et al. 2002).

B.5 Measuring and isolating economic benefits and costs: the issues

Advances in medical technology can have various economic impacts — that is, they can affect the way resources (including time, as well as physical resources) are used in society (section B.1). How these should be incorporated in evaluating the impact, and specifically the cost effectiveness, of advances in medical technology is an important and to some extent unresolved issue. The treatment of indirect benefits/costs (productivity effects) is the source of most of this debate.

Table B.1 **QALYs and DALYs — the differences**

	QALY	DALY
Reason for development	Evaluation of medical interventions.	Comparison of population health across populations.
What they measure	Health expectancy — a ‘good’ to be maximised.	Health gap — a ‘bad’ to be minimised.
Interpretation	One year of healthy life.	One year of healthy life lost, calculated relative to an ‘ideal’ life expectancy.
Weighting scheme		
<i>What weights represent</i>	Utility.	Disutility; age weights also generally used.
<i>Derivation</i>	Various HRQoL instruments.	PTO-based questionnaire of health professionals.
<i>What they weight</i>	Health states, so no specific diagnosis is required.	Specific diseases, not generic descriptive dimensions.
<i>Range</i>	0 (death) to 1 (full health), with negative values also possible for states worse than death.	0 (full health) to 1 (death).

Source: Gold et al. (2002).

Productivity losses due to particular health conditions can be due to the decline in output per hour worked (referred to as ‘presenteeism’) and/or a reduction in the hours worked per person (affected by absenteeism) (Lichtenberg 2002a).

Various studies have investigated the link between health and the productivity of individuals and firms/industries, with a number of methods used to measure these effects (box B.12). Taking a firm or industry-level perspective is especially useful when absent workers cannot be replaced perfectly, or in the case of team production, when the value of productivity losses can exceed the wage (Koopmanschap et al. 2005). In other words, productivity impacts can manifest in the work performance of the patient and the patient’s colleagues.

To the extent that studies rely on samples, the reliability of their results, and their ability to

provide generalisable information, is affected by factors such as size and composition of the sample group. Nonetheless, there does tend to be a positive relationship between health and productivity, although improved disease-specific status does not always affect work loss (Burton et al. 2003).

Box B.12 Methods for measuring health impacts on productivity

- **Direct measurement.** Involves observation of actual performance. Potentially the most reliable method but is very rare, partly because objective data on workplace productivity is limited in its coverage of occupations. In addition, it is difficult to measure objectively the productivity of most employees.
- **Survey instruments/questionnaires.** Often disease-specific, developed to quantify productivity impacts due to chronic disease, incorporating the patient's own assessment of percent effectiveness while working with symptoms. They are subjective approximations, and different instruments can produce different results.
- **Randomised control trials.** The most commonly used and accepted method.
- **Single-group pretest–post test studies.** Often produce results consistent with randomised control trials, but can produce spurious results because they may pick up trends unrelated to a condition/intervention.
- **Patient diaries,** which patients use to record events. Can be more reliable for recording absenteeism than methods where events from prior periods need to be recalled. Although they can overcome so-called recall bias, they are more onerous for respondents.

Source: Burton et al. (2003).

Advances in medical technology that are directed towards conditions that affect productivity may therefore improve work performance as well as health. A major issue is how to account for any work (productivity) impacts in economic evaluations. Three main approaches have been adopted.

- The *human capital-cost* approach, the traditional approach, uses monetary weights (usually market wage rates) to weight the gains/losses in hours worked, incorporating all absence and disability losses in its calculations.
- The *friction-cost* approach only includes the frictional element of productivity losses due to ill health. That is, it only considers the production loss avoided that would have occurred during the gap between the loss of a person and their replacement, not the loss over their remaining work life. It produces more conservative estimates than does the human capital-cost approach.
- The *QALY* approach assumes (or advocates) that a large proportion of indirect costs are (should be) included in the QALY weights (Liljas 1998a, 1998b; McIntosh et al. 1999).

Various arguments, both theoretical and empirical, have been made for and against all approaches (see, for example, Brouwer and Koopmanschap (1998); Koopmanschap et al. (2005); Liljas (1998a and b); McIntosh et al. (1999)).

At a broad level, the issues relate to which economic impacts are relevant in CEA (section B.1), and which of these are best considered costs and which are benefits (including the extent to which they are subsumed in the health benefit measure).

In general, Luce et al. (1996, p. 182) noted that the ideal way to deal with time in a CEA is ‘to maintain the distinction between opportunity costs in the numerator and health outcomes in the denominator’. In practice, maintaining this distinction is not easy.

As shown in figure B.1, an intervention that changes an individual’s health status has both an intrinsic value (C) and an impact on work and leisure time (so-called ‘production output’ — D) (Luce et al. 1996). Both can be valued in monetary terms but can also be captured in the health benefits measure (B in figure B.1), the most commonly used of which is the QALY (section B.3).

- As noted in section B.3, there is great variation in which aspects of health are captured in the weights and instruments that form the basis of the QALY calculation. It has been found, for example, that productivity (both absenteeism and presenteeism) affects QoL (Koopmanschap et al. 2005). Yet it is unclear whether people incorporate work productivity impacts in their QoL responses, or whether these are considered implicitly in role functioning.

On the costs side, costs can be ‘direct’ or ‘indirect’, and should reflect opportunity costs — that is, the value of the resource in its next best use. Direct costs reflect changes in resource use attributable to an intervention. These include the value of all goods, services and other resources consumed in providing the intervention or dealing with its current and future consequences (including side effects) (Luce et al. 1996). Indirect costs refer to the changes in productivity that result from illness or death, so tend to be referred to as productivity costs (Luce et al. 1996).

Although identifying and measuring direct costs is not easy, conceptually at least a degree of consensus about how to deal with most of these exists. The main difficulty arises in relation to patient time costs (H in figure B.1). The most substantial contention, however, surrounds the appropriate treatment of productivity costs (D in figure B.1).

Patient time costs

Patient time costs include the value to the patient of the time consumed in treatment but not the value of the intervention itself (Luce et al. 1996). Luce et al. (1996) noted that the time spent undergoing an intervention is a direct cost because it constitutes a real change in the patient's and society's use of resources, effectively constituting part of the intervention itself. This simple 'consumption of time' can be distinguished from the '(un)pleasantness' of the time spent undergoing an intervention. An exercise regime for heart disease, for example, may be enjoyable or unpleasant to the patient, producing costs or benefits over and above those generated by the use of time itself (Luce et al. 1996).

Under certain conditions, intervention-associated time costs technically could be included on the costs or benefits side of a CEA. If included in the benefits side, time in treatment (adjusted for the quality of that time) would be deducted from the QALYs. In reality, however, QALYs are rarely adjusted in this way, leading Luce et al. (1996) to recommend including these time costs on the cost side of the calculation. In contrast, they suggested that the enjoyment or dislike of the time spent undergoing the intervention is more appropriately incorporated in the QALY.

Productivity costs

Luce et al. (1996) identified two conceptually distinct categories of indirect/ productivity costs:

- the lost productivity due to death (mortality costs); and
- the costs associated with reduced ability to work or pursue leisure activities due to illness (morbidity costs), including time for recuperation and convalescence.

Changes in life expectancy are clearly included in the health benefits measure. Indeed, according to Luce et al. (1996, p. 183), 'the natural unit of time incorporated in the QALY captures the full value of the time lost in death'. Because it fully captures the value of that time, to value it in terms of productivity is not only unnecessary but would result in double counting.

On other hand, Luce et al. (1996) observed that, conceptually, morbidity costs could be incorporated in a CEA as either costs or benefits.

Gold et al. (1996) recommended that the HRQoL instrument used in a CEA should, at a minimum, implicitly incorporate the effect of morbidity on productivity and leisure, with health-related financial consequences reflected in the preference weights of the health benefits measure.

Luce et al. (1996) also preferred incorporating morbidity costs in the benefits measure because it:

- is difficult to separate the HRQoL impact of being ill from role function and other experiences associated with the use of time; and
- conforms more with the principle of CEA that ‘effects’ are included in non-monetised form in the denominator.

They nonetheless identified situations where this approach was not appropriate.

- Some QALY measures specifically exclude the effects of morbidity on time use. In this case, morbidity costs would appropriately be incorporated in the numerator to ensure they are not ignored. Although this is a technically correct approach, the resulting ratios are not directly comparable with those that include morbidity costs in the health benefit calculation.
- If QALYs are not used as the measure of benefits, then morbidity costs would not have been captured in the analysis. These could then be monetised and incorporated in the numerator without involving double counting.

Including morbidity costs in QALYs does not preclude trying to value the costs for illustrative purposes. Any such valuation should, however, be performed and presented separately, not included in the CEA ratio.

Friction costs

Friction costs are direct non-healthcare related transaction costs associated with the replacement of a worker that accrue to the employer and therefore are ‘real societal costs’. Any discrepancy between the productivity of substitute labour and the labour it replaces, which is not reflected in differences in wage rates, represents a cost. Also included are training costs.

Summing up

The appropriate treatment of costs and benefits in CEA is an important yet unresolved issue, especially in relation to (indirect) productivity effects. This uncertainty arises partly because the best approach will often depend on what is included in the benefits measure. Although there may be a theoretical ‘ideal’ for what this should include, what is included in practice varies. This makes it difficult to state categorically which aspects of an intervention should be included as costs or as benefits. Some uncertainties also relate to how the economy (and specifically the labour market) is seen to function. These continuing uncertainties are reflected in the pharmaceutical assessment process in Australia (box B.13).

What can be said is that double counting should be avoided. So, to the extent that indirect effects are incorporated in the benefits calculation, they should not also be valued as costs in the numerator. It should be noted, however, that results from different studies that adopt different approaches may not be directly comparable.

Box B.13 Productive capacity in Australian pharmaceutical assessment

The PBAC guidelines caution that ‘particular care is needed when considering indirect economic outcomes when using surrogate outcome indicators (their combination may be inappropriate) or utilities (to avoid double-counting the estimates of benefit ...)’. Therefore, the inclusion of productive capacity in submissions to PBAC tends to be discouraged (DoHA 2002b p. 62).

This view, and the suggested approach to dealing with indirect benefits ‘if consideration of such ... benefits can be justified’ (DoHA 2002b, p. 69), appear to reflect the underlying assumption that the Australian economy is constrained by macroeconomic factors, rather than a lack of healthy workers. DoHA (2002b, p. 69) commented, for example, that although changes in productive capacity:

... may improve quality of life for the patient and could be included, quite legitimately, in a quality of life scale, it should not be assumed that there is an economic benefit to society through the patient’s return to productive capacity ... [because] ...

- (a) for short-term absence, production will be made up on the return to work;
- (b) employers usually have excess capacity in the labour force to cover absenteeism; and
- (c) for long-term absence, production will be made up by a replacement worker otherwise unemployed.

DoHA noted further that:

... the marginal increase in production due to return of healthy workers to the workplace is over-estimated by simply multiplying the workers’ time regained by the labour market value of the workers (usually estimated by their wages). It is not always likely to be zero either, but some proportion in between. (2002b, p. 69)

Participants to this study suggested that this approach is inappropriate. For example:

- the Cancer Council Australia and Clinical Oncological Society of Australia (sub. 32, p. 25) suggested that indirect benefits should be included in the analysis, citing studies and a literature review that showed their importance and the support of ‘the majority’ of health economists; and
- as well as referring to the practical problems of adhering to the PBAC approach, Medicines Australia argued that:

... the claim that the lack of healthy workers is not a significant constraint on Australia’s economy does not acknowledge the concern about the impact of an ageing population on future economic prosperity. One of the concerns currently being debated is exactly whether an insufficient number of healthy workers in the future could constrain Australia’s economic growth. (sub. 30, p. 88)

B.6 Other measurement issues

Various other issues can arise in measuring the outcomes of healthcare interventions, including discounting, the use of marginal or average outcomes, and valuing a human life. These are discussed in this section.

Discounting health outcomes

As Viscusi (1996, p. 125) noted, intertemporal aspects are inherent in the medical decision making context — that is, expenditure on, and the benefits of, medical technology tend to accrue over a long period of time. Discount rates attempt to reflect the different value attached to events occurring at different points in time (reflecting both pure time preference and diminishing marginal utility of income, assuming real income is rising). Discount rates therefore allow consistent measurement of costs or benefits occurring at different times. Higher discount rates reflect a greater orientation to the present, while lower discount rates imply a greater orientation to future benefits (Viscusi 1996).

An accepted practice in relation to financial items, discounting health outcomes that are not expressed in financial terms is more contentious. This reflects in part the significant impact discounting can have on the outcomes of economic evaluations, on the rankings of different interventions (where the timing of benefits and costs differs) and, therefore, on any decisions based on the analysis (box B.14).

Box B.14 The impact of discounting health outcomes

In general, the rate of discount is the intertemporal rate of tradeoff reflecting the value the decision maker places on the effects being considered. Discount rates can be chosen to reflect the opportunity cost of capital, or the preferences of society or of individuals (using an average of individual rates), and can be nominal or real.

- Discounting gives less weight to changes in health states that endure for a long time or which occur in childhood (such as improved neonatal care, or public health interventions for children), and conditions with high levels of mortality at younger ages (such as traffic accidents and suicide), compared with those that last for shorter periods (such as cardiac stents in older patients).
 - This is especially important for evaluating preventative interventions such as vaccines. One study examining the treatment and prevention of acute myocardial infarctions found the results of a cholesterol screening program (with benefits much further in the future than the costs) were much more highly sensitive to the discount rate used than were other interventions.
- Not discounting future benefits dampens the relative impact of costs, potentially showing interventions to be more cost-effective than they actually are.
- A zero discount rate can result in health interventions being delayed indefinitely.

Sources: Manning et al. (1996); Mathers et al. (1999); Smith and Gravelle (2000); VDHS, sub. 24; Viscusi (1996).

The conceptual debate

Viscusi (1996, p. 131) argued that discounting health effects involves discounting the utility stream associated with the benefits, not the health effects *per se*. In his view, then, discounting health benefits should be no more controversial than discounting other utility streams. Nonetheless, whether health outcomes should be discounted (and, if so, at what rate), is a continuing debate in the health literature.

Reasons put forward in favour of discounting health outcomes (box B.15) tend to mirror the rationale for discounting in general. According to this view, any special issues arising in health are best dealt with directly by adjusting the health benefits measure rather than the discount rate.

Box B.15 The pros and cons of discounting health outcomes	
<i>Arguments in favour</i>	<i>Arguments against</i>
<p>Time preference due, for example, to impatience, moral urgency ('the currently sick deserve help') and moral myopia.</p> <p>Uncertainty and risk, leading to a preference for benefits now because what may happen in the future is unknown.</p> <p>Diminishing marginal utility combined with rising consumption — being better off overall means marginal benefits are valued less in future years.</p> <p>Opportunity cost of capital.</p> <p>Zero discounting in the presence of higher payoffs through future investment (because technology is improving), would mean postponing all current spending and an 'excessive sacrifice' by the current generation for future generations.</p>	<p>Life does not lose value to society if it is in the future rather than in the present.</p> <p>Discounting health consequences of prevention programs devalues the longer-term future benefits relative to the high initial costs.</p> <p>The social discount rate may not be constant every year into the future.</p> <p>Opportunity cost arguments do not apply because life cannot be valued in financial terms.</p> <p>If we are concerned about excessive sacrifice, this should be considered directly as an equity principle, rather than as a discount.</p>
Source: Mathers et al. (1999).	

Viscusi (1996, p. 144), for example, commented that although health is 'special' as an economic commodity (it cannot be traded across time or individuals, and many health outcomes are irreversible), the appropriate way to deal with its special status is 'through appropriate valuation of ... health status in different periods of time', not by 'distorting' intertemporal rates of time preference. He noted further that:

A failure to discount health effects altogether by employing a zero rate of discount may appear to be more farsighted in terms of its emphasis on the future, but in practice this no-discounting approach may have the opposite result. In particular, it may lead one to defer decisions in a manner that will enhance the well-being of future generations rather than those now alive. Similarly, discount rates that are excessively high are not ideal. (pp. 143–4)

The arguments against discounting future health benefits (box B.15) often (though not exclusively) reflect ethical concerns about, for example, what it implies about the relative value of people of different ages.

Even when the need to discount benefits is accepted, further issues arise when determining the level of this rate and, particularly, whether it should be the same as that used to

discount costs. As well as ‘appeals to simplicity and tractability’ (Lipscomb et al. 1996, p. 219), those who favour using the same rate for benefits and costs base their views on arguments including:

- consistency — benefits are discounted because they are being valued relative to discounted financial items, so the same rate should apply to both;
- that it leads to ‘time neutral’ resource allocation decisions (horizontal equity);
- that differential rates (below 10 per cent) will lead to continual deferral of investment (the ‘Keeler-Cretin’ paradox, although the practical importance of this paradox has been questioned) (Gravelle and Smith 2000; Lipscomb et al. 1996); and
- where adjustments can be justified, these should be made to the benefit measure, not to the discount rate (Lipscomb et al. 1996).

Arguments in favour of using differential rates are based largely on the view that health is different. It has been suggested, for example, that lower discount rates be applied to prevention programs to avoid undervaluing downstream benefits relative to costs (Lipscomb et al. 1996). Others have suggested that non-constant discount rates (decreasing as a function of time) be applied to health outcomes, to reflect the fact that the relative importance attached to the difference between two outcomes tends to fall as outcomes occur further in the future.

Other arguments for differential rates relate to the impact of changes in income, relative costs and value of health. It has been suggested, for example, that:

- if the relative resource cost of achieving gains in health changes over time, ‘appropriate adjustment’ to the real discount rate should be made; and
- if the real elasticity of demand for a health consequence, such as a QALY, is positive and real income is increasing over time, then a rate below the real market rate should be used to discount QALYs.

Gravelle and Smith (2000) observed that the rate of growth in the value of health—which depends on the rate of growth of: the price of healthcare; healthcare consumption and its effect on the marginal productivity of care, and technical progress and its effect on the marginal productivity of care—is likely to be positive. Although CEA does not require health to be valued, they argued that it ‘does require an estimate of the growth in the value of health’ (p. 10) and that:

If the value of health is growing over time some method of allowing for it in CEA must be found. It is simply incorrect to use the same discount rate for health and cost effects if the value of health is growing. (Gravelle and Smith 2000, p. 6)

They acknowledged, however, that adjusting the discount rate is one valid way to do this, with an equivalent procedure being to adjust the volume of health effects by the growth rate in the value of health, and then to discount at the same rate as costs.

Discounting health outcomes in practice

Viscusi (1996, p. 144) observed that ‘because there are no markets for explicitly trading health status across time, the choice of appropriate discount rate for health status has remained a substantial subject of debate’. It has been suggested, for example, that social discount rates are the most appropriate in the context of health outcomes because individuals may have different concerns for public and private issues, and also because the time preferences of individuals are not relevant to preferences for a stable society (Mathers et al. 1999). On the other hand, it has also been suggested that the private opportunity cost of capital ‘provides the most reliable guideline for the social rate of discount’ (Viscusi 1996, p. 132). In addition, Lipscomb et al. (1996) noted that a *real* discount rate must be used in CEA because:

To conduct a CEA in nominal terms would require that program effectiveness (e.g., QALYs) be converted from its natural unit of measure — which is ‘inherently’ real — into some other, inflation-multiplied unit of measure. While the arithmetic for carrying this out is straightforward, the exact interpretation of the resulting ‘nominal’ units of effectiveness is not. (p. 222)

In the face of these uncertainties, Manning et al. (1996) concluded:

One of the most important parameters that requires sensitivity analysis is the discount rate, because of the lack of consensus on the true or relevant real rate of discount for policies and treatments that have consequences over a number of years. If the costs and/or effectiveness of any of the interventions occur over several years, but with different patterns over time, then the cost-effectiveness of a specific program may depend critically on the rate of discount. (p. 251)

Estimates of individual discount rates

Various studies have tried to estimate the discount rates of individuals for health outcomes, such as through labour market data (with inferences drawn from wages received to bear higher fatality risks), or responses to hypothetical survey questions.

In general, individual discount rates have been found to vary from 0 to 10 per cent, although they often lie outside this range — some studies of purchasing decisions have even determined rates exceeding 200, and up to 300, per cent (Lipscomb et al. 1996; Mathers et al. 1999; Viscusi 1996). Implicit rates of discount for health derived from US labour market data ranged from 1 to 14.2 per cent (Viscusi 1996), while Viscusi (1996) commented that pharmaceutical companies appeared to be using a 9 per cent discount rate.

Behavioural evidence suggests, however, that individual preferences are not consistent with the constant-rate exponential discounting model (Lipscomb et al. 1996).

This variation in estimates may appear to provide little guidance for choosing a particular rate to apply for CEA. However, Viscusi (1996) noted that the range implied for health outcomes from labour market studies is lower than that found in other areas. He also noted that because the 9 per cent rate used by pharmaceutical companies incorporates a risk premium (which should not be factored into CEA for health effects), it exceeds that which should be used to discount health effects. Moreover, the confidence intervals generally include prevailing market rates of interest. Lipscomb et al. (1996) also noted that, although individual rates vary, this is to be expected, and more important for CEA as a prescriptive tool is what happens on average. In this vein, they noted that many studies find mean rates to fall within the 'conventional range', one study finding an average of 3.3 per cent.

Rates used in health economic evaluations

No standard discount rate has been applied in practice. In a survey of the literature from the United States, United Kingdom and Canada, Smith and Gravelle (2000) found that base real discount rates varied between 0 and 7 per cent, with the most commonly used being 0, 3 and 5 per cent. These were used in 35, 10 and 47 per cent of the included studies respectively. Over 90 per cent of the studies applied the same rate to discount health effects and costs, but 28 per cent of the sample did not discount costs or benefits.

Mathers et al. (1999, p. 157) suggested that 3 per cent is probably lower than the opportunity cost of capital but 'at the upper end of acceptability for those wanting to avoid the excessive sacrifice problem'. A 3 per cent discount rate implies that a year of life or health benefit gained in ten years' time is worth 24 per cent less than a year of life or health benefit gained now (Access Economics 2003c).

The practice is to some degree at odds with recommendations on discounting, both from official sources and in the academic literature. These sources all recommend a positive discount rate for costs and benefits, generally specified as 3 or 5 per cent (Smith and Gravelle 2000). Most recommend further that sensitivity analyses be conducted using a range of rates, while Lipscomb et al. (1996) also suggested that the recommended rate be reviewed periodically (but not more frequently than every 10 years) to ensure its continuing appropriateness.

Lipscomb et al. (1996), in the report of the US Public Health Service Panel on Cost Effectiveness in Health and Medicine, recommended a 3 per cent discount rate be used for both costs and benefits. They further suggested, however, that calculations using a

5 per cent rate should also be performed because so many CEA studies had used this rate in the past, with sensitivity analysis conducted for rates between 0 and 7 per cent. The recommended rate was consistent with the view of Viscusi (1996, p. 144) that real rates of return of no more than 3 per cent were more in line with US economic performance than was a 5 per cent rate. The World Bank has also used a 3 per cent rate to discount DALYs in its development reports.

DoHA (2002b) suggests that 5 per cent (real) be used to discount costs and benefits for submissions made to the PBAC.

Only the UK Department of Health recommends using different rates for costs and benefits. It suggests a 1.5 per cent rate for health effects that are not estimated in monetary values, and 3.5 per cent for all monetary values (including benefits if valued in monetary terms) (UK DH 2004). Its recommended rate for health effects reflects pure time preference, which it argues is ‘in practice the only reason to discount quantities of health’ (UK DH 2004, p. 31), and it is lower than the discount rate for costs to reflect the increasing value of health over time. These rates are based on the estimates of UK Treasury (2003), which recommends that the social time preference rate be used as the standard discount rate (box B.16).

Marginal or average outcomes?

Most information about outcomes in the health context is reported in terms of averages — that is, the total impact of a technology expressed as a proportion of the total affected population. In the context of CEA and resource allocation decisions, however, the usual approach is to use marginal analysis — where the outcome of interest is the additional impact of the technology, that is the impact on the last relevant unit (patient treated, for example) to which it is applied. An ‘optimal’ decision is said to occur when the marginal benefits of the intervention equal its marginal costs. The distinction is not important if marginal and average values are identical. However, as Segal and Richardson (1994) noted, this is unlikely to be the case in the healthcare context, where the net benefits of technology vary substantially across the patients or organisations that use them.

Box B.16 UK Treasury estimate of the social time preference rate (STPR)

Social time preference is the value society attaches to present, as opposed to future, consumption, with the STPR based on comparisons of utility across different points in time or different generations. The STPR comprises the following elements.

- The rate at which individuals discount future consumption over present consumption (assuming constant real income), which comprises:
 - *catastrophe risk* (likelihood of occurrence of an event so devastating that all returns are eliminated or substantially altered), which is difficult to quantify; and
 - *pure time preference* (individual preference for consumption now rather than later, with income per capita held constant).
 - UK Treasury (2003) estimated these two components to be 1.5 per cent per year (estimates from previous studies ranged from 1 to 1.6 per cent).
- An additional element if growth in per capita consumption is expected, comprising:
 - *marginal utility of consumption* (estimated to be about 1 in the United Kingdom, although studies have estimated values ranging from 0.7 to 1.5); and
 - *annual rate of growth of per capita consumption* (estimated to be about 2 per cent).

On this basis, the estimated real STPR for the United Kingdom was 3.5 per cent.

Source: UK Treasury (2003).

Malek (2001), using an example of treatments for metastatic breast cancer, showed that different inferences can be drawn from cost per QALY calculations, depending on whether average or incremental values are used. Average cost per QALY is calculated by dividing the cost of an intervention by the number of QALYs the intervention provides. Incremental cost per QALY is estimated by assessing the additional costs and benefits provided by one intervention compared with another. Malek (2001, p. 4) argued that his example showed ‘why average values can sometimes be misleading’, noting further that ‘incremental cost per QALY estimates assess the additional cost per health gain that is expected when choosing one intervention over another, and so most closely reflect the impact of choices in the real world’ (p. 3).

Nonetheless, some have argued that marginal analysis may not be sufficient for assessing health-related outcomes, and that marginal analysis should sometimes be complemented with an ‘overall’ analysis incorporating averages. Mathers et al. (1999, p. 2), for example, commented:

Some health economists have expressed concerns that burden of disease analyses may tempt planners to set priorities in terms of size of problem, arguing that priority setting requires knowledge only of cost effectiveness ratios at the margins of current activity

... While it is ... true that burden of disease estimates without economic analyses are insufficient to make decisions on resource allocation, there are good reasons to do both.

On the other hand, they also acknowledged that the size of the problem is not the only consideration in determining health priorities. Cervical cancer, for instance, is not in the top ten cancers for women but is a ‘priority cancer’ because ‘it is one of the few cancers where precancerous lesions are cost effectively detectable and treatable’ (Mathers et al. 1999, p. 2).

Valuing outcomes in healthcare

Summary health outcome measures use a common metric that allows the impact of different technologies and interventions to be compared, without the need to place a financial value on outcomes. This facilitates their use in CEA. Because they provide an indicator measured in terms of health outcomes, however, they cannot be used for broader resource allocation decisions — that is, comparing medical interventions with expenditure in non-health-related areas. Such comparisons, through cost–benefit analysis, require the use of a unit of measurement (in most cases, monetary units) that can be applied across all areas.

Thus, a literature has also developed in the valuation of outcomes — mortality and morbidity — in healthcare. There are two approaches to assess the value of mortality improvements, the:

- mortality approach, which multiplies the change in the mortality rate (weighted by the share of the population experiencing lower mortality) by the estimated value of lower mortality; and
- life-years approach, which multiplies the increase in life expectancy (weighted by the share of the population experiencing greater life expectancy) by the estimated value of an additional year of life (Access Economics 2003c; Nordhaus 2003). Calculating this is more complex — improved mortality increases life expectancy in the future (especially in the case of infant mortality) so discounting is required.

Crucial to both methods is quantifying the value of life, which can be done in various ways. The *restitution cost* approach, for example, values diminished health status in terms of the resources required to restore a victim and relatives to the earlier state (UK DH 2004). This can be proxied by the compensation allocated in court decisions, but the UK DH (2004, p. 35) noted that these decisions ‘do not systematically aim to provide an estimate of the value, either to an individual or society, of a life lost’.

Another, market-based, measure is the *human capital* approach. This values a person's life in terms of the production (at market prices) that would be lost if the person died or were ill. Within this broad approach, a number of variations are possible. For instance, additional consumption of other goods or unrelated medical costs are sometimes subtracted out, earnings figures are sometimes presented as gross estimates, and time not used in market work is sometimes valued as if it were used in market work — leisure time valued at the wage rate, and housework valued using the wage rate for professional housekeepers or what would be earned in the market (Pauly 1996). For productivity impacts in regular activities, a percentage of the losses in paid work productivity tends to be used (Wahlqvist 2001, p. S59).

There are many problems with the human capital approach, especially relating to what it implies about what makes a life valuable. The UK DH (2004, p. 35) noted, for example, that this approach:

- values 'livelihood rather than life';
- implies that 'the lives of those who earn little or nothing have no value'; and
- ignores the fact that people are willing to pay, or to risk their lives, to save the lives of others, a fact that should be recognised in economic analysis.

These shortcomings make it inconsistent with the welfare economics perspective, which acknowledges that value is derived from more than just 'market work'. Thus, the UK DH (2004, p. 35) noted that the human capital approach is 'now generally considered inadequate', and Pauly (1996) recommended it not be used in cost-benefit studies, commenting:

... the human capital measure is conceptually invalid as an economic measure of benefit from medical services exactly because it does not measure an approximate willingness to pay very well. At best, lifetime earnings might be interpreted as a lower bound on willingness to pay, as long as leisure has value ... The view that health only has value in adding to 'national output' is inconsistent with welfare economics, which recognises value in leisure time and in other activities that are not measured in gross national product. (p. 117)

The most common approach to valuing life, and one that is based on standard economic principles, is the 'willingness to pay' approach. Its underlying premise is that what a consumer is willing to pay for a good or service represents its economic value (in a broad sense) (UK DH 2004). It assesses how much people are willing to pay for small changes in their own or their household's risk of death or injury, from which an implicit 'value of life' can be estimated. Willingness to pay is affected by factors such as age, income and type of risk and death (Abelson 2003).

There are two broad approaches to assessing willingness to pay:

- ‘revealed preference’ techniques, which involve observing actual situations in which people trade the risk of death or injury for financial or other benefits — such as in labour markets or daily decisions (such as purchasing decisions); and
- ‘stated preference’ (contingent valuation) techniques, which involve the use of surveys to determine preferences for hypothetical situations (box B.17).

The willingness to pay approach is increasingly being used in the healthcare context, usually to value the overall benefits, rather than the individual health effects, of interventions (Dolan 2000, p. 1734). Nordhaus (2003) noted that most weight tends to be placed on the results of labour market studies because: they reflect actual behaviour; labour market decisions are repeated; and many such studies have been performed for different periods, countries, occupations and samples.

Nonetheless, the valuation of human life, even using the willingness to pay approach, is contentious at a number of levels (box B.17). Some issues relate to the ‘usual’ technical econometric and measurement issues. These include the fact that outcomes are influenced by model specification and statistical procedures used, and that it is problematic to extrapolate the value of life from a context of low risk of death (Peacock et al. 2001). In addition, Murphy and Topel (2003) noted that value of life calculations that focus on earned income underestimate willingness to pay because they do not account for nonmarket time, which may be especially important for older people post-retirement where income is relatively low.

In terms of revealed preference techniques, additional issues relate to the fact that the behaviour from which inferences are drawn may be motivated by factors other than risk assessment and/or be based on inadequate information (Pauly 1996; UK DH 2004). The situations from which the estimates are drawn also may differ from those to which they are being applied, and the results may not be transferable. Problems can also arise if people differ in the values they place on risks (box B.17).

As with other approaches to estimating the value of life, issues with willingness to pay techniques extend beyond the ‘usual’ technical and practical issues involved in measuring economic outcomes. These relate to ethical concerns, such as questions about what makes a life valuable (do we only value people to the extent that they are productive workers or according to their age?), and the fact that willingness to pay is affected by capacity to pay (income or wealth). Wang (1998) argued, however, that valuing life need not be controversial if viewed in its proper context (box B.18).

Box B.17 **Estimating the value of life — approaches to measuring willingness to pay**

Labour market studies examine the risk–wage tradeoff using econometric methods (hedonic wage equations), typically estimating the locus of market equilibria of money–risk tradeoffs rather than market supply or demand curves. The main advantage of these approaches is that they rely on observed incomes and wages, and there are established measures to distinguish risk levels across individuals. Results are, however, very sensitive to model (mis-)specification and statistical procedures used. In addition workers in risky jobs may be self-selected, have imperfect information about the risks involved, and have different risk preferences compared with other people. Where people differ in the values they place on risks, market values will not be able to describe the risk of all people. An average also cannot be inferred because market prices describe the value for the marginal person on the marginal unit. Therefore, most people who choose riskier jobs attach less value to that risk than the premium, while those who accept less risky jobs attach greater value to avoiding risk than the wage differential. Most studies focus on valuing fatality risks rather than risks of non-fatal health outcomes.

Inference from consumer decisions examines the risk–price tradeoff (using hedonic price equations), such as how much people spend on smoke alarms or how much less they are prepared to pay to rent houses in highly polluted areas, etc. The main disadvantage of this approach is that the risk facing the individual, or financial value of the attribute (such as travel time), is not observed. It has been suggested, therefore, that these approaches provide less direct and reliable measures than labour studies.

Contingent valuation studies determine individual preferences by examining stated preferences, generally in terms of what people are willing to pay for decreases in risk of death or morbidity (the direct method). If a person is prepared to accept \$10 000 for a 1 per cent increase in the risk of death, the imputed value of life is \$1 million (ie $\$10\,000 \div 1 \text{ per cent}$). Other techniques include offering pairwise comparisons (two jobs with different wage–risk tradeoffs, which are manipulated until indifference is achieved), or lottery methods. These studies have the advantage of not being constrained by available market data but are highly dependent on the truthful revelation of preferences, and the extent to which respondents actually understand the tasks and risks being evaluated. Potential sources of bias include cues that distort behaviour and non-random selection of participants.

Sources: Access Economics (2003c); Bloom et al. (2004); Pauly (1996); Peacock et al. (2001); UK DH (2004); Viscusi (1993); Viscusi and Aldy (2003).

Specifically, Wang (1998) noted that what is being measured is the value of a ‘statistical’ life: a measure of the observed price of fatality risks, which reflects an individual’s willingness to pay for small reductions in a very low risk of death. Viscusi and Aldy (2003, p. 6) also noted that ‘in the case of mortality risk reduction, the benefit is the *value of the reduced probability of death* that is experienced by the affected population, *not the value of the lives that are saved ex post*’ (emphasis added).

Box B.18 Interpreting the value of a statistical life

Underlying idea. A 1 in 100 000 risk of death to a person is equivalent in statistical terms to one death in a community of 100 000 people. What the community is willing to pay collectively to reduce the number of deaths by one, is a measure of the value that society places on a 'statistical' life. This equals what the average person in the community is willing to pay for a 1 in 100 000 reduction in the risk of individual death, multiplied by the number of people in the community. Thus, if each person in the community is willing to pay \$50 for a 1 in 100 000 reduction in individual death risk, then the value of a statistical life is $\$50 \times 100\,000 = \5 million .

What it does not imply. A \$5 million value of statistical life does not imply that a person would accept certain death for \$5 million, or a 0.50 increase in individual death risk for a payment of \$2.5 million. The value of statistical life can exceed a person's total lifetime earnings potential. A person with total lifetime earnings well below \$5 million may be willing to pay \$50 for a 1 in 100 000 reduction in death risk, implicitly valuing a statistical life at \$5 million in a community of 100 000 people.

What it does mean. The value of a statistical life is an 'average' for a given population — the price on fatality risks and the implied value of life will be higher for some groups of workers than for others, for example.

Source: Wang (1998).

Most work in this area has been done in the United States, although a literature is developing elsewhere. This work has produced wide variations in the estimates of the value of life. For example, the value of a statistical life estimated in US labour studies tends to fall between US\$3.8 million and US\$9 million (in year 2000 dollars), with a median value of US\$7 million, although some estimates have exceeded US\$12 million. The outcomes from product market studies tend to be similar, though somewhat lower, possibly due to the different nature of product markets and the need to infer rather than observe tradeoffs (Viscusi and Aldy 2003). Estimates for other countries also vary, but tend to be lower than for the United States.

In the United Kingdom, the Department of Transport has valued preventing the risk of death in the road transport context (incorporating willingness to pay, gross lost output, and medical and ambulance costs) at £1.145 million (in year 2000 prices). In contrast to most studies, it also calculated the value of non-fatal outcomes using a survey-based method and the SG technique (section B.2) — the value of preventing a serious injury being £128 650, and the value of preventing a slight injury being £9920 (in year 2000 prices). (UK DH 2004; UK Treasury 2003)

Combining QALYs and value of life estimates

Value-of-life estimates can be used in conjunction with QALYs and DALYs as a way to place a financial value on these outcomes. For example (ignoring discounting), if the statistical value of a life is calculated for a population with an average current age of 40, and life expectancy of 76, then immediate death would result in the loss of 36 life years. If, on average, 26 of these years are expected to be lived in full health and ten in a health state valued as 0.5 QALYs, then this represents a loss of 31 QALYs. In this scenario, if the value of a statistical life is estimated to be, for example, \$3.1 million, then the money value of a QALY would be \$100 000 (that is, \$3.1 million divided by 31 years) (UK DH 2004; Wang 1998).

The UK DH (2004, p. 38) noted, however, that there are difficulties applying this approach where an initiative affects health status as well as mortality, and that certain restrictive assumptions are needed for it to be valid.

In terms of DALYs, the Australian Centre for Asthma Monitoring (ACAM 2005b, p. 23) noted that it is 'informative' to use health burden estimates to calculate the economic burden of specific diseases. Using a 1996 estimate of the value of a DALY to the Australian community (\$60 000), it estimated that the 64 523 DALYs attributed to asthma in 1996 equated to \$4.3 billion in 2000–01 dollars. It indicated that:

This can be interpreted as burden, estimated in dollar units, attributable to projected disability arising from new cases of asthma and to premature mortality due to asthma, during 1996. (ACAM 2005b, p. 23)

C Health technology assessment in other countries

The terms of reference require the Commission to have regard to international experience in assessing the cost effectiveness of healthcare. This appendix outlines health technology assessment (HTA) arrangements in a selected number of countries, with the purpose of enabling relevant comparisons with HTA mechanisms and processes in Australia (chapters 8, 9 and 10). It does not seek to undertake a comprehensive evaluation of HTA in these countries. While overseas HTA processes may allow for community input on the importance of new medical technologies, the appendix does not describe processes that aim to determine the value the community places on healthcare relative to other priorities.

As noted in chapter 8, key elements of HTA processes comprise horizon scanning, technology assessment, monitoring and re-assessment. The information generated by HTA processes also may aid decisions about market authorisation and listing for reimbursement, as well as the development of clinical practice guidelines (figure 8.1). Based on this characterisation of HTA, this appendix highlights the main features of HTA processes in the following countries:

- Canada;
- Denmark;
- France;
- Sweden;
- The Netherlands;
- United Kingdom; and
- United States.

These countries were selected for several reasons. Most of the countries are known for undertaking a high level of HTA activity (McDaid et al. 2001; Oliver et al. 2004). Given that Australia is a federal system, it may be useful to look at how HTA is conducted and organised in other federations such as Canada and the United States — Professor Karen Facey (sub. 39) noted that Canada has independent provinces with one overarching HTA coordinator. Some participants, such as the Medical Industry Association of Australia (MIAA, sub. 40) and the National Centre for Social and Economic Modelling (NATSEM,

sub. 1), also pointed to features of HTA arrangements in Europe which might provide some lessons for Australia.

C.1 Canada

The federal authority responsible for authorising the sale of pharmaceuticals and medical devices in Canada is the Therapeutic Products Directorate (TPD) of Health Canada. In seeking market authorisation, a drug or medical device manufacturer must provide substantive scientific evidence on product safety, efficacy and quality as required by the Food and Drugs Act and Regulations (Health Canada 2003).

Post-approval surveillance of marketed health products is coordinated by the Marketed Health Products Directorate within Health Canada. The Biologics and Genetic Therapies Directorate regulates biological and radiopharmaceutical drugs which include blood products, viral and bacterial vaccines, genetic therapeutic products, tissues, organs and xenografts. Its role is to evaluate and monitor the safety, quality and effectiveness of these products (Health Canada 2003).

While TPD makes authorisation decisions regarding drugs and medical devices, most purchasing decisions are made at the provincial and territorial level. HTA activities have been funded by provincial governments for many years, although formal groups were not established until more recently (McDaid 2000). Provincial HTA agencies include, among others, the British Columbia Office of Health Technology Assessment, the *Conseil d'Evaluation des Technologies de la Sante* of Quebec, and the Manitoba Centre for Health Policy and Evaluation.

A national HTA body, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), was established in 1989 by federal, provincial and territorial ministers of health. Its role is to provide national information exchange, resource pooling and coordination of the assessment of healthcare technologies in order to ensure the appropriate use of cost-effective technologies for the benefit of all Canadians (Sanders 2002). Through its coordination role, CCOHTA aims to minimise duplication of HTA activities across the federation.

CCOHTA reports to the conference of deputy ministers of health through its board of directors who are appointed by the deputy ministers (CCOHTA 2003). The board determines the topics that will be assessed by CCOHTA, focusing on HTA issues of national concern. CCOHTA supports informed decision making through two programs: the Health Technology Assessment Program; and the Common Drug Review.

As part of the HTA Program, CCOHTA prepares or commissions technology reports which examine the clinical effectiveness, cost effectiveness and/or impact of health technologies in Canada. As well as undertaking evidence-based assessments, it monitors already-adopted technologies to determine whether a reassessment is needed due to a change in clinical or cost effectiveness (Sanders 2002). CCOHTA also examines and develops evaluation methodologies: for example, it published a set of guidelines for the economic evaluation of pharmaceuticals that influenced the development of similar guidelines in some of the provinces (McDaid 2000).

CCOHTA established the Canadian Emerging Technology Assessment Program (CETAP) in 1998, which now forms a permanent part of the HTA program. CETAP conducts national horizon scanning to alert decision makers to upcoming drugs, devices and procedures that may have a significant impact on healthcare in Canada. For instance, it prepares emerging drug and technology lists that highlight new pharmaceuticals and other medical technologies with potentially significant impacts while they are at an early stage of development (CCOHTA 2003).

HTA information is disseminated by CCOHTA in various ways, including by traditional and online distribution of its publications. CCOHTA promotes awareness of its HTA findings through regular newsletters and an email notification service.

The Victorian Department of Human Services (VDHS, sub. 24) noted that CCOHTA's mandate was expanded in 2002 to include responsibility for managing the Common Drug Review (CDR). CDR is a single process for reviewing new drugs and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial drug benefit plans (all jurisdictions except Quebec). CDR aims to provide a consistent and rigorous approach to drug reviews and to reduce duplication in the review processes of the jurisdictions.¹ The Canadian Expert Drug Advisory Committee (CEDAC) makes a listing recommendation after considering a brief on each drug submission. Each of the participating drug benefit plans then makes its own formulary listing and benefit coverage decisions based on CEDAC recommendations and other considerations (CCOHTA 2005).

Clinical guideline development in Canada appears to occur largely at the provincial or regional level. For example, in Ontario, the Guidelines Advisory Committee (which is sponsored by the Ministry of Health and the Ontario Medical Association) endorses each recommended guideline following an in-depth review (GAC 2005). However, at the national level, the Canadian Medical Association maintains a database of clinical practice

¹ Prior to the creation of CDR, each jurisdiction conducted its own drug reviews and had its own committee of experts to provide listing recommendations. Now, instead of filing separate submissions to each drug plan, manufacturers make one submission to CDR (CCOHTA 2005).

guidelines. To be entered into the database, a guideline must be produced or endorsed in Canada by a national, provincial/territorial or regional medical or health organisation, professional society, government agency or expert panel (CMA 2005).

C.2 Denmark

As Denmark is a member of the European Union (EU), pharmaceuticals may be authorised through EU procedures for sale in Denmark and other EU member states (box C.1). (These procedures also apply to EU members France, Sweden, The Netherlands and the United Kingdom, the HTA arrangements of which are described below.) Alternatively, drug companies may seek approval directly from the Danish Medicines Agency (DMA) which is responsible for authorising the sale of medicinal products in Denmark. DMA was established in 1997 as an independent agency under the Ministry for the Interior and Health. When a company applies for authorisation, DMA must verify that the medicine meets current requirements for quality, safety and effect.

Medical devices in Denmark are regulated by national laws that mirror EU directives (box C.1). Device manufacturers are responsible for ensuring that their devices are safe and harmless to use when put onto the Danish market (DMA 2004). DMA conducts post-market surveillance of devices as well as medicines.

In addition to market authorisation, DMA also decides which medicines may be subject to general and/or special reimbursement by the Danish National Health Service. For general reimbursement, DMA's assessment takes account of factors such as the effectiveness of the medicinal product relative to its price. A doctor can apply to DMA, on behalf of a patient, for special reimbursement. In this case, DMA assesses whether the medicine is of special significance in the patient's treatment and the extent to which other treatments may be sufficient (DMA 2004).

The development of HTA activities in Denmark reflects the decentralised nature of the healthcare system. County councils are responsible for providing health services, which includes running hospitals. While the national Ministry of Health provides advice to counties, it has little direct influence on health service provision (Nielsen et al. 2000). Historically, HTA has been undertaken by universities, research institutes and within county administrations.

Box C.1 **Market authorisation in the European Union**

European Union (EU) authorisation processes — which involve assessment of safety, quality and efficacy — differ substantially between pharmaceuticals and devices.

Pharmaceuticals

Drug companies may invoke one of two EU procedures to seek market authorisation:

- the centralised procedure; or
- the mutual recognition procedure.

The centralised procedure allows applicants to seek marketing authorisation that is valid throughout the EU. The company submits its application to the European Medicines Agency for assessment by the Committee for Medicinal Products for Human Use. The procedure results in a European Commission decision that is binding on all EU member states. The centralised procedure is mandatory for medicinal products manufactured by biotechnological means.

The mutual recognition procedure works on the principle of mutual recognition by EU member states of their respective national marketing authorisations. Any national marketing authorisation granted by an EU member state's national authority can be used to support an application for its mutual recognition by other member states. Since 1998, this procedure has been compulsory for all medicinal products to be marketed in a member state other than that in which they were first authorised.

While the evidence is incomplete, it appears that pharmaceutical companies tend to opt for the mutual recognition procedure.

Medical devices

Several EU directives provide for a harmonised regulatory environment for medical devices sold within the EU as well as the European Free Trade Association (EFTA). The key directives include the:

- active implantable medical devices directive;
- medical devices directive; and
- *in vitro* diagnostic medical devices directive.

These directives have been transposed into the national laws of member states of the EU and EFTA. They define the essential requirements that devices must meet before they can be put onto the market. Member states appoint competent authorities (typically, national ministries of health) to enforce the regulations and to designate certification bodies (that is, notified bodies) to carry out conformity assessment. By affixing *Conformite Europeenne* marking to a device, a manufacturer declares that the product conforms to all applicable requirements and that the appropriate conformity assessment procedures have been completed.

Sources: Altenstetter (2002); European Commission (2000).

National HTA mechanisms have only been established in the past decade. The key HTA body is the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA), which was formed in 2001 from the merger of the Danish Institute for Health Technology Assessment (created in 1997) and the Danish Hospital Evaluation Centre (created in 1998). DACEHTA is a separate entity within the National Board of Health, headed by a director and served by two boards: the Centre Advisory Board and the Scientific Advisory Board (DACEHTA 2005).

DACEHTA's mission is to promote the use of HTA in Denmark by providing information, advice, education and training on HTA. It undertakes assessments of health technologies and evaluations of public health services with the aim of improving quality, standards and value for money. In cooperation with health authorities at the county level, DACEHTA assesses new and existing equipment, pharmaceuticals, methods of examination, treatment and care, methods of rehabilitation, health education and preventive healthcare (DACEHTA 2005). Neither the county councils, the Ministry or Parliament can overrule DACEHTA's scientific or medical assessments. DACEHTA disseminates its HTA information mainly through printed reports, newsletters and its website (NEC 2003).

In an external review of DACEHTA, the Nordic Evaluation Committee found that areas for analysis had been determined by the legacy left by DACEHTA's predecessors, political desires, known needs for analyses within the National Board of Health, and by the quality of external grant applications for HTA projects (NEC 2003).

DACEHTA also operates an early warning system which aims to inform relevant decision makers of new health technologies and the expected consequences for the healthcare system. The target groups include health professionals, health managers and political decision makers. DACEHTA identifies new and emerging technologies by systematically searching the Internet and obtaining input from expert groups. Technologies are selected using two prioritisation criteria, namely that the technology is expected to lead to considerable health improvements for a large group of patients, and to have substantial economic and/or organisational consequences. Broad assessments are then prepared based on the best evidence available and are intended to provide a broad basis for planning (DACEHTA 2005).

Established in 2000, the Danish Secretariat for Clinical Guidelines (DSCG) fosters and supports the development of clinical guidelines by medical societies and other healthcare professionals. DSCG became part of DACEHTA in 2004. It has outlined several principles that guideline developers must follow to obtain its collaboration: guidelines should be evidence-based; based on interdisciplinary work involving relevant healthcare professionals; and integrate organisational and health economic aspects as well as patients' views. DSCG has published six clinical guidelines since 2000 (DACEHTA 2005).

C.3 France

In addition to EU procedures (box C.1), pharmaceutical companies may apply for market authorisation from the *Agence Francaise de Securite Sanitaire des Produits de Sante* (AFSSAPS) (French Health Products Safety Agency) which reports to the Health Directorate within the Ministry of Health. The main activities of AFSSAPS include evaluating, regulating and monitoring the safety and efficacy of medicinal products. Economic evaluation is not part of the authorisation process. While several bodies in France have the authority to give approval to medical devices, AFSSAPS can withdraw from use any medical devices that are deemed to present a risk (Orvain et al. 2004).

From 1996 to 2004, the key national body that performed cost–benefit HTA was the *Agence Nationale d’Accreditation et d’Evaluation en Sante* (ANAES) (National Agency for Accreditation and Evaluation in Health).² It was an advisory body under Health Directorate supervision that examined the clinical and cost effectiveness of non-pharmaceutical medical technologies. ANAES was involved in different types of HTA activities including arranging consensus conferences and the preparation of HTA reports and clinical practice guidelines. Its HTA reports were published and posted on the Internet.

ANAES’s annual program for HTA reports was defined after consultation (with government, professional groups and academic societies) and approved by its administrative board. ANAES produced two main streams of HTA reports: evidence-based assessment of widely-used technologies and those on the verge of dissemination; and rapid assessment of emerging and fast-developing technologies. Priorities for clinical guidelines were mostly determined by practitioners’ needs, although policy makers also could identify a need for guidelines (Orvain et al. 2004).

While ANAES provided scientific and technical advice on medical technologies, the decision whether to list a medical product or service and whether to reimburse fees remained with its customers; that is, the national health insurance funds, the Health Directorate and the Department of Social Security (Orvain et al. 2004).

In 2004, the French Government passed legislation which created the *Haute Autorite de sante* (HAS) (French National Authority for Health). HAS took over the work of ANAES and several other committees. HAS was established in response to a perceived need for a structure that would provide authoritative independent advice and consolidate a range of expertise into a single body. It will advise public authorities on the reimbursement of

² The National Agency for the Development of Medical Evaluation was established in 1990 and was renamed ANAES in 1996.

medical products and services, and aims to help improve the quality of care delivered to patients. Within HAS, a number of specialist committees will assess medical and surgical procedures, medicinal products, medical devices and other health technologies for reimbursement purposes. There is also a committee for clinical practice guidelines and practice improvement (HAS 2005).

Some HTA committees in France serve particular customer groups. For example, the Committee for the Evaluation and Diffusion of Innovative Technologies (CEDIT) is a hospital-based committee that advises *Assistance Publique-Hospitaux de Paris* (which is a group of about 50 university hospitals in the Paris area) on the diffusion of diagnostic and therapeutic innovations. CEDIT prepares reports to inform decisions about adopting new equipment and technologies (Orvain et al. 2004).

C.4 Sweden

Pharmaceutical companies who wish to market products on the Swedish market may invoke EU procedures (box C.1) or seek authorisation directly from the Medical Products Agency (MPA) — the national authority responsible for regulation and surveillance of drugs and other medical products in Sweden. MPA's task is to ensure that patients and healthcare professionals have access to safe and effective medical products and that these are used in a rational and cost-effective manner (MPA 2005a). Before medical devices can be released onto the market, manufacturers must ensure that their products meet current safety and performance requirements. For certain devices, accredited bodies must assess the products. In 2001, MPA assumed responsibility for market surveillance of devices (MPA 2005b).

HTA is well established at the national level — the *Statens beredning for medicinsk utvärdering* (SBU) (Swedish Council on Technology Assessment in Health Care) was created in 1987 as a government agency. It was later commissioned as an independent public authority for the evaluation of methods used to prevent, diagnose and treat health conditions. Its mission is to assess comprehensively health technologies from medical, economic, ethical and social standpoints. SBU prepares several types of assessment reports: Yellow Reports, Alert Reports and White Reports. These are intended to inform professional caregivers, healthcare administrators, planners and health policy makers (SBU 2005). The results of SBU's work are reported to the Ministry of Health and Social Affairs and the Committee for Social Affairs in Swedish Parliament (Jonsson 2002). Reports also are sent to administrators in county councils.

Yellow Reports are assessments undertaken by SBU project groups. The reports are based on systematic reviews of the scientific literature on a topic area. The executive summaries and conclusions of Yellow Reports are approved by the SBU Board and the SBU Scientific Advisory Committee (SAC). White Reports explore topics that may need to be assessed (SBU 2005).

Topics for assessment reports are received from numerous sources including individuals, healthcare organisations and government agencies. SAC, which represents a broad range of professions in healthcare, recommends topics for new projects. The topics selected are considered to be of major importance to public health and quality of life. Major public health problems (for example, back pain, depression and obesity) are prioritised rather than specific technologies. For each topic, all available technologies for prevention, diagnosis and treatment are then identified and assessed (Jonsson 2002). After considering initial reviews of the scientific literature on proposed topics, the SBU Board and SAC determine which topics will receive further assessment and be published as SBU reports.

Established in 1997, SBU Alert is a mechanism for the early identification and assessment of new healthcare technologies. It identifies relevant technologies and produces timely information on the medical effects and potential consequences for health services (Carlsson 2004). While topics may be suggested by individuals, organisations or government agencies, the Alert Advisory Board determines which topics will receive priority for assessment. SBU publishes Alert Reports which are an early assessment of new technologies being developed and disseminated in healthcare. As well as information on the new technology, Alert Reports discuss effectiveness, risks, cost effectiveness, ethical concerns and organisational impacts. The findings are approved by the SBU Board and Alert Advisory Board. In contrast to Yellow Reports, each Alert Report addresses a single intervention only (SBU 2005).

Although there does not appear to be a formal link between SBU assessments and reimbursement policy, Sweden established the Pharmaceutical Benefit Board (PBB) as a government agency in 2002 to negotiate prices and make decisions for the reimbursement of drugs. All new drugs are to be assessed for their clinical relevance and cost effectiveness based on submissions from pharmaceutical manufacturers. The PBB also will evaluate old drugs on the same basis as new ones. The decision-making committee will include, among others, health economists and patient representatives (Carlsson 2004).

The SBU also supports international collaboration between HTA agencies; the secretariat of the International Network of Agencies for Health Technology Assessment (INAHTA) is located at the SBU (box C.2).

Box C.2 **International Network of Agencies for Health Technology Assessment (INAHTA)**

INAHTA's mission is to provide a forum for identifying and pursuing interests common to HTA agencies around the world. It aims to:

- accelerate exchange and collaboration between agencies;
- promote information sharing and comparison; and
- prevent unnecessary duplication of activities.

The secretariat coordinates annual meetings, working groups, joint projects and dissemination activities. Joint projects involve member agencies in collaborative efforts to evaluate medical technologies of mutual interest.

INAHTA's membership has grown to 41 HTA agencies from 21 countries. The network includes countries from Europe, North and South America as well as Australia and New Zealand.

Source: INAHTA (2005).

Apart from national agencies, there are some local HTA units funded by county councils. This reflects the decentralised decision-making structure of the Swedish healthcare system. For example, the Centre for Assessment of Medical Technology in Orebro was created in 1999 and is financed by the Orebro County Council. Its purpose is to promote HTA and evidence-based medicine at the local–regional level (Carlsson 2004).

C.5 **The Netherlands**

New pharmaceuticals may be released onto the Dutch market once they have passed EU procedures (box C.1) or have been authorised as safe and efficacious by the Medicines Evaluation Board (MEB) in The Netherlands. The MEB requires evidence on the safety and efficacy of new products, but not on their cost effectiveness or societal need (Exter et al. 2004). Its decisions are implemented by the MEB Agency. Both the MEB Agency and the Health Care Inspectorate (HCI) of the Ministry of Health, Welfare and Sport have responsibilities regarding post-market surveillance of authorised medicinal products. The HCI is also the competent authority for medical devices.

Established in 1988, the main HTA program in the Netherlands is the *Fonds Ontwikkelingsgeneeskunde* (Fund for Investigative Medicine — FIM). Its objective is to fund research that will generate the evidence required for evidence-based policy making at the national level and evidence-based use of healthcare technologies at the clinical practice

level. FIM's research is funded mainly by government ministries. The Dutch Health Research and Development Council (DHRDC) recently assumed responsibility for administering FIM from the Health Insurance Council (Berg et al. 2004).

In FIM's early years of operation, topic selection was 'bottom up' with topics being suggested by researchers submitting proposals. However, these research proposals often were not directly linked to areas of healthcare that were considered problematic or underdeveloped (Exter et al. 2004). A 'top down' approach was later adopted. Topics are drawn from a number of priority lists prepared by different advisory groups and agencies. One of the first lists was that prepared by a group of experts who identified and ranked 126 routinely-used medical services of doubtful cost effectiveness.

Aside from FIM, there are a number of other national and local HTA initiatives. For example, The Netherlands Organization for Scientific Research funds HTA research programs and the *Gezondheidsraad* (Health Council of The Netherlands) issues HTA reports on a regular basis. At the local level, all academic hospitals have some form of HTA unit (Berg et al. 2004).

Although HTA studies have contributed to government decisions on new technologies, there are no categories of technology (drugs, diagnostic or therapeutic instruments) that have to pass an economic evaluation before they are included in the Dutch insurance package (Berg et al. 2004). That said, pharmaceutical companies often will include HTA studies in their applications to add a new drug to the insurance package, even though there is no formal requirement to do so.

The most established clinical guideline development programs are run by the Dutch Institute for Healthcare Improvement and the Dutch College of General Practitioners. The guidelines draw on evidence in the scientific and medical literature. According to Berg et al. (2004), existing guidelines incorporate cost effectiveness only to a limited extent.

C.6 United Kingdom

Pharmaceuticals may be authorised through EU procedures (box C.1) or by the Medicines and Healthcare Products Regulatory Agency (MHRA) which is an agency of the Department of Health (DoH). MHRA aims to safeguard public health by ensuring that medicines sold in the United Kingdom meet acceptable standards of safety, quality and efficacy. In the case of medical devices, MHRA seeks to ensure that these products meet appropriate standards of safety, quality and performance. It conducts post-marketing surveillance for reporting, investigating and monitoring adverse reactions to medicines and adverse incidents involving medical devices (MHRA 2005).

HTA activity in the United Kingdom traditionally has been carried out at several levels — locally by health authorities, regionally, and nationally by a variety of organisations (Stevens and Milne 2004). HTA activity became more centralised with the establishment of the National Institute of Clinical Excellence (NICE) in 1999. NICE is a special health authority for England and Wales, the major function of which is to evaluate new medical technologies for clinical and cost effectiveness. It also prepares clinical guidelines for the National Health Service (NHS) and runs a research and development program.

Medical technologies are referred to NICE by government. NICE is asked to look at particular drugs and devices where availability of the drug or device varies across England and Wales³ or where uncertainty exists over the value of a drug or device. It also makes recommendations about whether interventional procedures used for diagnosis and treatment are safe enough and work well enough for routine use. Many of the procedures are new, but NICE also looks at more established procedures if there is uncertainty about their safety or effectiveness. NICE guidance on interventional procedures covers Scotland as well as England and Wales (NICE 2004b and c).

As noted by Medicines Australia (sub. PR62), NICE recently joined with the Health Development Agency to become the National Institute for Health and Clinical Excellence (still known as NICE). Consequently, NICE also will produce guidance on the promotion of good health and the prevention and treatment of ill health.

The process for prioritising technologies for NICE consideration has several stages, which largely occur within DoH. An initial list of candidate technologies is compiled in consultation with the NHS, professional associations and national policy makers. DoH is provided with an additional list prepared by the National Horizon Scanning Centre the remit of which is to provide early warning of emerging and new technologies. The Centre also functions as the secretariat for EuroScan — an international network of horizon scanning agencies (box C.3). These lists are then merged and considered by DoH committees using priority-setting criteria. Health ministers consider DoH recommendations, announce their provisional decision, conduct consultation and then make the final decision on NICE's work program (Stevens and Milne 2004).

³ Guidance for the NHS in Scotland is developed by NHS Quality Improvement Scotland (technology appraisals) and the Scottish Intercollegiate Guidelines Network. The Northern Ireland Executive is in the process of deciding who will develop guidance for the NHS in Northern Ireland (NICE 2004c).

Box C.3 **EuroScan**

The European Information Network on New and Changing Health Technologies (known as EuroScan) is a collaborative network of HTA agencies established to facilitate the exchange of information on important emerging new drugs, devices, procedures, processes and settings in healthcare. The network of member agencies aims to:

- evaluate and exchange information on new and changing technologies;
- develop the sources of information used;
- develop applied methods for early assessment; and
- disseminate information on early identification and assessment activities.

Benefits of membership include access to database information produced in agreed formats by the EuroScan secretariat, member agency reports (published reports or confidential reports after review and approval by the original source), and the results of studies conducted by the secretariat.

Current members include HTA agencies in Canada, Denmark, France, Israel, Norway, Spain, Sweden, Switzerland, The Netherlands and the United Kingdom as well as Australia and New Zealand.

Source: EuroScan (2005).

The NICE appraisal process involves scoping, assessment and appraisal. During the scoping phase, NICE determines the boundaries of the appraisal and the questions to be addressed, after consulting with relevant stakeholders. The assessment is undertaken by an independent academic centre which prepares an assessment report. Comments are sought from consultees on this report, and an evaluation report is prepared. An appraisal committee considers the evaluation report, judging whether the technology can be recommended as a cost-effective use of NHS resources or whether it can be recommended for specific indications or patient groups. The committee submits a determination for NICE approval. If there are no appeals from consultees, the determination becomes the basis of the guidance that NICE issues to the NHS in the relevant jurisdictions.

Consultation is an integral part of the NICE process. As noted by Professor Karen Facey (sub. 39), NICE seeks to create dialogue and participation of all stakeholders including healthcare professionals, industry and patient groups throughout the HTA process. The MIAA (sub. 40) also commented that the NICE process of consultation with all stakeholders and public consultation on its forward work program was desirable.

Since 2002, the NHS has been legally obliged to provide funding and resources in England and Wales for medicines and treatments recommended by NICE's technology appraisals (NICE 2005a). That said, NICE's capacity to assess new health technologies is limited. According to Steven and Milne (2004), NICE assesses some 50 technologies a year, representing only a fraction of new technologies.

NICE also prepares evidence-based clinical guidelines that aim to help health professionals and patients make informed decisions about healthcare in specific clinical circumstances. The guidelines must take account of clinical and cost effectiveness, and advise on the appropriate management of specific conditions. NICE has established a number of National Collaborating Centres (NCCs) that develop guidelines for the NHS on behalf of NICE. In preparing guidelines, NCCs draw on the expertise of the Royal Medical and Nursing Colleges, professional bodies and patient/carer organisations (NICE 2004a).

Apart from preparing technology appraisals and clinical guidance, in 2003 NICE established a Research and Development Program with the aim of identifying and stimulating work on those aspects of health services and clinical research that support the development of national guidance for the NHS in England and Wales. As part of this program, NICE runs confidential enquiries that examine how patients are treated to identify ways of improving quality of care (NICE 2004a).

C.7 United States

The Food and Drug Administration (FDA) within the Department of Health and Human Services (DHHS) is responsible for ensuring the safety and efficacy of drugs and biologics as well as medical devices in the United States. Regulatory approvals by the FDA are not required to consider the effectiveness or cost of a new therapy relative to currently marketed products.

The FDA's Center for Drug Evaluation and Research assesses new drugs for marketing approval.⁴ The FDA's Center for Devices and Radiological Health aims to ensure that new medical devices are safe and effective before they can be marketed. The FDA also sets standards for product manufacturing quality, and monitors both drugs and devices throughout their product life cycles using a nationwide post-market surveillance system. Both consumer and patient representatives provide input to the FDA process (box C.4).

⁴ Accelerated approval may be granted to drugs that show promise in the treatment of serious and life-threatening diseases where no adequate therapy exists (FDA 2002b).

Box C.4 Consumer and patient involvement in therapeutic product evaluation in the United States

Several decades ago, the FDA recognised that consumers provided valuable perspectives on regulatory issues that were not readily apparent to legal and scientific experts. The FDA began to include consumer representatives on scientific committees to advise it on whether or not to approve new products. The FDA subsequently formalised a selection process whereby consumer organisations — after considering the qualifications of candidates — nominated lay representatives to serve on advisory committees.

In the early 1990s, the patient representative program was established after Congress passed legislation requiring consumer representation on advisory committees. Patient representatives provide the FDA and its advisory committees with a perspective from patients and family members directly affected by a serious or life-threatening disease. Patient representatives primarily serve on committees that review products and therapies for the diagnosis and treatment of HIV/AIDS and cancer. However, they have also served on committees examining products relating to other diseases such as arthritis, diabetes, Hepatitis B and C, and Parkinson's disease.

Sources: FDA (2003); Holston (1997); Meadows (2002).

Although the United States was a leader in establishing HTA agencies at the national level in the 1970s (namely, the Congressional Office of Technology Assessment and the National Center for Health Care Technology), these agencies were subsequently abolished. Outside the federal government, HTA activity has grown rapidly in many healthcare sectors, including medical professional societies, academic centres, health insurers, independent HTA units, networks of hospitals and health plans (Perry and Thamer 1999).

In 1989, the Agency for Health Care Policy and Research (AHCPR) was created as an agency within DHHS. The AHCPR was re-authorised and renamed as the Agency for Healthcare Research and Quality (AHRQ) in 1999. It is the lead US agency charged with supporting research that provides evidence-based information on healthcare outcomes, quality, costs, use and access. The information is intended to help healthcare decision makers (that is, patients, clinicians, health system leaders, purchasers and policy makers) make more informed decisions and improve the quality of healthcare services (Blum 2003).

A major program of AHRQ is the Center for Practice and Technology Assessment which provides national leadership in evidence-based systematic assessment of clinical practices and technologies. Through this program, the AHRQ provides assessments to the Medicare Coverage Advisory Committee which advises Medicare staff on scientific issues relevant

to coverage decisions (Eisenberg and Zarin 2002).⁵ These assessments are prepared by AHRQ staff or by AHRQ Evidence-Based Practice Centers (which are mainly university-based centres that perform focused reviews and analyses of the scientific literature on selected clinical topics). These reports are used by federal and state agencies, private sector professional societies, health delivery systems, providers and payers (VDHS, sub. 24).

AHRQ has played a role in bringing together information on evidence-based clinical guidelines (Eisenberg and Zarin 2002). It has developed the National Guideline Clearinghouse (NGC), in collaboration with the American Association of Health Plans and the American Medical Association. The NGC is an Internet-based repository of clinical practice guidelines, including those with a major focus on technology assessment (Blum 2003).

Early identification of emerging medical technologies is also conducted in the United States. For example, the Clinical Technology Advisory service informs clinicians and managers about developments relating to innovative, emerging, high-impact clinical technologies including devices, surgical procedures and pharmaceuticals (University HealthSystem Consortium 2005). Horizon scanning, as well as technology assessment, is undertaken by ECRI which is a non-profit health services research agency (VDHS, sub. 24).

C.8 Concluding comments

Although HTA arrangements in other countries have been shaped by their respective healthcare systems, the international experience can highlight areas where Australia's HTA mechanisms and processes are comparatively strong and areas where there is scope for improvement.

Like Australia, some other countries have strengthened the links between HTA advice and funding decisions. For example, Canada and Sweden have established committees to assess the clinical and cost effectiveness of pharmaceuticals. While Canada's CEDAC makes listing recommendations, Sweden's PBB also decides whether to list drugs for reimbursement. In England and Wales, there is a direct link between NICE recommendations and NHS funding; that is, the NHS in relevant jurisdictions is required to fund medical treatments recommended by NICE in its technology appraisals.

⁵ Unlike Australia's Medicare which is a universal health insurance system, US Medicare is a federal health insurance program for people aged 65 years or older, certain younger people with disabilities, and people with end-stage renal disease.

Because HTA activities in many countries initially developed at the regional and local levels, this often has led to duplication of effort and inconsistent approaches. Similar issues have arisen in Australia (chapter 8). A common response to such issues overseas has been the adoption of national approaches, often including the creation of national HTA bodies. For instance, Canada set up CCOHTA to coordinate national HTA priorities and to reduce duplication across jurisdictions. In England and Wales, NICE was established to promote consistency in the use of health technologies in the NHS by issuing national guidance.

While key national HTA committees in Australia allow limited opportunity for community input, some HTA agencies overseas have attached greater importance to broader consultation. For example, in the United States, the FDA includes consumer and patient representatives on advisory committees that assess new therapeutic products. NICE in the United Kingdom identifies and invites organisations to participate in its appraisal process. Some countries also receive consumer and patient input for determining national HTA work programs.

As noted in chapter 8, clinical guideline development in Australia is not linked closely or systematically to the HTA advisory process. In some countries such as Denmark, France and the United Kingdom, national HTA agencies are responsible for preparing and/or coordinating guidelines as well as undertaking technology appraisals. NICE, in particular, has a systematic process for developing clinical guidance for the NHS.

D Case studies: an overview

Terms of reference (f) ask the Commission to examine the net impact of individual technologies on economic, health and social outcomes, as well as on the overall cost effectiveness of healthcare delivery. The Commission has undertaken nine case studies of advances in different categories of medical technology, namely:

- Pharmaceuticals.
 - Statins.
 - Selective serotonin reuptake inhibitors (SSRIs).
 - *Trastuzumab* (Herceptin).
- Devices and surgical procedures.
 - Drug eluting stents (DES).
 - Joint replacement surgery.
 - Cataract surgery.
- Screening and testing technologies.
 - Prostate specific antigen (PSA) tests.
 - Genetic testing of women for breast cancer.
- Administrative support systems.
 - Information and communications technology (ICT).

Ideally, the case studies would provide a representative sample of medical technologies. However, it is difficult to ascertain the population of technologies from which a sample can be drawn. This may mean that selection is biased towards prominent (for example, high cost) technologies at the expense of lower profile, but nonetheless equally important, technologies.

In selecting individual technologies for the case studies, the Commission has focused on technologies that have at least one or more of the following characteristics:

- they have had a significant impact on healthcare expenditure (either decreasing or increasing) over the past ten years;
- they represent a significant advance in the treatment of major diseases;

-
- they have been the subject of extensive research and analysis both in Australia and overseas with regard to their clinical and cost effectiveness;
 - they have made a considerable contribution to improving economic, health and social outcomes;
 - they affect a significant proportion of the population; and/or
 - they are likely to have a significant impact on healthcare expenditure over the next ten years. This impact could be due to endogenous factors (such as increased use and diffusion of the technology and incremental improvements in the technology itself) or exogenous factors (such as population ageing).

Case studies on DES and statins demonstrate the large burden of cardiovascular diseases such as coronary heart disease (CHD) and stroke. CHD is the largest single cause of death in Australia, responsible for approximately 26 000 or 19 per cent of deaths in 2002, while stroke is the second largest cause of death, responsible for approximately 12 500 or 9 per cent of all deaths in 2002 (AIHW and NHF 2004). The Australian Institute of Health and Welfare (AIHW 2004c) has estimated that the treatment and prevention of cardiovascular disease cost \$5.4 billion in Australia in 2000-01, or 11 per cent of total allocated health expenditure.

Similarly, the SSRI case study reflects the large economic and social cost of depression to the Australian community. Hu (2004) has estimated that in 1997-98, the direct costs associated with the treatment of affective disorders (including depression) were \$615 million, while the indirect costs were \$2.8 billion.

Case studies on joint replacement and cataract surgery highlight recent increases in the number of surgical procedures that aim to improve quality of life for older age groups. Significant growth in these procedures has been facilitated by the development of new surgical techniques and improvements in prosthesis design. The demand for these surgeries is projected to continue to rise due to factors such as population ageing, increased use of safer and more effective surgical techniques and changing patient expectations.

The development of Herceptin for treatment of metastatic breast cancer is an example of how pharmacogenomics can improve the targeting of drugs. Herceptin is a significant technological advance associated with improvements in survival times for some women with end-stage breast cancer. The Herceptin case study also highlights the controversy that may arise over subsidisation of expensive but life-prolonging treatments and the challenges that such treatments may provide for health technology assessment processes in future.

Advances in screening and testing technologies are represented in case studies on PSA tests and genetic testing for breast cancer. Potential benefits of screening and testing

technologies include increases in life expectancy as gene mutations are identified and cancers are recognised at an earlier stage. But the cost effectiveness of these technologies has been questioned because of uncertainty over the most appropriate response to diagnosis.

The ICT case study demonstrates the significant impact that ICT has had on the healthcare industry over the past decade, in areas such as administration and support systems, telehealth and telemedicine, diagnostics and medical research and development. In the future, ICT appears to offer significant opportunities to improve the way healthcare is delivered, the range and nature of treatment options, and the wellbeing of the community. However, based on experience to date, implementation and gaining the full potential from this technology will be challenging.

E Joint replacement surgery

E.1 Introduction

Joint replacement surgery for hips and knees is one of the most frequently performed and successful types of surgery for improving patients' quality of life (Hart 2004; McMurray et al. 2002). The surgery is commonly used to treat severe osteoarthritis (OA) of the joints. OA is a degenerative condition that develops when articular cartilage starts to break down, usually as a result of trauma, ageing, or failure of joint repair and maintenance mechanisms (Access Economics 2001a). In 2004, OA was estimated to affect approximately 1.57 million or 7.8 per cent of Australians, and to directly cost the health system over \$1.4 billion per annum (Access Economics 2005).

Joint replacement surgery is considered necessary when non-surgical treatments for OA, such as weight reduction, modification of lifestyle, drug therapy, physiotherapy and occupational therapy, do not succeed in relieving severe pain and in allowing normal daily living (Hart 2004).

Total knee replacement (known formally as total knee arthroplasty) and total hip replacement (known formally as total hip arthroplasty) involve the surgical replacement of the hip or knee joint with an artificial joint known as a prosthesis. A knee replacement involves 'the complete replacement of articulation surfaces of both the femur and the tibia' (MIAA, sub. 17, p. 107). A hip prosthesis generally consists of three elements:

- a metal ball that replaces the original femoral head;
- a metal stem which is inserted into the femur; and
- a plastic cup that is inserted into the acetabulum (the hollow, cuplike portion of the pelvis into which the femur fits).

Advances in medical technology, including the discovery of new bearing surfaces, have facilitated the development of many different hip and knee prostheses (Hart 2004). Traditionally, hip replacements were fixed with cement, however, over the last fifteen years, technology has evolved to incorporate more expensive cementless and hybrid (a cemented stem with a cementless cup) designs (KPMG Consulting 2001; NICE 2000). In

addition, there have also been advances in cementing techniques, which have contributed to a rise in the cost of cemented prostheses. In Australia, there are over 100 different prostheses used for hip replacement and more than 50 prostheses used for knee replacement (Graves et al. 2004).

Knee prostheses are usually fixed with cement, however, technological advances have also facilitated a slight increase in entirely cementless total knee replacement in Australia (AOA NJRR 2004a).

In addition, there have also been recent advances in the technology used to undertake joint replacement surgery, in particular, minimally invasive surgery and computer assisted surgery.

E.2 Number of procedures

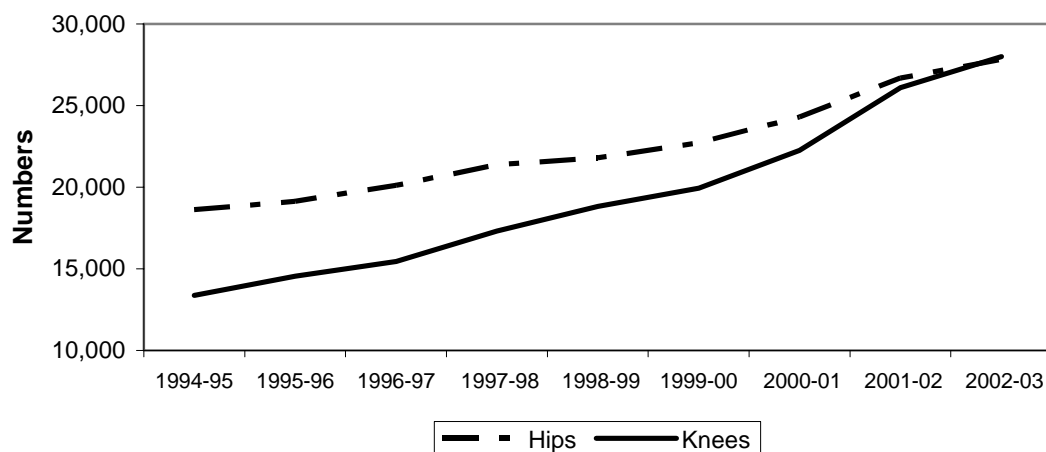
As stated earlier, hip and knee replacements are amongst the most common forms of routine surgery performed in Australia. There were 55 836 joint replacement procedures performed in 2002-03, comprising 27 833 hip replacements and 28 003 knee replacements (figure E.1) (AOA NJRR 2004a). In 2002-03, the number of joint replacement procedures per 100 000 persons was about 281, compared with about 207 in 1997-98 (AOA NJRR 2004a).

Since 1994-95, the total number of hip and knee replacements performed has increased by approximately 7 per cent per annum (AOA NJRR 2004a). In 2002-03, the number of joint replacements was approximately 75 per cent higher than 1994-95 levels. Hip replacement procedures increased by approximately 50 per cent while knee replacement procedures increased by approximately 110 per cent (AOA NJRR 2004a).

Joint replacement surgery is more commonly carried out in private hospitals than in public hospitals. In 2002-03, approximately 34 000 procedures (or 60 per cent) were carried out in the private sector compared with approximately 21 800 procedures undertaken in the public sector (AOA NJRR 2004a).

Growth in joint replacement surgery has also been significantly higher in the private sector. From 1998-99 to 2002-03, the total number of joint replacement procedures performed in the private sector increased by approximately 11 per cent per annum, while growth in the public sector averaged only 3 per cent (AOA NJRR 2004a). This reflects a more general trend towards increased use of the private system as reflected in other procedures such as chemotherapy, where approximately 50 per cent of procedures are now undertaken in the private sector, and haemodialysis, where private hospitals accounted for 14 per cent of total separations in 2001-02, up from 8 per cent in 1993-94 (AIHW 2004b).

Figure E.1 **Number of hip and knee replacement procedures, 1994-95 to 2002-03**



Data source: AOA NJRR (2004a).

A significant contributor to the increase in joint replacement surgery has been an increase in the number of revision procedures, which are required when a prosthesis fails. All prostheses are expected to fail eventually, with the main causes of revision surgery being dislocation, loosening, fracture and infection (AOA NJRR 2004a; NHS 2004). From 1 September 1999 to 31 December 2003, revision procedures accounted for approximately 13 per cent of all hip replacements and approximately 9 per cent of all knee replacements (AOA NJRR 2004a). Rates of revision surgery have increased in recent years due to increased joint replacement surgery in younger patients, who are more likely to outlive the life expectancy of their original prosthesis (AOA NJRR 2004a).

Other possible reasons for the recent increases in joint replacement surgery include:

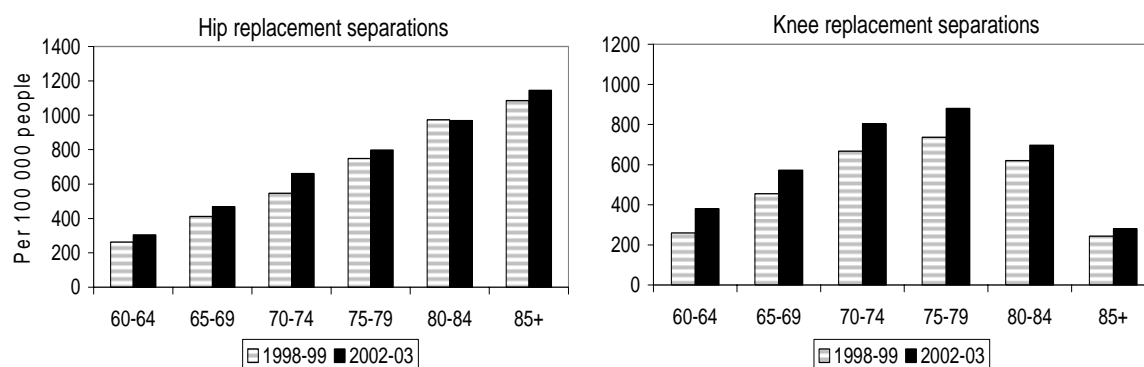
- the ageing of the population (AOA NJRR 2004a);
- advances in associated medical disciplines such as anaesthesia, which is now safer due to more effective drugs, improved techniques, better monitoring and improved post-operative pain control (Hart 2004);
- changing patient expectations, with increasing numbers of people willing to undertake surgery at a younger age to remain active and pain free (Wells et al. 2002); and
- increased private health insurance coverage resulting from several policy changes, including the 30 per cent private health insurance rebate. In addition, from 2001, private health insurers were precluded from charging a 'gap' for listed prostheses including artificial hips and knees. Chapters 2 and 10 detail these policy changes.

Gender, age and socioeconomic profile

The majority of joint replacement surgery is undertaken on female patients, reflecting the increased prevalence of OA in women over 50 (AOA NJRR 2004a; March and Bagga 2004). The Australian Orthopaedic Association National Joint Replacement Registry (National Joint Replacement Registry) (AOA NJRR 2004a) reported that from 1 September 1999 to 31 December 2003, females accounted for 57 per cent of hip replacement procedures and about 55 per cent of knee replacement procedures. The median age for females undergoing joint replacement surgery was 74 years for a hip and 70 years for a knee, while the median age for males was 69 years for a hip and 70 years for a knee.

Figure E.2 demonstrates that the oldest age groups tend to have the highest number of joint replacements per 100 000 persons, and that the rate of joint replacement in these groups is generally increasing. In addition, there have been substantial increases in rates of joint replacement surgery in the 60–64 and 65–69 age groups. For example, between 1998–99 and 2002–03, the number of knee replacements per 100 000 persons in the 60–64 age group rose by approximately 45 per cent, compared to rises of approximately 12 and 15 per cent in the 80–84 and 85+ age groups respectively. This suggests that ‘younger’ age groups (below 70) are increasingly willing to undertake surgery to remain active and pain free.

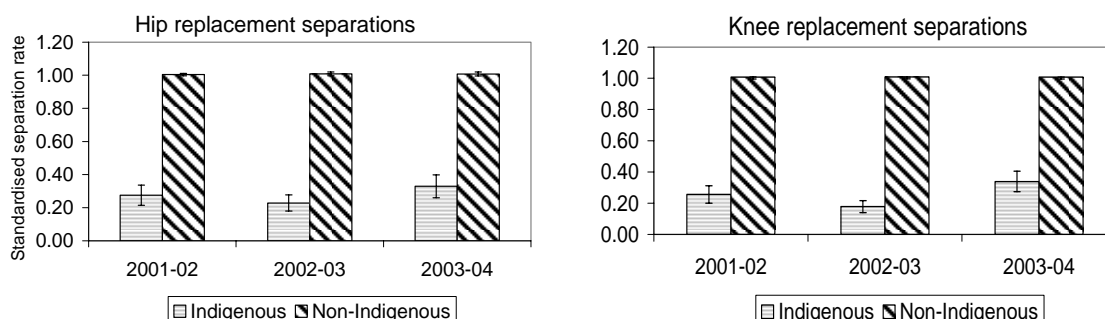
Figure E.2 Age specific rates of hip and knee replacement



Data sources: ABS (2004b); AIHW (2005b).

Figure E.3 shows that Indigenous people have significantly lower age standardised rates of joint replacement surgery than non-Indigenous people. However, this gap narrowed slightly in 2003–04.

Figure E.3 Age standardised rates of hip and knee replacement by Indigenous status ^a



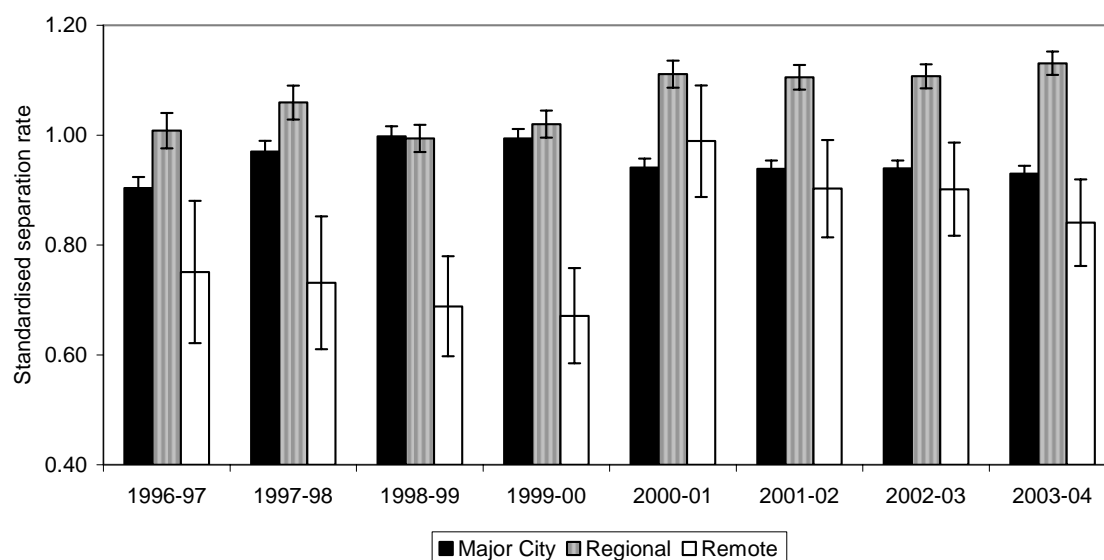
^a Age standardised rates are per 1000 population. 95 per cent confidence intervals shown for each data point.
Data source: AIHW (unpublished data). Data available in technical paper 4.

The prevalence rate of self-reported OA is slightly higher outside capital cities — 8 per cent compared to approximately 7 per cent in capital cities — suggesting greater need for joint replacement surgery in these areas (ABS 2002a). However, there is some evidence to suggest that people in remote areas have lower age standardised rates of joint replacement than persons living in regional areas and major cities (figure E.4). On the other hand, it would also appear that this differential has narrowed somewhat over the past four years, as age standardised rates of joint replacement in remote areas have increased, while rates in major cities have remained relatively stable.¹

Table E.1 presents ratios of hip and knee procedure rates for those in the most disadvantaged socioeconomic group to those in other socioeconomic groups. Ratios less than one indicate that those in most disadvantaged regions have higher procedure rates. The prevalence of self-reported OA in Australia is highest among persons living in most disadvantaged areas, suggesting that these groups should have higher procedure rates (figure E.5). However, table E.1 indicates that this is the exception rather than the rule across all age groups. In many age groups, those in the second most advantaged group were more likely to undergo joint replacement surgery than those in the least and most disadvantaged groups. In addition, given that the prevalence of OA increases with age and is highest in most disadvantaged areas, the data suggest that Australians aged 70 years and over in the most disadvantaged areas were least likely to receive a procedure, despite being more likely to be in need.

¹ A possible explanation for the increase in the rate of procedures in remote areas could be that people in these areas are increasingly travelling to regional areas or major cities for the procedure.

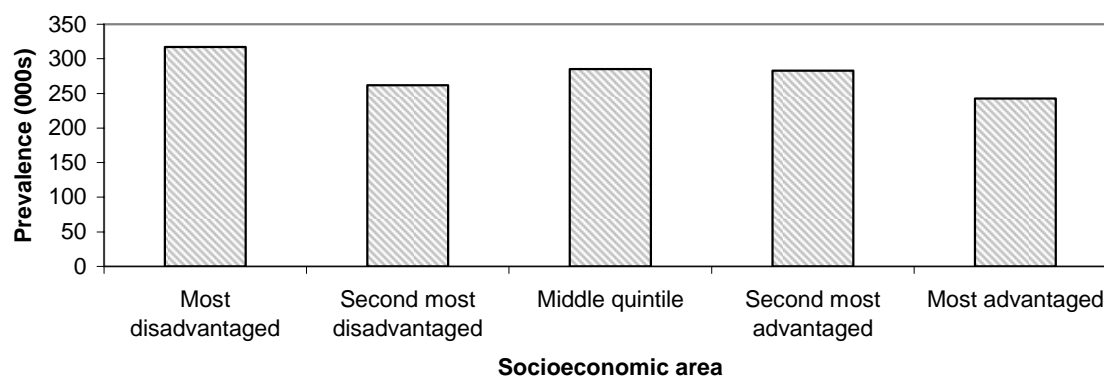
Figure E.4 Age standardised rates of knee replacement by remoteness area ^a



^a Age standardised rates shown are per 1000 population. 95 per cent confidence limits shown for each data point.

Data source: AIHW (unpublished data). Data available in technical paper 4.

Figure E.5 Prevalence of osteoarthritis by socioeconomic area, 2001



Data source: ABS (2002a).

Table E.1 Hip and knee replacement separation rates by socioeconomic status, 1998-99 to 2003-04^{a, b}

	20-29 years	30-39 years	40-49 years	50-59 years	60-69 years	70+ years
	Rate ratio					
Hip replacements						
2/1	1.7	1.3	1.3	1.3	1.4	1.3
3/1	1.5	1.1	1.2	1.2	1.4	1.4
4/1	1.8	1.3	1.3	1.4	1.6	1.7
5/1	1.1	0.9	0.9	1.0	1.1	1.3
Knee replacements						
2/1	1.4	1.0	1.3	1.3	1.4	1.4
3/1	1.0	1.1	1.1	1.1	1.2	1.3
4/1	1.7	1.2	1.2	1.2	1.2	1.5
5/1	1.0	0.5	0.6	0.6	0.8	1.0

^a A high index score (5) means the area has few families of low income and few people with little training and in unskilled occupations. A high score reflects lack of disadvantage (ABS 2001). Rate ratios reflect differences between each level of disadvantage, for example, the least disadvantaged over the most disadvantaged (age specific procedure rate for group five divided by age specific procedure rate for group one). ^b Separation rates are calculated for each age group and each socioeconomic region (age specific and socioeconomic status specific rates).

Source: Productivity Commission calculations based on AIHW unpublished data and ABS unpublished population data.

Another Australian indicator of access to joint replacement surgery is median waiting times for this type of elective surgery in the public sector. Long waiting times are likely to reflect unmet need for elective surgery (National Health Performance Committee 2003). In 2003-04, approximately 25 per cent of patients on waiting lists for knee replacement surgery waited for more than a year, with a median waiting time of 168 days (AIHW 2004a). This compares with a median waiting time of 112 days in 1999-00 (AIHW 2000). Similarly, in 2003-04, 12 per cent of patients on waiting lists for hip replacement surgery waited more than a year. Median waiting time for hip replacement surgery increased from 88 days in 1999-00 to 91 days in 2002-03 (AIHW 2005b).

The impacts of increased waiting times for joint replacement surgeries reported in overseas studies are unclear (Dixon et al. 2004). For example, Mahon et al. (2002) found clinically important losses in health-related quality of life and mobility in patients waiting more than six months for total hip replacements, whereas Kelly et al. (2001) concluded that waiting time did not appear to have a negative impact on the amount of pain and dysfunction experienced by patients.

Overseas studies also suggest that socioeconomic disparities exist for both primary (the initial procedure) and revision joint replacement surgery, with:

... lower rates among those of lower social class or socioeconomic status, despite equal or greater indications of need. (Dixon et al. 2004, p. 825)

In the United Kingdom, Dixon et al. (2004), established that primary hip and knee replacement rates were significantly lower in the most disadvantaged fifth of the population compared to the remaining four fifths. Yong et al. (2004) also examined inequalities in knee replacement procedures in the United Kingdom and found significant age, sex, geographical and deprivation inequalities in levels of need and access to services. In addition, the US National Institute of Health (2004) found significant evidence that women and racial minorities had lower rates of total knee replacement than white males.

E.3 Expenditure

The increase in the number of joint replacements has had a significant impact on acute care (hospital) expenditure by government and private health insurers. The National Joint Replacement Registry (AOA NJRR 2004a) estimated that in 2001-02, total acute care expenditure on hip and knee replacement by third party payers (government and private health insurers) was \$815.5 million, an increase of \$158 million or 24 per cent on the previous financial year (AOA NJRR 2004a). Expenditure data for more recent years are not currently available.

The National Joint Replacement Registry (AOA NJRR 2004a) also found a significant difference in the change in expenditure in the private sector compared with the public sector between 2000-01 and 2001-02:

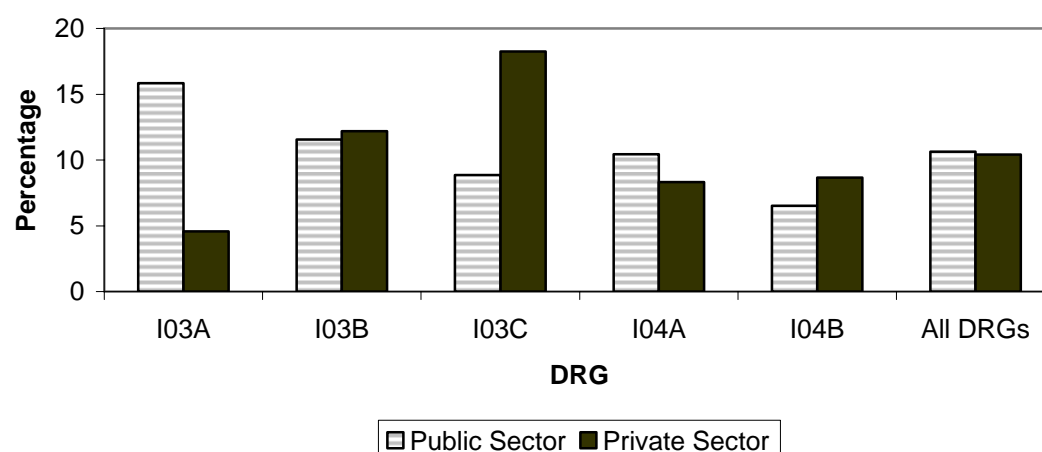
- the rate of increase in expenditure for hip replacements was about 38 per cent in the private sector, compared with about 10 per cent in the public sector; and
- the rate of increase in expenditure for knee replacements was about 63 per cent in the private sector, compared with about 11 per cent in the public sector.

Growth in unit prostheses costs

Apart from the large increase in the number of procedures performed, an important driver of the increase in acute care expenditure on hip and knee replacement has been an increase in unit prostheses costs (Faulkner et al. 1998; KPMG Consulting 2001). Increases in the unit costs of prostheses reflect the incorporation of expensive new technology aimed at reducing the failure rate of prostheses, and thus the need for revision surgery (KPMG Consulting 2001). In 2001, the average cost of a traditional cemented prosthesis was estimated at between \$2000 and \$3500 (with an additional \$500–\$1000 for cement and disposal costs), whereas the cost of newer cementless and hybrid prostheses was estimated at between \$8000 and \$10 000 (KPMG Consulting 2001).

National hospital cost data published by the Department of Health and Ageing (DoHA 2005b) support the view that unit prostheses costs have increased significantly over the last five years (figure E.6).

Figure E.6 Average annual growth in unit prostheses costs for hip and knee replacement DRGs^a, 1998-99 to 2002-03



^a For a description of each Diagnostic Related Group, see table E.2 below.

Data source: DoHA (2005b).

According to DoHA (2005b) statistics, unit average prostheses costs by DRG in 2002-03 were significantly higher in the private than public sector (table E.2). However, the Victorian Department of Human Services (VDHS, sub. 24) noted that these statistics are likely to under-report prostheses unit costs in public hospitals, since public hospitals may not always record prostheses costs for their private patients.

Using 2001-02 DoHA data, and 2004-05 Victorian public hospital data, the VDHS (sub. 24) suggested that prostheses unit costs for knee and hip replacements are between 12 and 30 per cent higher in the private sector. BUPA Australia (sub. 28), a private health insurer, also presented evidence of differences between public and private unit prices for joint prostheses — it stated that it pays \$2630 for a DePuy Charnley Hip System, while the price paid by the public sector is \$1450.

Table E.2 Hip and knee prostheses average costs by AR-DRG, public and private sectors, 2002-03

DRG	DRG description	Average prostheses cost		Cost difference
		Public sector	Private sector	
		\$	\$	%
I03A	Hip revision with catastrophic or severe complications and comorbidity	7301	8241	13
I03B	Hip replacement with catastrophic or severe complications and comorbidity /Hip revision without catastrophic and severe complications or comorbidity	3231	6602	104
I03C	Hip replacement without catastrophic and severe complications or comorbidity	3460	7580	119
I04A	Knee replacement and reattachment with catastrophic complications and comorbidity	4372	6696	53
I04B	Knee replacement and reattachment without catastrophic complications and comorbidity	3876	5497	42

Source: DoHA (2005b).

There are a number of possible reasons for the large differentials in hip and knee prostheses unit costs and growth between the public and private sectors. The VDHS suggested that the differentials may be partly explained by:

... a relaxing of price discipline since 2000 with health funds being obliged to reimburse the full cost of whatever listed device was used, plus a handling charge of up to 10 per cent. (sub. 24, p. 50)

Another possible reason for the cost differential between the public and private sector may be that privately insured patients are younger and thus require more expensive prostheses that are designed to last for a longer time. As discussed above, substantial increases in joint replacement procedures have occurred in the private sector and in the 60–64 and 65–69 age groups. These age groups are also more likely to have private health insurance than those aged 75 and over (ABS 2002a). These figures suggest that the trend for younger age groups to undergo joint replacement surgery has contributed to the higher cost of prostheses in the private sector.

Furthermore, BUPA Australia (sub. 28) argued that private sector prostheses prices were higher than public sector prices due to legislative restrictions which prohibit health funds from effectively negotiating prostheses prices on behalf of their members.

While budget constraints and clinical and purchasing guidelines may limit the public sector's access to newer, more expensive forms of prostheses, evidence suggests that

surgeons in both the public and private sectors are increasingly using more expensive cementless and hybrid prostheses. An Australian survey of surgeons performing hip replacement surgery on younger patients found that only 14 per cent of surgeons cemented both the femur and acetabulum, whereas a comparable UK survey found the majority of public hospital surgeons preferred to cement both components (Hardidge et al. 2003; Tennent and Goddard 2000).

The variation in choices made by surgeons in the United Kingdom and Australia are likely to reflect strict budget constraints in the United Kingdom public hospital system and greater autonomy for Australian surgeons in both the public and private sectors (Hardidge et al. 2003). In turn, the wide range of prostheses used by Australian surgeons is likely to place a limit on the ability of public hospitals to negotiate bulk purchasing agreements with prostheses suppliers.

Rises in prostheses costs, including for joint replacement, have been cited as a key factor in recent increases in private health insurance premiums (Abbott 2005b; PHIAC 2004). Total benefits paid by private health insurers for all types of prostheses rose by approximately 19 per cent in 2003-04 (PHIAC 2004). Dr Stan Goldstein (sub. 5) estimated that prostheses for hip and knee replacement procedures account for about 50 per cent of the overall prostheses benefits paid by health funds. These figures suggest that rises in hip and knee prostheses costs may have been a significant factor in premium rises over the last few years.

In 2003, the Australian Government announced its intention to introduce new arrangements between private health insurers and suppliers of prostheses and devices (Patterson 2003d). DoHA expects that the main impact of the arrangements will be on:

... new products where sponsors requesting a higher benefit will be required to establish that their product(s) has clinical advantages over existing listed products. (sub. 34, pp. 13–14)

Chapter 10 contains a description of the proposed new prostheses arrangements. Amendments to the *National Health Act 1953* (Cwlth) to implement these arrangements were passed by Parliament in March 2005.

Cost savings

Expenditure on hip and knee replacements may result in cost savings in other areas of the health system. For example, the Medical Industry Association of Australia (MIAA) (sub. 17) cited a US study by Gottlob et al. (1996), which found that total knee replacements save an average per patient of US\$50 000 in hospital costs and US\$40 000 in

nursing home costs. Overall, the study estimated that total savings for 266 000 patients who received knee replacements totalled more than US\$13 billion.

Further advances in the technology used to undertake joint replacement surgery may also deliver offsetting cost savings in the health system. For example, new prosthetic devices that enable minimally invasive surgery (smaller incisions) can provide significant hospital savings by reducing the length of hospital stay from 4 to 1.5 days (MIAA, sub. 17). Furthermore, computer assisted surgery has the potential to result in improved alignment and accuracy compared with traditional knee and hip replacement surgery (Holt and Gregori 2005; KPMG Consulting 2001). According to the MIAA (sub. 17), computer assisted surgery for knee replacement that results in improved accuracy can potentially reduce the length of hospital stay and patients' requirements for physiotherapy, home care and pain medication following surgery. Improved accuracy could also result in an increase in the life of prostheses and thus reduce the rate of revision surgery (MIAA, sub. 17). However, the US National Institute of Health (2004) has cautioned that, at this point in time, computer navigation for knee replacement is expensive, increases operating room time, and its benefits are unclear.

E.4 Benefits

Joint replacement surgery is considered to be extremely effective in improving health-related quality of life outcomes in individuals suffering from OA and other joint disorders (AOA NJRR 2004a). For example, a US National Institute of Health (2004) review of twenty years data on knee replacement surgery found that the surgery was an effective means of alleviating pain and improving physical function in the vast majority of patients who do not respond to non-surgical therapies (Vastag 2004).

Analysis of the results of a validated patient-completed questionnaire by March et al. (1999) also demonstrated that hip or knee replacement for OA significantly improves patient health and wellbeing twelve months after surgery. Similarly, a review of the health-related quality of life literature by Ethgen et al. (2004) found that joint replacement surgery was quite effective in improving patients' health-related quality of life. This review also found that hip replacements delivered a greater return to patients than knee replacements, and that primary surgery offered greater improvement than revision surgery.

E.5 Cost effectiveness

According to an Australian study by Segal et al. (2004), joint replacement (like exercise and strength training for the knee, knee bracing, and the use of certain pharmacotherapies) is highly cost effective for the treatment of OA. Segal et al. (2004) estimated a cost per quality-adjusted life-year (QALY) at A\$7500 for hip replacement surgery and A\$10 000 for knee replacement surgery.

March and Bagga (2004) argue that the increased prevalence of OA needs to be addressed through primary and secondary prevention programs aimed at reducing obesity, preventing injury and improving rehabilitation. However, a lack of research on the cost effectiveness of these preventative interventions currently hinders a comparison of cost effectiveness between joint replacement and primary prevention programs (which aim to reduce the risk of developing OA) and secondary prevention programs (which aim to reduce the risk of OA developing to a stage that joint replacement surgery is required) (March and Bagga 2004; Segal et al. 2004).

Joint replacement surgery is also considered one of the most cost effective operations relative to other surgeries (Brooks et al. 2004). For example, Lavernia et al. (1997) estimated the cost per QALY for knee replacement at approximately US\$9500 one year after surgery. While this figure was above that estimated by Segal et al. (2004), the authors contended that the surgery was cost effective as it was below the threshold of US\$30 000 considered acceptable by many health economists. Similarly, Chang et al. (1996) found that the cost effectiveness of hip replacement surgery was similar to, or better than, that of coronary artery bypass surgery and renal dialysis, two widely accepted and costly technologies that extend life.

However, the cost effectiveness of new prostheses aimed at reducing the revision rate has been questioned. Indeed, the long-term effectiveness of the new prostheses in terms of reducing the need for revision surgery is unknown (Faulkner et al. 1998; Graves et al. 2004; KPMG Consulting 2001). In its submission, the VDHS cited a study it commissioned from KPMG Consulting (2001) that found:

... new forms of hip replacement technology are introduced without the support of cost effectiveness information. (sub. 24, p. 32)

Similarly, the UK National Institute for Health and Clinical Excellence (NICE 2000) concluded that:

Economic modelling supports the belief that expensive cementless/hybrid hip prostheses are unlikely to achieve relative improvements in the revision rate sufficient to achieve equivalent or greater cost effectiveness than cheaper cemented prostheses. (p. 4)

To improve knowledge of the longer-term outcomes of joint replacement surgery, particularly for newer prostheses, the Australian Government has funded the establishment of the National Joint Replacement Registry. Through the collection of national data on the number of hip and knee replacements, and the type of prostheses used, the National Joint Replacement Registry aims to address gaps in the evaluation of prostheses using new technologies for which the mid to long-term survival rate of the prostheses are unknown (AOA NJRR 2004b). To date, the Registry has already identified specific prostheses or prosthetic combinations with high early failure rates (Graves et al. 2004). In the long-term, these evaluations should assist in identifying the most cost effective prostheses (Graves et al. 2004).

E.6 Future developments

Over the next ten years, continued improvements are expected in both hip and knee prostheses design and materials (Schurmann and Smith 2004). For example, hip prostheses are now being designed with a larger femoral head to reduce the risk of dislocation (Schurmann and Smith 2004). In addition, as an alternative to total hip replacement, metal on metal hip resurfacing (which involves replacing diseased or damaged surfaces in the hip joint with metal surfaces) is now being used in younger patients considered likely to outlive a hip prosthesis (NICE 2002; Schurmann and Smith 2004).

The use of computer assisted surgery in joint replacement procedures is also expected to increase, providing the reliability of the surgery can be comprehensively proven. As stated earlier, computer assisted surgery has the potential to improve surgical accuracy and alignment resulting in an increase in the life of prostheses and a subsequent reduction in the rate of revision surgery (MIAA sub. 17; Schurmann and Smith 2004). Moreover, minimally invasive surgery also offers the potential to reduce soft tissue trauma and hospitalisation time. However, critics of minimally invasive surgery are concerned that such procedures may:

... introduce new potential problems related to reduced visualisation at the time of the operation, such as implant malposition, neurovascular injury, poor implant fixation, or compromised long-term results. (Berry et al. 2003, p. 2235)

Horizon scanning analysis suggests that new drug treatments for OA, such as *licofelone* and *acetaminophen* (anti-inflammatory painkillers) may assist in alleviating pain from OA (National Horizon Scanning Centre 2003; Schurman and Smith 2004). Furthermore, clinical trials with glucosamine sulphate (a nutritional supplement) have recently shown that it could be effective in slowing disease progression in patients with knee OA (Reginster et al. 2001).

In the longer term, advances in biology may allow prostheses to be constructed out of cartilage and bone. For knee replacements, current technology has already permitted the removal of cartilage cells to be grown for reimplantation (KPMG Consulting 2001). In future, stem cells may be used to repair articular cartilage, while bone morphogenetic proteins may be effective in inducing bone formation following joint replacement surgery (Mont et al. 2004; Schurmann and Smith 2004). Chapter 11 details possible applications of stem cell technology.

In Australia, the need for joint replacement surgery is likely to continue to increase in the future for several reasons (March and Bagga 2004):

- population ageing and obesity trends — in its report on ageing, the Commission (PC 2005) drew attention to US data from Fuchs (1998) demonstrating an increase in the incidence of hip replacements in the ‘oldest old’;
- increasing expectations for improved quality of life; and
- improved surgical and anaesthetic techniques making surgery possible for more people.

It is difficult to accurately predict future Australian demand for hip and knee replacement surgery over the next ten years. For example, a study by Wells et al. (2002) on changing rates of joint replacement surgery in Australia concluded that future estimates would be unreliable until unmet demand for the surgery is fulfilled and rates stabilise.

Two UK studies examining projections of need for joint replacement surgery provide a starting point for estimating future Australian need. Using demographic projections and the extrapolation of arthroplasty rates from Sweden, and assuming no change in age and sex specific arthroplasty rates, Birrell et al. (1999) estimated that the number of hip replacements would increase by 40 per cent by 2026. Similarly, Dixon et al. (2004) predicted a large rise in the number of hip and knee replacements required in the United Kingdom by 2010, with primary hip replacements rising by up to 22 per cent and primary knee replacements rising by up to 63 per cent.

In estimating future need for joint replacement surgery in Australia, the Commission has based its analysis on one of the methods used by Dixon et al. (2004). This method assumes that:

.... current rates will remain stable and that changes in the numbers at risk will be the only cause of change in the number of operations. (Dixon et al. 2004, p. 826)

Applying 2002-03 age specific separation rates (sourced from the AIHW National Hospital Morbidity Database) to ABS (2002b) population projections for 2014-15, the Commission estimates that, at a minimum, the demand for both hip and knee replacement procedures is

likely to rise by approximately 40 per cent by 2014-15. These figures are likely to be an underestimate of future need, as they make no allowance for:

- current unmet demand for joint replacement surgery; or
- likely increases in the rate of joint replacement surgery caused by factors such as improvements in prostheses design and materials, improved surgical techniques and changing patient expectations.

The projected increase in demand for joint replacement surgery is likely to see further increases in acute care expenditure on knee and hip replacement procedures. However, cost growth may be restricted by:

- the Australian Government's reforms aimed at restricting the growth in the rate of prostheses costs in the private sector (chapter 10);
- better information on the effectiveness of new prostheses through ex-post evaluation by the National Joint Replacement Registry — if this reduces the use of prostheses with high failure rates, and thus reduces the need for revision surgery; and
- new advances in joint replacement technology — such as computer assisted surgery and prostheses that facilitate the use of minimally invasive surgery — if these advances deliver offsetting cost savings in other parts of the health system and if they also assist in reducing the need for revision surgery.

E.7 Conclusion

Joint replacement surgery is considered one of the most effective procedures for improving quality of life for patients with severe OA. It is also estimated to be one of the more cost effective procedures for OA. Nevertheless, further research is required to establish the cost effectiveness of joint replacement surgery compared with primary and secondary strategies for the prevention of OA.

The number of joint replacement procedures has risen significantly over the past decade, and this trend could be expected to continue given an increase in the prevalence of OA, higher quality of life expectations and advances in surgical procedures. However, there would also appear to be some regional, socioeconomic and Indigenous status inequalities in rates of joint replacement surgery.

The forecast growth in procedures would be expected to significantly impact on acute health care expenditure. However, this forecast growth could be offset in part if preventative measures aimed at reducing the prevalence of OA were successful.

In addition, the increase in joint replacement surgery may also deliver some offsetting cost savings in other areas of the health system, particularly if surgery reduces an individual's need for aged care facilities. Advances in prostheses enabling minimally invasive surgery and the use of computer assisted surgery may also reduce the length of hospital stay. These advances may also deliver benefits to patients in the form of reduced care requirements and a lower need for revision surgery. Furthermore, recent Australian Government initiatives aimed at restricting the growth of prostheses costs in the private sector, and improving information on the effectiveness of different prostheses, may also assist in containing cost growth.

F Statins

F.1 Introduction

Statins (known formally as ‘HMG-CoA reductase inhibitors’) are a class of cholesterol-lowering drugs used to reduce the morbidity and mortality associated with cardiovascular diseases such as coronary heart disease (CHD) and stroke.

Statins lower levels of low-density lipoprotein (LDL) cholesterol by inhibiting production of HMG-CoA reductase, the enzyme necessary for cholesterol biosynthesis (Bryant et al. 2003). CHD mortality is attributable mainly to LDL cholesterol, whereas high-density lipoprotein (HDL) cholesterol is inversely correlated with CHD mortality (Tobert 2003).

For the treatment of cardiovascular disease, statins are used in both primary prevention (preventing a CHD event before it occurs) and secondary prevention (preventing a recurrence of a CHD event). Statins are considered more effective and tolerable in managing the risk of cardiovascular disease than alternative lipid-lowering drugs such as bile-acid sequestrants, nicotinic acid, the fibrates and probucol (Tobert 2003).

In primary prevention of CHD and stroke, statins are commonly used to treat hyperlipidaemia, a metabolic disorder characterised by increased concentrations of plasma cholesterol and triglycerides, two of the major lipids in the body. High levels of these lipids have been shown to contribute to atherosclerosis, a causative factor in CHD (Bryant et al. 2003). Statins and other lipid-lowering drugs are typically used in primary prevention when other primary interventions to reduce the risk of CHD and stroke (such as exercising, cholesterol-lowering diets and stopping smoking) have failed to reduce high lipid levels (Bryant et al. 2003).

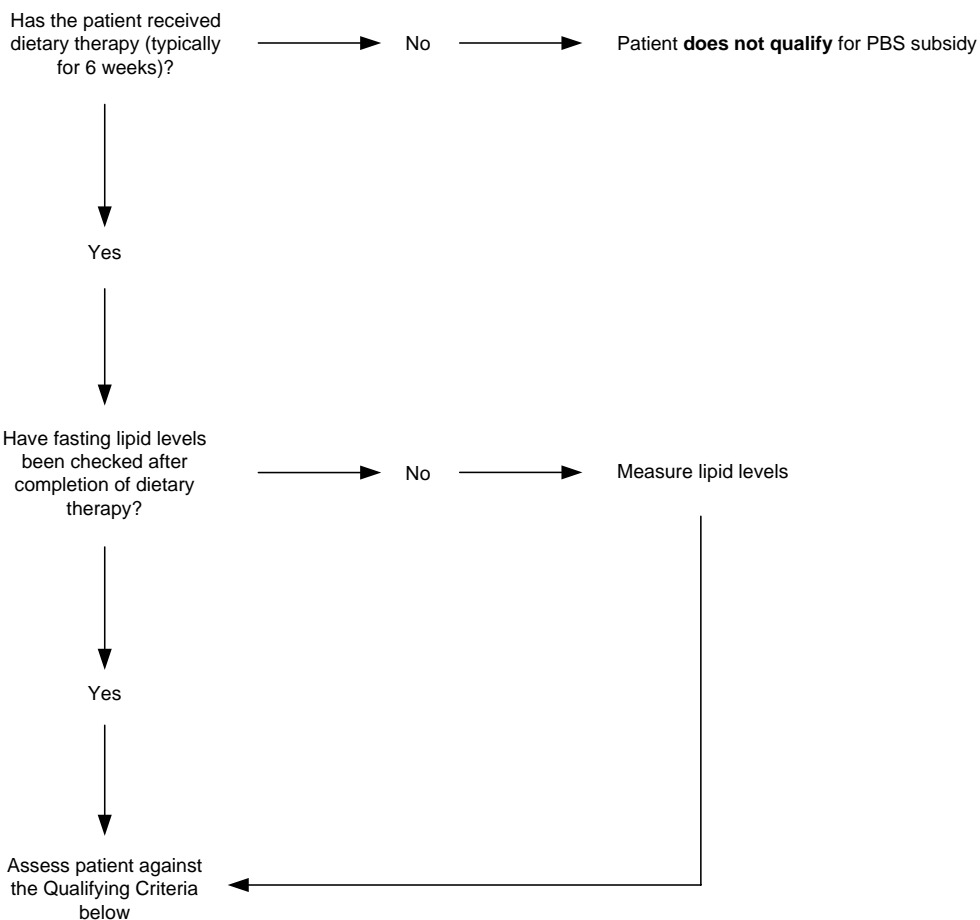
Statins are used in secondary prevention to assist individuals with established cardiovascular disease to avoid further deterioration (NHS 2003). Clinical trials have demonstrated that for secondary prevention, statins deliver additional benefits for those at higher levels of risk when used in conjunction with other CHD treatments such as aspirin, antihypertensives and beta-blockers (Ebrahim et al. 1999).

In Australia, access to subsidised statins is governed by the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS) criteria (box F.1). The PBS criteria (which also apply to RPBS patients) require that a patient must first receive diet therapy (typically for six weeks) and have their lipid levels checked. Eligibility is then determined according to a patient's lipid levels and whether a patient is in a category considered at risk of CHD (DoHA 2004b). The National Heart Foundation of Australia (NHF) also periodically issues lipid management guidelines for medical professionals, which include guidelines for the use of lipid-modifying drugs such as statins.

There are currently four types of statins listed on the PBS — *atorvastatin*, *fluvastatin*, *pravastatin* and *simvastatin*. *Cerivastatin* — another type of statin — was listed on the PBS in 1998-99, before being withdrawn worldwide by its manufacturer in August 2001 because of a large number of reports that it caused rhabdomyolysis (Tobert 2003).¹

¹ Rhabdomyolysis refers to the breakdown of muscle fibres resulting in the release of muscle fibre contents into the circulation, which often leads to kidney damage (MedlinePlus 2003).

Box F.1 PBS/RPBS criteria for access to lipid-lowering drugs



QUALIFYING CRITERIA

PATIENT CATEGORY	LIPID LEVEL FOR PBS SUBSIDY
<i>Patients with existing coronary heart disease</i>	cholesterol > 4 mmol/L
<i>Other patients at high risk with one or more of the following:</i> <ul style="list-style-type: none"> • diabetes mellitus • familial hypercholesterolaemia • family history of coronary heart disease (first degree relative less than 60 years of age) • hypertension • peripheral vascular disease 	cholesterol > 6.5 mmol/L or cholesterol > 5.5 mmol/L and HDL < 1 mmol/L
Patients with HDL < 1 mmol/L	cholesterol > 6.5 mmol/L
<i>Patients not eligible under the above:</i> <ul style="list-style-type: none"> • men 35 to 75 years • post-menopausal women up to 75 years 	cholesterol > 7.5 mmol/L or triglyceride > 4 mmol/L
Other patients not included in the above	cholesterol > 9 mmol/L or triglyceride > 8 mmol/L

Source: DoHA (2004b).

F.2 Number of prescriptions

In 2003-04, there were over 15 million prescriptions recorded for statins. *Atorvastatin* and *simvastatin* were the most prescribed of all of the drugs listed on the PBS/RPBS. Collectively, the statins listed on the PBS/RPBS had an average dispensed price of prescription of just over \$65 and accounted for approximately \$880 million or 16 per cent of total PBS/RPBS expenditure by the Australian Government (DoHA 2004a; HIC 2005b).²

Table F.1 summarises 2003-04 prescription volumes, average dispensed price per prescription and PBS/RPBS expenditure for each of the four statins listed on the PBS/RPBS.

Table F.1 **Statin prescription volumes, average price of prescription and PBS/RPBS expenditure, 2003-04**

Type of statin	Prescription volume	Average dispensed price of prescription ^a	PBS/RPBS expenditure
	m	\$	\$m
<i>Atorvastatin</i>	6.9	64	391
<i>Simvastatin</i>	6.0	67	360
<i>Pravastatin</i>	2.1	66	125
<i>Fluvastatin</i>	0.1	na	4
Total	15.1	66 ^b	880

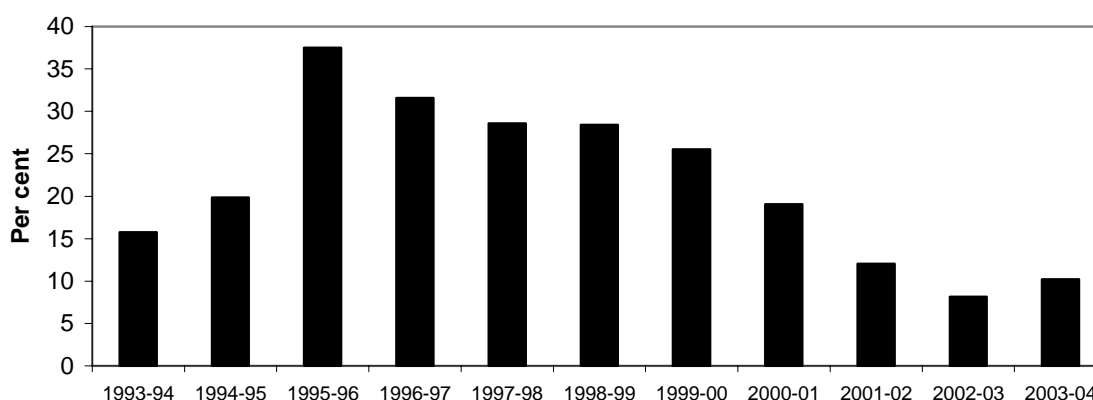
^a See footnote 2 for a description of the components of average dispensed price of prescription. ^b Average dispensed price of prescription for *atorvastatin*, *simvastatin* and *pravastatin*. na: Not available.

Data sources: DoHA (2004a); HIC (2005b).

The use of statins has increased dramatically since 1994, when their effectiveness in lowering lipid levels was established conclusively in clinical trials (Mathur 2002). Figure F.1 shows that from 1993-94 to 2003-04, statin prescriptions increased by an average of 21.2 per cent per annum. By 2003-04, the number of prescriptions was more than 600 per cent higher than in 1993-94. However, statin prescription growth rates fell in both 2001-02 and 2002-03 (probably due to the withdrawal of *cerivastatin*). Growth increased in 2003-04.

² The average dispensed price of prescription is based on the government approved dispensed price for each statin listed on the PBS. Pharmacists participating in the PBS agree to dispense medicines at the dispensed price. The consumer pays a set co-payment (which is lower for healthcare card holders), and the government pays the difference up to the dispensed price. In agreeing to a dispensed price, the government includes allowances for the manufacturer's price, a margin for the wholesaler, a mark-up by the pharmacist and the pharmacist's dispensing fee. All components of the dispensed price are paid direct to participating pharmacies who make their own pricing arrangements with wholesalers and/or manufacturers for particular medicines (DoHA 2005c).

Figure F.1 **Growth in Australian statin prescriptions, 1993-94 to 2003-04**



Data source: HIC (2005b).

Gender, age and socioeconomic profile

Recent Australian analysis from Stocks et al. (2004) for statin prescriptions filled between May and December 2002 shows that statins were primarily prescribed to individuals aged over 45. For all ages, the rate was 56.8 scripts per 1000 population per month. The highest rates were recorded in the:

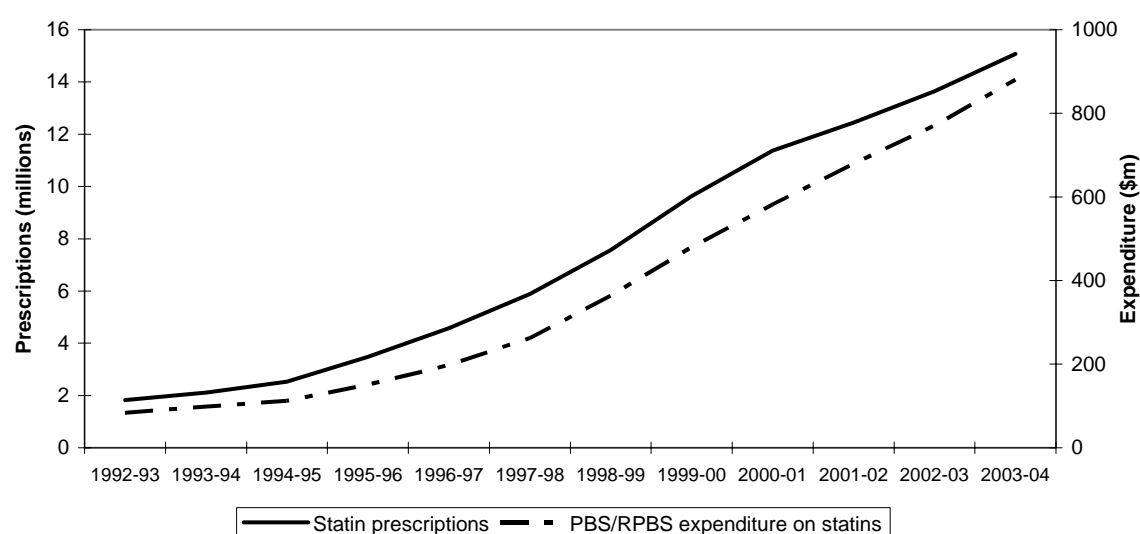
- 65–74 age group, approximately 270 scripts per 1000 population per month;
- over 75 age group, approximately 230 scripts per 1000 population per month; and
- 55–64 age group, approximately 160 scripts per 1000 population per month.

There is some evidence to suggest that statins are being under-utilised by the groups most at risk of developing CHD. Males, older Australians, Indigenous people, and people from lower socioeconomic groups are at greater risk of developing CHD compared with other Australians (AIHW 2004e). Stocks et al. (2004) report differences in statin prescribing by socioeconomic quintile for males at risk of cardiovascular disease, with men living in more advantaged socioeconomic areas of Australia having higher rates of statin prescribing relative to their cardiovascular risk compared with other men. Possible explanations for this include that men in higher socioeconomic groups may be better informed about their health and may have longer general practitioner consultations. Furthermore, despite being at lower risk of death from CHD, women are generally prescribed more statins than men. This finding may also be explained by the fact that women visit their general practitioner more frequently than men.

F.3 Expenditure

From 1992-93 to 2003-04, the total cost of statins to the PBS/RPBS increased by approximately 24 per cent per annum, to be around 800 per cent higher than 1992-93 levels (HIC 2005b). It would appear that an increase in the volume of prescriptions has been the major contributor to the increase in PBS/RPBS expenditure on statins (figure F.2).

Figure F.2 **Statin prescriptions and PBS/RPBS expenditure on statins, 1992-93 to 2003-04**



Data source: HIC (2005b).

Cost savings

It is difficult to attribute causality between growth in statin use and cost savings in other areas of the health system such as hospitals and aged care facilities, given the:

- concurrent use of other preventative CHD drugs (such as blood pressure lowering agents, aspirin, betablockers, antiplatelet agents and inhibitors of angiotensin-converting enzyme) and the use of non-drug preventative treatments (such as smoking cessation); and
- debate in the academic literature over the ability of statins to deliver cost savings (see below).

Nevertheless, there is some *prima facie* Australian evidence to suggest that recent increases in pharmaceutical expenditure (the majority of which was spent on statins) to treat cardiovascular disease have resulted in lower rates of growth for hospital and aged

care expenditures on cardiovascular disease. Over the period 1993-94 to 2000-01, there was a 62 per cent increase in pharmaceutical expenditure on the treatment of cardiovascular diseases. The corresponding period also saw a 27 per cent increase in hospital expenditure on cardiovascular disease, however, this was below the average rate of growth in hospital expenditure for all diseases (AIHW 2004c).

In addition, over the same time period, the increase in pharmaceutical expenditure corresponded with a 25 per cent decline in aged care expenditure on cardiovascular disease. This reduction in aged care expenditure is likely to reflect a decline in stroke morbidity and mortality — stroke death rates fell by 28.1 per cent among males and 27.3 per cent among females over the period 1991–2002 (AIHW and NHF 2004).

Clinical trials also provide some support for the hypothesis that statins have the potential to reduce hospital costs by lowering hospital admissions for CHD events and strokes. For example, Medicines Australia (sub. 30) cited the Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) trial, where savings in hospital costs were estimated to offset one third of the costs of *pravastatin* treatment. Similarly, in its report for GlaxoSmithKline Australia (sub. 21), the Allen Consulting Group presented evidence from the US Cholesterol and Recurrent Events (CARE) trial, which demonstrated that early treatment with statins reduced the risk of fatal heart disease or a fatal heart attack by 24 per cent.

F.4 Benefits

The availability and use of statins is considered to be a key contributor to the large decline in CHD deaths recorded in many industrialised countries since the 1960s (Tobert 2003). In Australia, between 1998 and 2002, the CHD death rate declined annually by 5.7 per cent in males and 5.5 per cent in females, while stroke mortality fell by 3.7 per cent annually in males and 3.4 per cent in females (AIHW and NHF 2004).

It is difficult to isolate the effects of statins in reducing CHD events from other primary and secondary treatments. However, the UK Department of Health (2004) has stated that statins are thought to save 6000 to 7000 lives in the UK per annum. Furthermore, Yusuf (2002) suggests that a combination of drug treatment (including statins), smoking cessation and blood pressure treatment may make it possible to lower the risk of future CHD events by more than four-fifths in high risk individuals.

The effectiveness of statins in primary and secondary prevention of CHD has also been tested in a number of clinical trials. A survey of these trials by Ebrahim et al. (1999) found

that statins reduced LDL cholesterol levels by 20 per cent and the risk of CHD mortality by 27 per cent. Box F.2 summarises key primary and secondary prevention statin trials that are commonly cited as evidence of the benefits of statins.

Box F.2 Outcomes of key primary and secondary prevention statin trials

Primary prevention trials

- The West of Scotland Coronary Prevention Study (WOSCOPS) showed that treatment with *pravastatin* significantly reduced the incidence of fatal and non-fatal coronary events in individuals with moderate to severe hypercholesterolaemia (Hay et al. 1999).
- The UK Heart Protection Study confirmed the benefit of *simvastatin* in women and its effectiveness in reducing the risk of CHD events and stroke (Tobert 2003).

Secondary prevention trials

- The Scandinavian Simvastatin Survival Study (4S) of patients with CHD demonstrated a 30 per cent reduction in all-cause mortality, due to a 42 per cent reduction in CHD deaths (Tobert 2003).
- The US Cholesterol and Recurrent Events (CARE) Trial demonstrated that the benefit of cholesterol-lowering therapy extends to the majority of patients with CHD who have average cholesterol levels (Sacks et al. 1996).
- The Australian and New Zealand Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) trial showed a 22 per cent reduction in all-cause mortality in patients who had unstable angina or an acute myocardial infarction (Glasziou et al. 2002).

While the benefits of statins in secondary prevention of CHD are generally accepted, considerable debate remains over their effectiveness in primary prevention. For example, the University of British Columbia (2003) recently examined data from five primary prevention trials and concluded that statins did not result in a reduction in the number of serious adverse events.³

Furthermore, Thompson and Temple (2004) have questioned whether these clinical trials have proven the efficacy of statins for the general public. They made a number of criticisms of primary and secondary statin trials, including:

- the use of a variety of endpoints — such as death, myocardial infarction and stroke — to evaluate the effectiveness of statins;

³ A serious adverse event was defined as any untoward medical occurrence that results in death, is life threatening, requires hospitalisation or prolongation of hospitalisation, or results in persistent or significant disability (University of British Columbia 2003).

-
- a lack of rigorous reporting of all-cause mortality (considered to be the most important endpoint) following statin treatment;
 - no measurement of overall quality of life following statin treatment; and
 - problems with the presentation of trial data. For example, small reductions in all-cause mortality can be made to look impressive by expressing results as relative rather than absolute differences.

F.5 Cost effectiveness

A number of pharmacoeconomic studies have been undertaken examining the cost effectiveness of statins relative to other primary and secondary prevention treatments for CHD (for example, Ebrahim et al. 1999; Hay et al. 1999; McMurray 1999). The cost effectiveness of statins is commonly assessed by comparing the net cost per year of life saved (YOLS) from statins with the net cost per YOLS of other CHD treatments. Net costs usually take into account potential savings from avoiding CHD events and associated costs of hospitalisation (Ebrahim et al. 1999).

As highlighted by Thompson and Temple (2004), few economic evaluations of lipid-lowering strategies have used quality of life estimates to assess cost effectiveness. One exception to this is McMurray (1999), who estimated that statins for secondary prevention cost between £5000 and £10 000 per quality-adjusted life-year gained (QALY). Reasons for the absence of QALY estimates in cost effectiveness analysis of statins include:

- accurate and valid measures of quality of life weights are generally not available. This would appear to be a problem for all pharmacoeconomic and other studies assessing cost effectiveness (chapter 5; Hay et al. 1999; Johannesson et al. 1997); and
- in the LIPID trial, there was no significant difference in quality of life reported between the patient group taking the statin and the patient group taking the placebo, therefore life years were not adjusted for quality differences (Glasziou et al. 2002).⁴

Statins are generally considered a cost effective treatment in the secondary prevention of CHD morbidity and mortality. For the LIPID trial, Glasziou et al. (2002) estimated net cost per YOLS at about A\$10 900 (discounted at 5 per cent). The authors contended that this result was within an acceptable range and was comparable with many other treatments.

⁴ Quality of life estimates were based on a sub-sample of patients who survived throughout the trial.

Similarly, for the 4S trial, Johannesson et al. (1997) estimated the net cost per YOLS in the range of US\$3800 to US\$27 400 in various patient groups and concluded that *simvastatin* therapy was cost effective among men and women at the ages and cholesterol levels studied.

While there is little debate over the cost effectiveness of statins in secondary prevention, the use of statins in primary prevention is contentious due to broad CHD risk factors and the potentially high costs of treatment (Lim et al. 2001).

Proponents of statin treatment for primary prevention have argued that lowering the eligibility requirements for lipid-lowering drugs for those at risk of CHD can significantly reduce CHD events in a cost effective manner. Wald and Law (2003) claimed that a single daily pill — a ‘Polypill’ (containing six agents including a statin) — could largely prevent heart attacks if taken by every person who either has cardiovascular disease, is age 55 or older, or both. They also suggested that the ‘Polypill’ could be developed at low cost by using generic components that are not subject to patent protection. Hay et al. (1999) reviewed statin cost effectiveness studies and identified large variations in reported cost per YOLS for different statins. However, they concluded that statins have been shown to reduce CHD in a cost effective manner for both primary and secondary prevention (cost per YOLS less than US\$50 000), and that statin therapy would be cost effective in any patient with an annual CHD risk exceeding 1 per cent.

Critics of the use of statin treatment for primary prevention of CHD have disputed the cost effectiveness of such treatment. For example, for low risk individuals, Thompson and Temple (2004) argued that statin therapy is extremely expensive (more than US\$300 000 to prevent a single CHD event) compared to other primary intervention alternatives such as diet therapy.⁵ Similarly, Prosser et al. (2000) found that primary prevention with a statin may not be cost effective for younger men and women with few risk factors, while Marshall (2003) concluded that offering aspirin and initial hyperintensive treatment would be a more efficient preventative strategy for CHD than *simvastatin*.

Other researchers such as Messori et al. (2003a, 2003b) pointed to the wide variation in cost per YOLS cited in studies (from Can\$7700 to US\$420 000) as evidence of the lack of data demonstrating the cost effectiveness of statins in primary prevention. They cautioned that Wald and Law (2003) may have:

... over-estimated the clinical and economic evidence about primary prevention with statins. (Messori et al. 2003b)

⁵ In Australia, patients are required to undertake diet therapy before being granted access to subsidised statins (box F.1).

In Australia, debate has occurred as to whether statin treatment for primary prevention of CHD according to PBS criteria is cost effective. For example, Lim et al. (2001) found that PBS criteria did not identify those most at risk of CHD, and that treatment according to PBS criteria is not likely to be the most cost effective option. They recommended that, for optimal cost effectiveness, primary CHD prevention should be based on criteria that take into account a person's age, gender and an assessment of major risk factors such as smoking, cholesterol and blood pressure levels.

In November 2001, the NHF issued revised lipid management guidelines to address concerns raised by researchers such as Lim et al. (2001) and Forge and Briganti (2001) over the appropriateness of Australian guidelines for statin prescribing. In line with a growing international consensus, the NHF recommended that lipid-modifying medication should be used only in people at high absolute risk and then only if the recommended lipid levels are not achieved by reasonable lifestyle modification (NHF and the Cardiac Society of Australia and New Zealand 2001). However, Jackson (2001) criticised the revised guidelines for not including a rigorous cost-benefit analysis. He noted that the revised guidelines could result in statins being prescribed to hundreds of thousands of Australians with only a modestly raised risk of CHD, resulting in a large increase in PBS expenditure on statins.

F.6 Future developments

Australian patent protection for the statins currently listed on the PBS will progressively expire from July 2005, providing an opportunity for equivalent products (generic medicines) to be listed on the PBS. The Australian Government has announced it will negotiate with pharmaceutical companies to reduce the government benchmark price by 12.5 per cent for all medicines in a therapeutic group when the first generic drug enters that group (Abbott 2005c). This policy was originally intended to apply to all cholesterol-lowering drugs listed on the PBS (Abbott 2005c). However, the government recently announced that *atorvastatin* would be exempt from a price reduction, as it was considered:

... more effective at lowering cholesterol than simvastatin, and therefore warrants a higher price for PBS subsidy. (Abbott 2005c, p. 1)

The Department of Health and Ageing (DoHA) also saw a need for medication to be better targeted to patients with CHD, or at high risk of CHD. It foresees the net result of improved targeting as:

... improved patient outcomes, decreased costs to treat recurrence of vascular disease and most likely some decrease in the rapid growth of the use of these medications ... (sub. 34, p. 20).

In the United States and United Kingdom, regulators have considered allowing statins to be available over the counter (OTC) at low doses without prescription (Thompson and Temple 2004; Tobert 2003). In May 2004, the UK Government made *simvastatin* available without prescription in a 10 mg dose to people at moderate risk of heart attacks. This decision was criticised in an editorial by the UK medical journal *The Lancet* (2004), which cited a lack of trials of OTC statins for primary prevention of heart disease and a lack of data on compliance with OTC statins. It also noted that two US applications for OTC statins were rejected on safety and efficacy grounds, and suggested that the decision may be based on a desire to transfer statin costs from the UK Government to patients.

To assist in providing further information on the benefits and cost effectiveness of statins, clinical trials are continuing internationally on the use of statins in primary and secondary prevention. Examples of recent statin trials include the UK Heart Protection Study, the Prospective Study of Pravastatin in the Elderly at Risk (PROSPER) and the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT-LLT) (University of British Columbia 2003).

Furthermore, partly in response to rising health expenditure on statins, the UK Government has commissioned the National Institute for Health and Clinical Excellence to report by September 2005 on the clinical and cost effectiveness of the use of statins for the management of patients at increased risk of death or other cardiovascular events from CHD. The report will also advise on any patient groups for which statins would be particularly appropriate (NICE 2004d; Pharmafocus 2003).

F.7 Conclusion

Over the past decade, the use of statins in primary and secondary prevention of cardiovascular disease has increased considerably. Statins are now considered the 'agents of choice' for reducing LDL cholesterol levels (NHF and the Cardiac Society of Australia and New Zealand 2001). Supporters of statin treatment commonly cite clinical trials showing a reduction in cardiovascular disease morbidity and mortality and the role of statins in reducing hospital and aged care expenditure to advocate a greater role for statins in primary and secondary prevention of CHD. While critics of statin treatment generally accept the efficacy of statins in secondary prevention, they are particularly sceptical of the efficacy and cost effectiveness of statins in primary prevention and oppose proposals to

make statins widely available to the general public. Research is continuing internationally and in Australia into the clinical and cost effectiveness of the use of statins.

In Australia, improved targeting of statin therapy to those with established CHD and to those at high risk of CHD may assist in decreasing the rapid growth in government expenditure on statin therapy. To date, NHF guidelines on statin treatment have been amended to assist in ensuring that statins are only used in people at high absolute risk and then only after lifestyle modification has been prescribed. While these guidelines have aligned Australian lipid management practice more closely with international standards, and while they may improve targeting in future, they have been criticised by some for not being based on a rigorous cost–benefit analysis.

G Selective Serotonin Reuptake Inhibitors

G.1 Introduction

One example of pharmaceuticals which have brought significant benefits to Australians over the past ten years or more, albeit at a considerable cost, is the selective serotonin reuptake inhibitors (SSRIs). SSRIs are a class of antidepressants that are commonly used to treat depression (Hegarty et al. 2003). There are six SSRIs listed on the Pharmaceutical Benefits Scheme (PBS), and all are listed as restricted benefit. In most cases, they are restricted to the treatment of major depressive disorders but, in some cases, they are also listed for the treatment of obsessive-compulsive disorder and panic disorder (DoHA 2004b).

The first SSRI to become available in Australia was Prozac (*fluoxetine*) in 1990. Four years later, two other well-known brand names, Zoloft (*sertraline*) and Aropax/Paxil (*paroxetine*), were also listed on the PBS. Before the 1990s, the most commonly used antidepressants were the tricyclic antidepressants (TCAs) (McManus et al. 2004).

The social and economic costs of depression in Australia are considerable. For example, according to Hu (2004), in 1997-98 the direct costs associated with the treatment of affective (mood) disorders (including depression) were estimated to be \$615 million. In addition, the indirect costs of absenteeism from work and reduced productivity (both as a result of reduced functionality at work and premature death) were estimated to be \$2.8 billion.

The *Burden of Disease and Injury in Australia* report (Mathers et al. 1999) named depression as the top-ranking cause of disability burden in 1996, and suicide — one risk factor for suicide is depression (Hall et al. 2003) — as the fourth-ranking cause of mortality burden. By the year 2020, depression is expected to be the second-ranked cause of all disability and death worldwide (Murray and Lopez 1996).

G.2 Use and expenditure

Currently, SSRIs are the most widely prescribed class of antidepressants in Australia, accounting for over 58 per cent of antidepressant prescriptions that were subsidised by the Australian Government under the PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS) in 2003-04 (HIC 2005b). During the 2003-04 financial year, *sertraline* was the most frequently prescribed antidepressant — over 2.4 million scripts, making it the fourteenth most frequently prescribed PBS drug for that year. At an average dispensed price of about \$39 per script¹, the cost to government of *sertraline* amounted to over \$70 million — the fifteenth highest expenditure item on the PBS. In addition, the private out-of-pocket cost of *sertraline* was over \$27 million, taking the total cost to over \$97 million (DoHA 2004a).

Prior to 1990, the market for antidepressants was stable at around 10 defined daily doses per 1000 people per day (DDDs/1000/day). After the first SSRI (*fluoxetine*) was listed on the PBS in 1990, both use of, and expenditure on, antidepressants in Australia increased dramatically. Between 1990 and 2002, the use of antidepressants increased by 352 per cent to around 51 DDDs/1000/day in 2002, with an average annual growth rate of around 13 per cent over this period (Mant et al. 2004).

The use of antidepressants in Australia increased more quickly than in other countries. McManus et al. (2000) reported that of eight developed countries, Australia had the second highest rate of increase in use between 1993 and 1998 (behind Sweden). In 1998, the use of antidepressants in Australia in terms of DDDs/1000/day, was lower than in France and Sweden, comparable to the United States, and higher than in Germany, Italy, Canada and the United Kingdom.

Figures G.1 and G.2 illustrate the use of, and government expenditure on, the five most widely prescribed PBS/RPBS listed SSRIs (*sertraline*, *citalopram* (Celexa), *paroxetine*, *fluoxetine* and *fluvoxamine* (Luvox)) from 1992-93 to 2003-04. The number of government-subsidised PBS/RPBS scripts for SSRIs increased substantially from around 240 000 in 1992-93 to almost 7 million in 2003-04 (HIC 2005b). As a result of increased use, expenditure on SSRIs rose from almost \$12 million in 1992-93 to nearly \$205 million

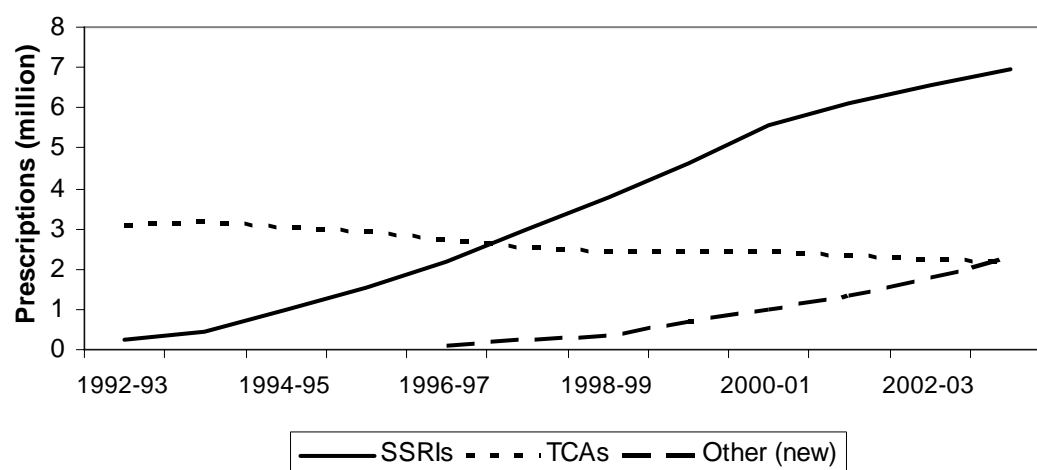
¹ The average price of prescription is based on the government approved dispensed price. Pharmacists participating in the PBS agree to dispense medicines at the dispensed price. The consumer pays a set co-payment, and the government pays the difference up to the dispensed price. In agreeing to a dispensed price, the government includes allowances for the manufacturer's price, a margin for the wholesaler, a mark-up by the pharmacist and the pharmacist's dispensing fee. All components of the dispensed price are paid direct to participating pharmacies who make their own pricing arrangements with wholesalers and/or manufacturers for particular medicines (DoHA 2005c).

in 2003-04 (HIC 2005b). (Expenditure on SSRIs fell between 1995-96 and 1996-97 due to a fall in the price of *fluoxetine*.)

Between 1992-93 and 2003-04, the use of TCAs fell by almost 29 per cent, and government expenditure on TCAs fell by around 18 per cent. Over the same period, two relatively new drugs, *venlafaxine* (Efexor — an inhibitor of both serotonin and norepinephrine reuptake) and *mirtazapine* (Remeron — an atypical antidepressant that acts on specific subtypes of serotonin receptors), were responsible for the biggest increases in antidepressant use and government expenditure. The average dispensed price of *mirtazapine* — around \$40 per script — is comparable to that of the SSRIs, but *venlafaxine* is more expensive, with an average dispensed price of around \$55 per script (DoHA 2004a).

However, these figures do not reflect PBS/RPBS antidepressants that are priced below the relevant maximum patient co-payment amount. This has a greater impact on TCAs than on the new, and more expensive, antidepressants. For example, in 2000, government-subsidised use of *fluoxetine* represented around 99 per cent of total community use. By comparison, almost 77 per cent of community use of *amitriptyline* (a TCA) was government subsidised (DoHA 2003a).

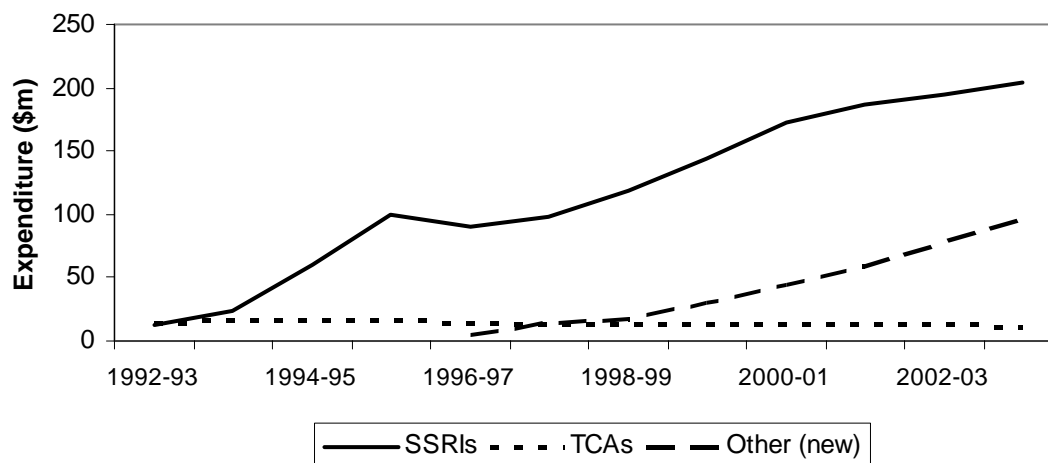
Figure G.1 **PBS/RPBS antidepressant prescriptions, 1992-93 to 2003-04^{a,b,c,d}**



^a Other (new) includes *venlafaxine* and *mirtazapine*. The first PBS/RPBS scripts for *venlafaxine* and *mirtazapine* were filled in 1996-97 and 2000-01 respectively. ^b The data do not reflect PBS/RPBS scripts that are priced below the relevant patient co-payment amount. ^c Use of antidepressants in 2004-05 is not presented because consistent data on the average dispensed price of the antidepressants were not available. ^d The same pattern of use of antidepressants is evident when data are in terms of DDD/1000/day (DoHA unpublished data).

Data source: HIC (2005b).

Figure G.2 **PBS/RPBS expenditure on antidepressants, 1992-93 to 2003-04^{a,b,c}**



^a Other (new) includes *venlafaxine* and *mirtazapine*. The first PBS/RPBS scripts for *venlafaxine* and *mirtazapine* were filled in 1996-97 and 2000-01 respectively. ^b The data do not reflect PBS/RPBS scripts that are priced below the relevant patient co-payment amount. ^c Expenditure on antidepressants in 2004-05 is not presented because consistent data on the average dispensed price of the antidepressants were not available.

Data source: HIC (2005b).

Whilst it is difficult to pinpoint the exact reasons for the proliferation in antidepressant prescribing since the 1990s, the most probable explanation is the superiority of SSRIs (and other new antidepressants) in terms of their tolerability (fewer side effects) and lower toxicity in comparison to TCAs. The lower toxicity meant that prescribers were less concerned about the risk of overdose (Mant et al. 2004).

Another contributing factor to the increased prescription of antidepressants has been increased awareness, and more widespread acceptance, of depression as a treatable condition. Patients are more willing to talk about their symptoms with their general practitioners (GPs), and GPs are better equipped to diagnose and treat depression. GPs prescribe the vast majority (86 per cent) of scripts for PBS listed antidepressants (McManus et al. 2003).

Mant et al. (2004) reported that the increased volume of antidepressant prescriptions over the last ten years reflected prescriptions for new patients rather than switching of existing patients from their old antidepressants to the new SSRIs. This conclusion was based on the relatively small impact of the listing of SSRIs on the volume of TCAs prescribed (figure G.1). It is possible that new prescriptions of antidepressants have been for patients with previously undiagnosed major depression. On the other hand, it is also possible that many of the new patients are sufferers of mild depression (see below).

Aside from prescriptions for new patients, another possible explanation for the increased use of antidepressants is that patients are taking antidepressants for a longer period of time (Meijer et al. 2004).

Profile of the need for SSRIs

It is difficult to ascertain which groups have the greatest need for antidepressants. Information about the prevalence of clinically diagnosed depression is limited. The most recent national survey data are for 2001, showing levels of psychological distress in the community based on the Kessler 10 (K10) scale (ABS 2002a). The K10 scale measures anxiety and depressive symptoms experienced by respondents. Those reporting a 'very high' level of psychological distress are likely to need professional help. However, this category may not be consistent with PBS restrictions that apply to the prescribing of SSRIs, because a person who reports that they are experiencing 'very high' levels of psychological distress may not have major depression, and vice versa.

According to the K10 data, women are more likely to need professional help for psychological distress than men (ABS 2002a). More disadvantaged people were more likely to need professional assistance for psychological distress than the less disadvantaged. Persons living in major cities were just as likely as persons living outside of major cities to need professional help for psychological distress. 18–24 year olds, and 45–54 year olds, were more likely to report very high levels of psychological distress compared to other age groups. However, it is possible that the survey results underestimate the prevalence of 'very high' levels of psychological distress amongst older persons because the survey does not cover hospitals or nursing homes (ABS 2002a), where a significant proportion of patients are elderly.

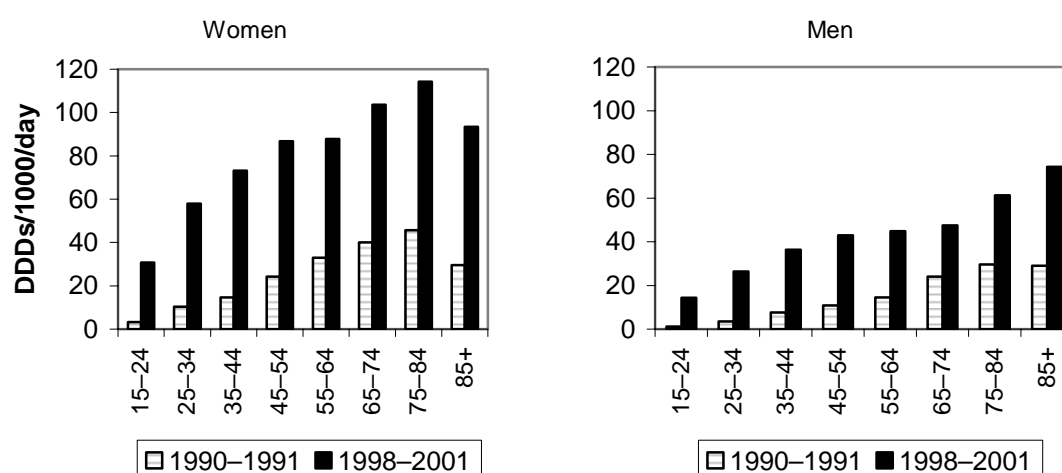
In contrast to the K10 data, data on recorded suicides suggest death rates from suicide are higher outside capital cities, and that men are around four times more likely to commit suicide than women. There is also evidence which points to lower rates of attempted (unsuccessful) suicide for men than for women (ABS 2000). It is unknown whether or not the higher rate of prevalence of psychological distress for more disadvantaged people is reflected in the suicide rate for this group.

Profile of SSRI use

Hall et al. (2003) compared their estimates of DDDs/1000/day of antidepressants taken by Australian men and women of different age groups in three time periods from 1990 to 2001. They generated gender and age profiles with the use of antidepressant sales data and

three surveys of the prescribing practices of GPs conducted between 1990 and 1991, in 1995, and between 1998 and 2001. The authors reported that, in general, women used antidepressants more than men (figure G.3), and that the use of antidepressants for men and women of all age groups increased over the period. With the exception of the oldest age group for women (aged 85 years or older), there was a positive relationship between age group and the use of antidepressants.

Figure G.3 Estimated daily use of antidepressants, gender and age
1990–1991, 1998–2001^a



^a Surveys of the antidepressant prescribing practices of GPs were conducted in 1990 to 1991 and 1998 to 2001.

Data source: Hall et al. (2003).

The Commission used HIC data to examine patterns of use of subsidised antidepressants by age group (table G.1), gender (table G.2), region (table G.3) and socioeconomic status (table G.4) for the period 2002 to 2004. Data on patient characteristics are limited prior to 2002, so it is not possible to examine changes over time in use by group. While it would have been useful to compare the distribution of new antidepressants and TCAs, this has not been possible because data about TCAs priced under the general patient co-payment amount are not available.

Table G.1 shows that the age-specific rate of use of new antidepressants is lowest for the youngest age groups, peaks between the ages of 45 and 64, declines between the ages of 65 and 74, and increases for the oldest age groups. While the rate of use of SSRIs was stable between 2002 and 2004, the rate of use of the other new antidepressants generally increased. By 2004, around 7 per cent of the population aged between 45 and 54 years were taking SSRIs, and around 2 per cent were taking either *venlafaxine* or *mirtazapine*. Of those aged 85 or older, almost 13 per cent were taking SSRIs, compared to around 4 per

cent for the other new antidepressants. The high age-specific rate of use of new antidepressants by those in the 45–54 age group in comparison to other age groups is consistent with the prevalence of ‘very high’ levels of psychological distress based on the K10 scale in 2001. However, the relatively low age-specific rates of use among adults aged 18–24 are not.

Antidepressant use by gender is consistent with the prevalence of ‘very high’ levels of psychological distress recorded amongst women. The new antidepressants were more frequently supplied to females than to males — around 34 in 1000 males, and around 65 in 1000 females took SSRIs in 2004 (table G.2). However, the 1997 *National Survey of Mental Health and Wellbeing of Adults* (ABS 1998) identified a second factor that is responsible for the low rate of use of antidepressants by men. The survey indicated that just 29 per cent of men who had a mental health problem had sought treatment, compared to 46 per cent of women.

Table G.1 Age-specific rates of use of new antidepressants, 2002 to 2004^a

	2002		2003		2004	
	SSRIs	Other (new)	SSRIs	Other (new)	SSRIs	Other (new)
Persons taking antidepressants per 1000 population						
0–14	2.8	0.2	3.1	0.2	2.8	0.2
15–24	31.6	6.7	32.9	8.8	30.8	9.1
25–34	53.7	13.3	54.7	16.8	51.8	18.1
35–44	64.9	16.9	66.7	21.2	65.0	22.9
45–54	69.9	18.9	71.4	23.7	69.3	26.2
55–64	71.3	18.0	74.6	23.4	73.8	26.5
65–74	65.0	14.8	67.5	19.3	67.1	22.6
75–84	90.7	20.1	92.9	26.8	89.6	31.3
85 or older	127.4	23.3	130.7	33.1	128.3	40.2
Total ^b	49.4	12.1	51.2	15.5	49.8	17.3

^a Other (new) includes *venlafaxine* and *mirtazapine*. ^b Total use rates vary for some of the tables in this appendix because the classification systems used (for example, socioeconomic status and remoteness area) had different missing data.

Sources: ABS (2004b); HIC unpublished data.

Table G.2 **Gender-specific rates of use of new antidepressants, 2002 to 2004^a**

	2002		2003		2004	
	SSRIs	Other (new)	SSRIs	Other (new)	SSRIs	Other (new)
Persons taking antidepressants per 1000 population						
Females	64.4	14.6	66.9	18.6	65.2	20.7
Males	34.3	9.5	35.2	12.4	34.2	13.8
Total ^b	49.4	12.1	51.2	15.5	49.8	17.3

^a Other (new) includes *venlafaxine* and *mirtazapine*. ^b Total use rates vary for some of the tables in this appendix because the classification systems used (for example, socioeconomic status and remoteness area) had different missing data.

Sources: ABS (2004b); HIC unpublished data.

Between 2002 and 2004, people living in inner regional areas were the most likely to use SSRIs or other new antidepressants, followed by those living in outer regional areas and by people living in major cities. Australians living in very remote and remote areas have relatively low area-specific rates of use of new antidepressants compared with those living in other areas (table G.3). In 2004, the rate of use of SSRIs and other new antidepressants was respectively 21.9 and 7.1 persons per 1000 of the population living in very remote areas. Both rates are much lower than the respective national rates of 51.0 and 17.7 persons per 1000 of the population. The rates of use of antidepressants in remote areas was not as low as the rates of use of antidepressants in very remote areas — 43.4 and 14.8 persons per 1000 of the population living in remote areas took SSRIs and other new antidepressants respectively. This is inconsistent with reported prevalence based on K10 data (ABS 2002a), and also with suicide rates (SCRGSP 2005).

However, the differences in rates across the regions may be partly attributable to regional differences in gender profiles. In 2001 there were proportionately more males outside major cities — around 50 per cent in inner regional areas, 51 per cent in outer regional areas, and about 53 per cent in remote and very remote areas compared to 49 per cent in major cities.

Table G.3 Region-specific rates of use of new antidepressants, 2002 to 2004^a

	2002		2003		2004	
	SSRIs	Other (new)	SSRIs	Other (new)	SSRIs	Other (new)
Persons taking antidepressants per 1000 population ^b						
Major cities	47.6	11.4	49.8	14.8	48.9	16.7
Inner regional	56.4	14.2	59.1	18.5	58.5	21.0
Outer regional	51.4	13.0	53.8	17.2	53.5	19.1
Remote	40.8	10.1	43.0	13.4	43.4	14.8
Very remote	19.7	4.5	21.3	6.0	21.9	7.1
Total ^c	49.5	12.0	51.8	15.7	51.0	17.7

^a Other (new) includes *venlafaxine* and *mirtazapine*. ^b Population by postcode based on 2001 census. ^c Total use rates vary for some of the tables in this appendix because the classification systems used (for example, socioeconomic status and remoteness area) had different missing data.

Sources: ABS unpublished data from the 2001 census; HIC unpublished data.

There is less variation in the use of antidepressants across socioeconomic groups than across regional areas. Nonetheless, those that are living in more disadvantaged areas — in the second and third quantiles of the index of relative socioeconomic disadvantage — have the highest quantile-specific rates of use (table G.4). The most and the least disadvantaged Australians have similar quantile-specific rates of use of SSRIs, although the prevalence of ‘very high’ levels of psychological distress is highest in areas of greatest socioeconomic disadvantage and lowest in areas of least socioeconomic disadvantage.

Table G.4 **Rates of use of new antidepressants by socioeconomic status, 2002 to 2004^{a,b}**

	2002		2003		2004	
	SSRIs	Other (new)	SSRIs	Other (new)	SSRIs	Other (new)
Persons taking antidepressants per 1000 population ^c						
1 (Most disadvantaged)	47.7	12.1	49.5	15.8	48.4	17.9
2	51.8	13.0	53.8	16.9	53.0	19.1
3	52.4	12.8	54.9	16.8	54.2	19.0
4	49.0	11.8	51.3	15.4	50.8	17.4
5	46.8	11.0	49.2	14.3	48.4	16.1
6 (Least disadvantaged)	47.3	11.3	50.1	14.6	49.0	16.2
Ratio 5/1	0.98	0.91	0.99	0.90	1.00	0.90
Ratio 6/1	0.99	0.93	1.01	0.92	1.01	0.90
Total ^d	49.5	12	51.8	15.7	51.0	17.7

^a Based on socioeconomic index of relative disadvantage (ABS 2001). ^b Other (new) includes *venlafaxine* and *mirtazapine*. ^c Population by postcode based on 2001 census. ^d Total use rates vary for some of the tables in this appendix because the classification systems used (for example, socioeconomic status and remoteness area) had different missing data.

Sources: ABS unpublished data from the 2001 census; HIC unpublished data.

There is some evidence to suggest that SSRIs are not being prescribed in accordance with the PBS restrictions, which state that SSRIs are for the treatment of major depressive disorders (and in some cases also for the treatment of obsessive-compulsive disorder and panic disorder). A survey of GPs revealed that the majority of patients treated for depression had ‘chronic mild depression’ (McManus et al. 2003). Dr Yolande Lucire (sub. PR47, pp. 3 and 4) claimed that ‘the vast majority of those getting these drugs do not suffer from depression, but from anxiety and ‘stress’, and that antidepressants are ‘now being provided for menopause and stress incontinence’.

G.3 Benefits

SSRIs represented a major advance in the treatment of depression, even though they are similar to other antidepressants in terms of their ability to relieve the symptoms of depression.

Clinical trials show that first-line treatment with antidepressants is effective in about two-thirds of patients (although the same antidepressant can have varying effectiveness across patients) but trials also highlight a strong placebo effect (Rang et al. 2003).

In some countries, such as Sweden (Isacsson 2000 cited by Hall et al. 2003) and Hungary (Rihmer 2001 cited by Hall et al. 2003), the introduction of SSRIs has been associated with a decline in the rate of suicide. In Australia, a negative relationship between suicide rates and exposure to antidepressants has been demonstrated for some age groups:

In Australia, older adults had the highest growth in antidepressant use and the greatest decline in suicide ... Thus, even if some antidepressant prescribing is unnecessary or ineffective, increased exposure to these agents through prescribing in general practice may have produced a measurable reduction in the burden of depression in the population. (Mant et al. 2004, p. S23)

The rate of suicide for persons aged 45 or older was lower in 2001 compared to 1991 (ABS 2003a). Lower suicide rates for these age groups may be attributable to the lower toxicity in overdose of SSRIs compared with TCAs. There is debate, however, over whether or not SSRIs increase the risk that a patient will attempt suicide (Cipriani et al. 2005). Dr Yolande Lucire (sub. PR47, p. 1) asserted that since the introduction of the newer antidepressants (and antipsychotics) in the early 1990s there has been a ‘trebling of suicides under mental health care and [a] trebling of suicide attempts’ in New South Wales. On the other hand, McManus et al. (2000, p. 6) advised that the ‘benefits of this major change in drug use (e.g. reductions in suicide rates) are anticipated in the long term’.

The key benefit of SSRIs relative to other antidepressants is their tolerability, that is, the uncommonness of severe side effects. While SSRIs are not without side effects — for example, they are associated with discontinuation reactions, and in some cases these are severe (Goldstein and Goodnick 1998) — most studies indicate that they are more tolerable than the older antidepressants (Donoghue and Hylan 2001). Tolerability is important because patients’ compliance with their course of treatment, and compliance over a reasonable period of time, are necessary to prevent relapse (Donoghue and Hylan 2001). Treatment guidelines suggest that a reasonable duration of therapy for major depression is between six and twelve months (Ellis et al. 2003; McManus et al. 2004; Meijer et al. 2004). Compliance is also improved with the simpler dosing regimes of SSRIs (Hall et al. 2003).

It has been suggested that positive experiences with SSRIs have also been partly responsible for improvements in social attitudes towards seeking treatment for depression, and towards taking antidepressants (Hickie et al. 2001 cited by Hall et al. 2003; Jorm et al. 2000 cited by Hall et al. 2003).

G.4 Cost effectiveness

There is some dispute on the cost effectiveness of SSRIs in comparison to psychotherapy and TCAs. Dr Jeff Brownscombe (sub. PR55, p. 3) stated that ‘medical evidence shows both SSRI medications and six sessions of cognitive behavioural therapy (delivered by psychologists) can have a similar impact on outcomes’, and indicated that SSRIs may possibly be less cost effective than psychotherapy because ‘SSRI scripts are often ongoing’. However, according to Cutler and McClellan (2001), SSRIs are more cost effective than psychotherapy because they are cheaper and because their drop out rates are lower. A recent review of the few studies that have investigated the cost per quality-adjusted life-year (QALY) of treatments for depression revealed that ‘pharmacologic treatment, either alone or in combination with psychotherapy, had a lower cost per QALY than psychotherapy alone’ (Pirraglia et al. 2004, p. 2157).

SSRIs are more expensive than TCAs — for example, in 2001, the cost per daily dose of *sertraline* (a SSRI) was \$1.30, while the cost per daily dose of *amitriptyline* (a TCA) was around 40 cents (Hegarty et al. 2003). Even so, SSRIs are more cost effective than TCAs (Barrett et al. 2005). Revicki et al. (1995) estimated that the cost per QALY of *fluoxetine* was slightly lower than that of *imipramine* (a TCA) — in 1993 dollars this was around Can\$3700 (roughly equivalent to A\$4600 in 2002 dollars) and Can\$4000 (around A\$5000 in 2002 dollars) respectively.

There are several reasons why SSRIs are cost effective in comparison to TCAs, even though full courses of SSRIs are roughly equivalent to full courses of TCAs in terms of efficacy. Firstly, as noted above, patients generally tolerate the side effects of SSRIs better than the side effects of TCAs, and SSRIs are less frequently associated with adverse events (Donoghue and Hylan 2001). Consequently, SSRIs have reduced the cost of hospitalisation and visits to GPs (Panzarino and Nash 2001). Patients are more likely to take efficacious doses of SSRIs in comparison to TCAs, less likely to stop treatment, and less likely to need to change the prescribed dose (Goldstein and Goodnick 1998). Evidence suggests that patients taking SSRIs are also more likely than patients who take TCAs to continue therapy for long enough to prevent relapse (Donoghue and Hylan 2001; McManus et al. 2004).

Secondly, SSRIs are cost saving within the hospital setting because any hospital admissions following overdoses on SSRIs are less expensive and of shorter duration, than overdoses with TCAs. An English study (Ramchandani et al. 2000) found that the mean length of stay following an overdose on a TCA was slightly longer than the mean length of stay following an overdose on a SSRI (about 2.6 days compared to just under two days). But, more significantly, hospital admissions following overdoses on TCAs are

considerably more expensive than those for overdoses on SSRIs because of admissions to intensive care units, which explain 73 per cent of the cost difference (Ramchandani et al. 2000).

As a result of their greater tolerability, and the lower incidence of adverse events, SSRIs have improved the quality of life of those suffering from depression and also resulted in increased productivity (Cutler and McClellan 2001). For example, one study suggested that patients taking TCAs are more than twice as likely to be absent from work than patients taking SSRIs (Souetre et al. 1997 cited by Panzarino and Nash 2001).

G.5 Future developments

While the 1990s saw the emergence of a new market for antidepressants in Australia, there may still be many people who could benefit from antidepressants because only a small proportion of those who suffer from mental illness actually seek treatment (ABS 1998) (although this may have improved somewhat since the *National Survey of Mental Health and Wellbeing of Adults* was conducted in 1997). As indicated earlier, the burden of depression is not expected to decrease in the near future (Murray and Lopez 1996). These factors suggest that expenditure on antidepressants as a whole will continue to increase.

It is unclear, however, whether expenditure on SSRIs will continue to increase. For example, expenditure on new antidepressants (*venlafaxine* and *mirtazapine*) has been steadily increasing since their listing, while growth in expenditure on SSRIs appears to be easing.

It is possible that any future growth in expenditure may be directed towards other new antidepressants. As many as fifty new antidepressants could become available in the next ten years (including triple uptake inhibitors, corticotropin releasing factor antagonists and substance P antagonists), but only five or so of these are in phase III clinical trials or awaiting approval (Becker 2005). It is unlikely that they will have the same market impact that SSRIs had in the 1990s, but nonetheless, the antidepressants that are in the pipeline show promise of improved tolerability, greater potency, and earlier onset of action (Merck & Co. Inc. 2004; Neurocrine Biosciences Inc. 2004) — attributes which are likely to appeal to medical practitioners and their patients.

Another factor that may affect expenditure on antidepressants is that the prices of many of the SSRIs are likely to fall in the near future as their patents are approaching expiry — for example, the patent for *sertraline* will expire in late 2005 (Cresswell 2005).

G.6 Conclusion

SSRIs were a major advance in the treatment of depression. Their listing on the PBS in the 1990s resulted in dramatic growth in the use of antidepressants in Australia. As a consequence, expenditure on antidepressants also increased significantly. Surveys of prevalence of psychological distress indicated that females, people in the 18–24 and 45–54 age groups, and people living in more disadvantaged areas are more likely to need professional assistance for psychological distress. In general, the new antidepressants were supplied to these groups. However, there is an indication that there are relatively more men with untreated depression than women.

While the more widespread use of antidepressants most likely satisfied some unmet demand, there is evidence that there are still a number of Australians suffering from untreated depression. Further, there is still scope for ensuring that patients receive effective doses of antidepressants for an adequate duration. Thus it is likely that the coming years will see continued growth in the use of antidepressants — including those that are currently available (such as SSRIs), and those that are in the pipeline.

H Drug eluting stents

H.1 Introduction

Stents are medical devices for treating coronary heart disease (CHD). A stent acts as scaffolding to hold open an artery following coronary angioplasty (and more than one stent is generally used per procedure). Stenting was first performed on a human coronary artery in 1986 and introduced in Australia in 1994 (Angioplasty 2005; Mathur 2002).

Drug eluting stents (DES) are stents coated in drugs that inhibit the re-growth of tissue at the site of the stent, which is known as restenosis (a re-narrowing of the blood vessel or heart valve caused by scar tissue).

The process for introducing DES into Australia was somewhat unconventional (chapter 10). The first DES approved in Australia were Cypher stents, manufactured by Johnson & Johnson. They were added to the Australian Register of Therapeutic Goods (ARTG) as a non-current entry in 2000-01 (MSAC 2002). The entry was conditional on the drug with which DES are coated (*sirolimus*) being approved for treating CHD. This approval was granted by the Therapeutic Goods Administration (TGA) in June 2002 and required a change to TGA regulations to allow DES to be assessed as a combination of a medicine and a medical device (TGA, Canberra, pers. comm., 4 February 2005).

Prior to this approval, in February 2002, DES were added to Schedule 5 under the *National Health Act 1953*. At this time, the Medical Services Advisory Committee (MSAC) also examined DES as an emerging technology (MSAC 2002). In 2005, MSAC carried out an assessment of DES for the Health Policy Advisory Committee on Technology (MSAC 2005). (More detail on the outcomes of the MSAC assessment is provided in box H.1.)

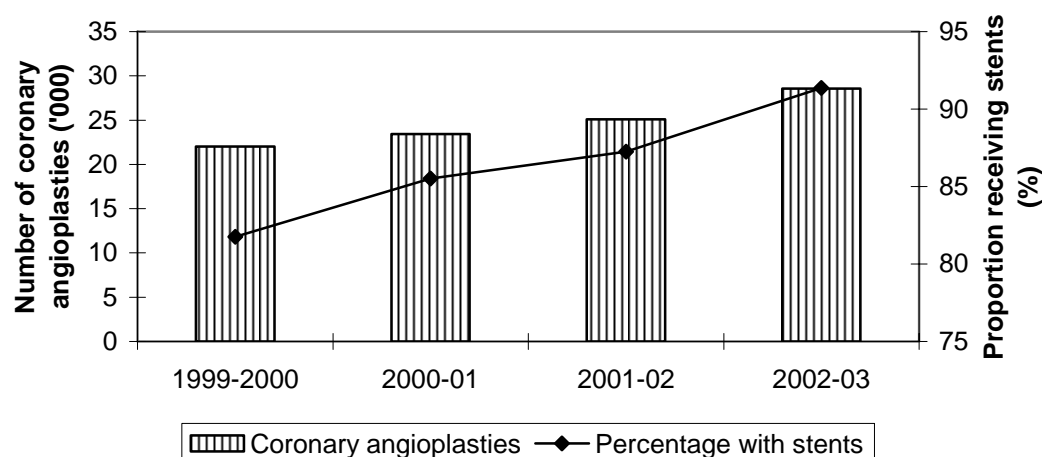
H.2 Use

Coronary heart disease, coronary angioplasty and stenting

Stents are used to treat CHD in conjunction with coronary angioplasty. Hence, their use is linked to the prevalence of CHD as well as the propensity to treat it with coronary angioplasty. There was an 11.7 per cent increase in the age-standardised rate of hospitalisations for which CHD was the principal diagnosis between 1993-94 and 2001-02 (AIHW and NHF 2004). Over the same period, the age-standardised use of coronary angioplasty doubled (AIHW 2004b).

In 2003-04, 32 134 coronary angioplasty procedures were reported in Australian hospitals (figure H.1). Accompanying this increase has been a sharp increase in the insertion of stents following coronary angioplasty. In 1994-95, stents were used in 12 per cent of coronary angioplasty procedures; by 2003-04, this figure was 93 per cent (or 30 017 cases) (AIHW and NHF 2004; figure H.1).

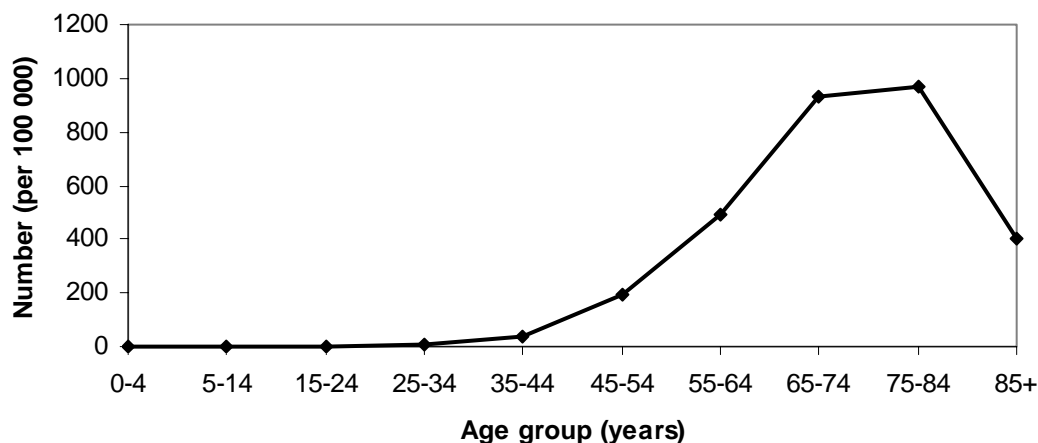
Figure H.1 **Coronary angioplasties in Australia, total and proportion with stents, 1999-2000 to 2003-04**



Data source: AIHW (2005d).

The likelihood of receiving a coronary angioplasty with stenting is also directly linked to age (figure H.2). In general, for private patients there is a greater number of coronary angioplasties with stenting for older than younger patients. However, the number plateaus for the 65–74 age group and then declines sharply.

Figure H.2 **Number of coronary angioplasty procedures with stenting for private patients by age group, 2003-04**



Data sources: HIC (2005a); PHIAC (2005b).

Drug eluting stents

It is difficult to obtain comprehensive data about DES in Australia, even though they were subject to horizon scanning as an emerging technology by MSAC in February 2002. Current national data collected by statistical agencies such as the ABS and Australian Institute of Health and Welfare (AIHW) do not distinguish between DES and bare metal stents (BMS) — they are both classified simply as stents. In contrast, the United States created a method for identifying DES separately from BMS before DES received approval from the Food and Drug Administration (FDA) (Greenberg et al. 2004).

There have been submissions to the National Centre for Classification in Health (NCCH) to identify DES separately (NCCH, Sydney, pers. comm., 3 February 2005; chapter 10). However, the Coding Standards Advisory Committee of the NCCH has recommended against creating codes for DES as:

- collection of the pharmacological properties of the stent is outside the scope of the Australian classification system, which classifies the intervention performed (insertion of the stent) rather than the device employed; and
- there are other mechanisms already available to identify the cost of the procedure (NCCH, Sydney, pers. comm., 25 July 2005).

The only Australia-wide data about DES available to the Commission have been provided by the Australian Health Insurance Association (AHIA). These data separately identify

DES from BMS for stenting procedures given to private patients in both private and public hospitals. Although these data cover all States and Territories, they do not cover all private patients. They represent approximately 42 per cent of all coronary angioplasties carried out on private patients in 2002-03 and 49 per cent in 2003-04. The data indicate that there has been a very rapid uptake of DES for private patients, whether treated in private or public hospitals, growing from none of the stents purchased in 2001-02 to 67 per cent in 2002-03 and 88 per cent in 2003-04 (table H.1). However, private patients are more likely to receive DES if they are treated in a private hospital than a public hospital, although the gap is narrowing (table H.1).

Table H.1 Coronary angioplasties with stenting

Private patients, 2002-03 to 2003-04

Year	Stent	<i>Private patients</i>					
		Private hospitals		Public hospitals		All hospitals	
		<i>no.</i>	<i>%</i>	<i>no.</i>	<i>%</i>	<i>no.</i>	<i>%</i>
2002-03	BMS	1890	30.9	302	55.1	2192	32.9
	DES	4218	69.1	246	44.9	4464	67.1
	All	6108	100.0	548	100.0	6656	100.0
2003-04	BMS	817	10.2	258	30.2	1085	12.2
	DES	7219	89.8	595	69.8	7814	87.9
	All	8036	100.0	853	100.0	8889	100.0

Source: Data obtained from private health funds by the AHIA for the Productivity Commission.

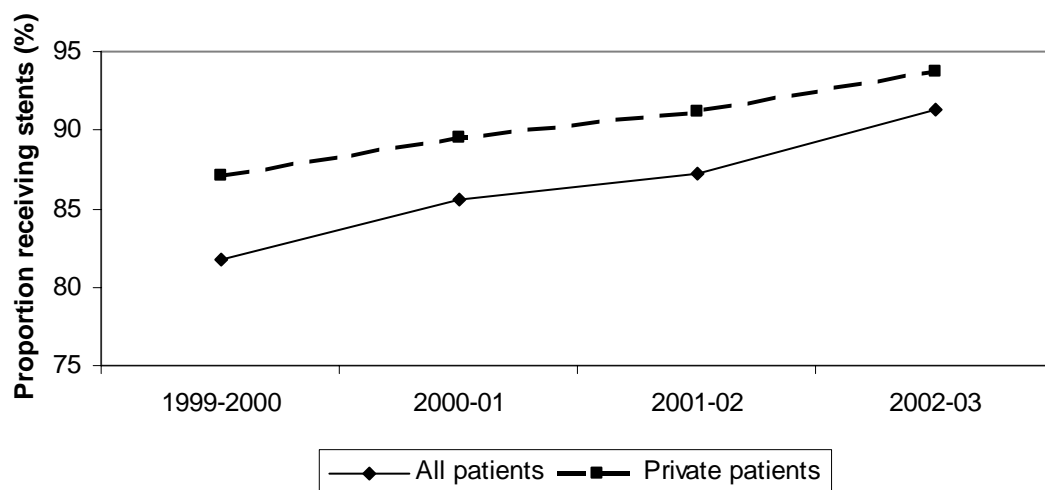
Between 2002-03 and 2003-04, the number of coronary angioplasties carried out with DES increased by 3350 (table H.1). Over the same period, the number of coronary angioplasties carried out with BMS fell by 1107. The increasing use of DES reflects:

- a substitution of DES for BMS;
- an increase in coronary angioplasty procedures; and
- AHIA's sample of data covering a greater proportion of coronary angioplasties performed on private patients in 2003-04 than 2002-03 (accounting for an increase of approximately 1000 angioplasties).

Private and public patients

In terms of coronary angioplasty more generally, a greater proportion of private patients receive stents than all patients (figure H.3). This implies that public patients are less likely to receive stents than private patients, although this gap has been narrowing over time.

Figure H.3 **Proportion of coronary angioplasties receiving stents, all and private patients, 1999-2000 to 2002-03**



Data sources: AIHW (2004a); HIC (2005a).

Furthermore, there is some evidence to suggest that public patients are less likely to receive DES than private patients in some Australian states. For example, in its assessment of DES, MSAC reported:

... marked variation in the selection of drug-eluting stents for public patients between different states and regionally between different hospitals due to the higher cost of these devices compared to bare metal stents. (2005, p. 9)

Western Australia is currently the only state where DES are widely funded by the State Government for use in public patients. It has been estimated that more than 95 per cent of public and private patients receive DES in Western Australia (MSAC 2005). In contrast, one major New South Wales coronary catheter clinic was found to use DES in 43 per cent of public patients, compared to 96 per cent use in private patients (MSAC 2005).

In addition, the Commission has received relevant data from Victoria, where clinical guidelines and reimbursement rules (including reporting requirements) have been in place for public hospitals since October 2003. The data show that 48 per cent of public patients receiving stents in 2004 were given DES (VDHS, Melbourne, pers. comm., 24 March 2005). The equivalent figure for Victorian private hospitals in 2003-04 was 90 per cent (and private patients in public hospitals was 70 per cent) (AHIA, Melbourne, pers. comm., 10 March 2005).

Disparity in the use of stents (and DES in particular) between public and private patients could be explained by the different constraints faced by doctors in the two sectors (chapter 2 and Steketee 2005). In the public sector, doctors have faced rationing in using DES

through limits created by hospital budgets and government guidelines for use. In contrast, doctors in private hospitals have faced neither price nor quantity constraints. In the private sector, the choice of prosthesis lies with the doctor and the patient and, until recently, health funds have been required to cover fully the cost of medical devices (chapter 10). However, there is also evidence of convergence between the two sectors in use of technology over time.

H.3 Expenditure

According to MSAC (2005) the average selling price of the two types of DES approved for use in Australia was approximately \$3600, compared to approximately \$1500 for a BMS. This comparison was based on 1.5 stents per patient.

However, the absolute procedural cost difference of using DES instead of BMS may be greater than revealed by this comparison, as AHIA data suggest that more DES are used per patient than when BMS are used: an average of 1.4 stents for DES compared with 1.3 stents for BMS. This might reflect a tendency for DES to be used in more complicated cases of CHD (even in the private sector).

There is also some evidence to suggest that the price of DES is higher in private hospitals compared to public hospitals (BUPA Australia, sub. 28 and Teachers' Union Health 2004). Data provided by the AHIA indicate that the average benefit per stent paid by private health funds was greater for DES than BMS, although there was some convergence between 2002-03 and 2003-04 (primarily because less expensive DES became available in 2003-04). In addition, the amount paid by health funds for stents was lower if the procedure were carried out in a public hospital, regardless of whether DES or BMS were used (table H.2).

Table H.2 Average benefit paid per stent

Private patients, 2002-03 and 2003-04

<i>Year</i>	<i>Stent</i>	<i>Private patient in a private hospital</i>	<i>Private patients in a public hospital</i>	<i>All hospitals^a</i>
		\$	\$	\$
2002-03	BMS	1667	1539	1650
	DES	4828	4804	4827
2003-04	BMS	1972	1477	1858
	DES	3783	3149	3731

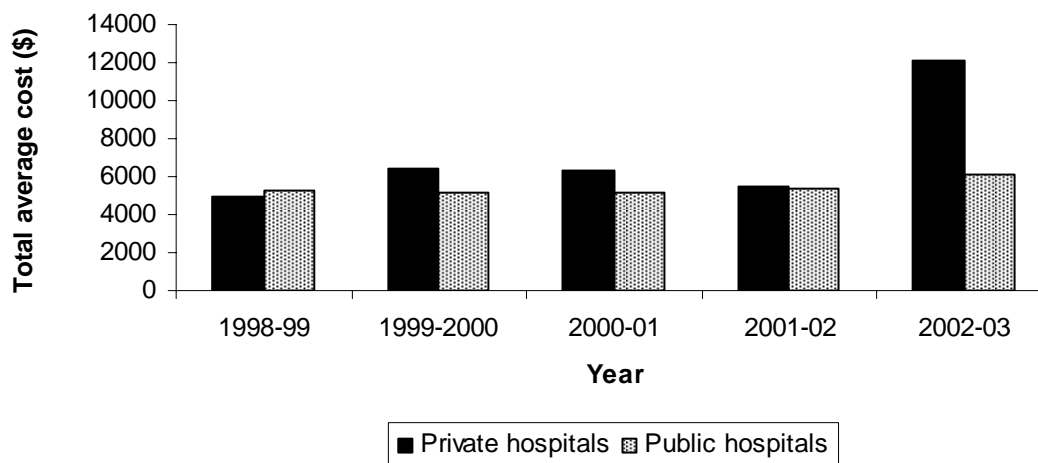
^a 'All hospitals' are a weighted average of private and public hospitals. Since the vast majority of private patients are treated in private hospitals, the weighted average reflects costs in private hospitals far more strongly than public hospitals.

Source: Data obtained from private health funds by the AHIA for the Productivity Commission.

The higher cost of DES compared to BMS is likely to contribute to an increase in the procedural cost of carrying out coronary angioplasty (Hodgson et al. 2004). For example, data from the National Hospital Cost Data Collection (DoHA 2005b) suggest that the introduction of DES to Australia had an immediate effect on the costs of performing coronary angioplasties with stenting in the private sector. DES began to be widely used in the private sector following TGA approval at the end of the 2001-02 financial year. Accordingly, the total average cost of carrying out coronary angioplasties with stenting in the private sector doubled between 2001-02 and 2002-03, with an associated quadrupling in the stent costs per patient (DoHA 2005b; figure H.4). In contrast, the costs of performing coronary angioplasty with stenting in public hospitals remained relatively stable, where DES uptake has been slower (BUPA Australia, sub. 28; VDHS, sub. 24).

In 2003-04, 19 205 coronary angioplasty procedures were carried out on private patients and 95 per cent used stents (HIC 2005a). These data, together with data about DES prices and use, imply the introduction of DES would have caused a \$50 million increase in the cost of carrying out coronary angioplasties in the private sector between 2001-02 and 2003-04, an increase of more than 33 per cent. The impact on healthcare expenditure might be even greater than this assuming that private hospitals charge a premium (such as a return on capital) to private health insurers and patients above the costs that they incur, including for prostheses (Harper et al. 2000; Dr Trevor Kerr, sub. 16).

Figure H.4 **Total average cost to hospitals of carrying out coronary angioplasty with stenting,^a 1998-99 to 2002-03**



^a The costs in the private and public sectors are presented together to compare their movements over time. However, the data for public and private sectors should not be compared directly at any single point in time because components such as medical ward costs are treated differently across the two sectors.

Data sources: DoHA (2005b).

However, DES might offer potential cost savings if fewer repeat procedures are required. While it is commonly accepted that DES have lower rates of further intervention than BMS, there is debate about the size of the difference. Most DES clinical trials have been carried out over short periods of time with patients that have quite specific characteristics, producing different rates of subsequent procedures. Further, DES are a recent innovation so the results of these trials have tended to be presented at conferences instead of peer-reviewed journals (Hill et al. 2004). The trials have produced a range of data, suggesting that from 6 to 23 patients out of 100 do not require repeat procedures because they received DES instead of BMS (Medscape 2004). The results vary according to the characteristics of the patients in the trial and the time period over which the trial is run. No single trial seems to be accepted as the benchmark. However, UK, US, Swedish and Australian studies (Greenberg et al. 2004; Hill et al. 2004; MSAC 2005; SBU Alert 2004) agree that providing DES to all patients is cost increasing compared to using BMS, because the higher initial costs of DES outweigh their cost savings from fewer repeat procedures. This conclusion is very sensitive to the data used about costs, absolute risk reduction and the number of stents used.

H.4 Benefits

As outlined above, the key benefit of DES is a lower rate of restenosis than BMS, which implies that patients receiving DES have a higher quality of life because they are less likely to:

- suffer from angina (and its associated pain and physical limitations); and
- require repeat revascularisation procedures such as coronary angioplasty or coronary artery bypass grafting (MSAC 2005).

However, while studies have found that restenosis has a negative effect upon quality of life, its impact is considered to be small because it generally only lasts for short periods and has no direct link to mortality (Hill et al. 2004; Greenberg et al. 2004). Nevertheless, avoidance of further procedures may be valued significantly by most patients due to benefits such as a faster return to work and/or other daily activities.

Compared to BMS, there is no evidence to suggest that DES reduce major events associated with CHD, such as strokes, heart attacks and mortality (Babapulle et al. 2004; Hodgson et al. 2004; MSAC 2005). This finding means that the cost effectiveness of DES is often assessed on the cost of avoiding a repeat revascularisation procedure, rather than more common cost-effectiveness measures such as cost per quality-adjusted life-year (QALY) or the cost per year of life saved (see below) (Chew 2005).

H.5 Cost effectiveness

The limitations of clinical trials make it difficult to determine with any precision the cost effectiveness of DES, especially because these trials have been run over relatively short periods (between one and two years) (Hodgson et al. 2004). The usefulness of cost-effectiveness estimates of DES based on a cost per QALY measure are also limited by the fact that:

... there is no evidence to suggest that restenosis affects short or long-term survival after percutaneous coronary intervention. Therefore, one would not expect treatment whose sole benefit is a reduction in restenosis (such as DES) to improve population-level life expectancy (Hodgson et al. 2004, p. 6).

In addition, estimates of the cost effectiveness of DES based on cost per QALY appear to be extremely sensitive to the assumptions made regarding waiting times for repeat revascularisation procedures and the disutility from undergoing a repeat procedure (Hill et al. 2004). For example, one estimate by Hill et al. (2004) found the incremental cost per QALY for DES over BMS as ranging from £700 000 to £1 000 000 and concluded that:

... the use of DES for elective treatment of uncomplicated single-vessel disease cannot be justified, in that the claimed reduction in the need for repeat interventions has not been shown to result in more than very minor and uncertain utility gains, but certainly incur substantial additional net treatment costs ... (2004, p. 135).

However, by assuming that the average waiting time for a repeat procedure doubled from six to twelve weeks (and therefore disutility from angina greatly increased¹), Hill et al. (2004) also found the incremental cost per QALY of DES over BMS to be £24 325 for straightforward cases of CHD (single vessel without complications such as diabetes). Similarly, a US study estimated the incremental cost per QALY for DES over BMS as US\$27 540 and suggested DES was reasonably cost effective compared to BMS and vascular brachytherapy² (Cohen 2004).

Hill et al. (2004) also found that it is not cost effective to give DES to all patients receiving stents because of their substantially higher costs and uncertain and potentially small benefits. However, it is likely to be more cost effective to provide DES instead of BMS to those patients where there is a greater risk of restenosis, particularly if there are complications, such as diabetes, small vessel size and long narrowed sections (lesions) (Meskan 2004). The UK and Victorian Governments have issued guidelines that encourage the use of DES only in these more complicated cases (NICE 2003; VDHS, sub. 24).

As an alternative to cost per QALY, several authors have estimated the cost effectiveness of DES compared to BMS on the basis of cost per revascularisation procedure avoided. For example, Cohen et al. (2004) reported the cost per repeat procedure avoided as US\$1650, while Greenberg et al. (2002) found a range of values up to US\$12 500. The key limitation of this approach is that:

... it is specific to the field of cardiology and cannot be compared with cost-effectiveness ratios for other conditions, or against cost-effectiveness analyses using different outcome measures (Hodgson et al. 2004, pp. 6–7).

In Australia, MSAC (2005) has recently estimated the cost per repeat revascularisation procedure avoided using overseas data and Australian cost information (box H.1). It found that the net cost of avoiding a repeat procedure using DES instead of BMS in Australia was between A\$3700 and A\$6200, and concluded that DES may be cost effective compared to BMS if the benefits to the patient of avoiding a repeat procedure are valued at least in this range. However, these estimates are also sensitive to the data used about costs, absolute risk reduction and number of stents used.

¹ Hill et al. (2004) assumed that patients requiring a repeat revascularisation procedure would suffer from angina while waiting for that procedure.

² Vascular brachytherapy is used to treat in-stent restenosis (Cohen et al. 2004).

Box H.1 Recommendation of the MSAC assessment of DES

- The technology is as safe as bare metal stents for the treatment of *de novo* atherosclerotic lesions of the coronary arteries at up to one year post-procedure.
- The technology is more effective than bare metal stents in reducing the rates of revascularisation procedures at up to one year.
- There is insufficient evidence at this time to demonstrate a difference in the rates of myocardial infarction, coronary artery bypass grafting or mortality in patients receiving this technology compared to those receiving bare metal stents.
- There is some evidence that the technology is more effective than bare metal stents in reducing the rates of revascularisation at up to one year in patients with diabetes, long lesions greater than 18mm and small vessels less than 2.5mm. However, there is insufficient evidence at this time to demonstrate any additional benefit in these and other subgroups of patients at high risk of stent restenosis.
- Cost effectiveness is based on *de novo* single vessel lesions.
- On the basis of trial data alone, the technology is cost effective if a cost of \$3700–\$6200 is considered acceptable to avoid a target lesion revascularisation. However, a sensitivity analysis to estimate the cost effectiveness in Australian clinical practice indicates that the cost per ‘target lesion revascularisation avoided’ may be higher than this figure. Australian clinical practice data are required to resolve this uncertainty.

Source: MSAC (2005).

H.6 Future developments

In the longer term, the cost effectiveness of DES in Australia could be more accurately assessed through the development of national systems, such as registries, to assess the long-term outcomes of all patients undergoing coronary angioplasty (Chew 2005; MSAC 2005). Other benefits of this approach could include improved targeting of DES to patients most likely to benefit, and effective surveillance of unexpected adverse events caused by the technology (Chew 2005). It is also expected that over time, the cost of DES and BMS will fall, given:

- the introduction of Taxus, a competitor to the Cypher stent, which has seen the average price of DES fall; and
- the 60 per cent decline in the cost of BMS over the past ten years (Chew 2005).

There is also ongoing research into the development of stents, including refinements to BMS and DES as well as innovations in stenting such as bio-absorbable stents. Medtronic and Guidant are currently developing new DES products (Angioplasty 2005;

Heartdisease 2005). Guidant and Igaki-Tamai are developing a stent that is bio-absorbable — the stent, or components of it, are absorbed by the patient's body after six months or more (CCOHTA 2004). The advantage of this absorption is that it limits the long-term problems associated with permanent stents, such as inflammatory responses and thrombotic reactions. The outer coating of the Guidant stent (Champion) is bio-absorbable and FDA and European approval is anticipated in 2005 (CCOHTA 2004).

Some authors have also suggested that coronary angioplasty with DES will increasingly substitute for coronary artery bypass grafting (CABG) surgery. For example, Baim (2004) suggests that recent and ongoing improvements in coronary angioplasty, including the development of DES, will make CABG largely obsolete over the next few years. The MIAA (sub. PR54) also cited the importance of considering outcomes, such as reduced discomfort and faster recovery times, when assessing DES against CABG.

As CABG is a more expensive procedure than coronary angioplasty with DES, switching to DES for treatment of ordinary two-vessel CHD can save money (Hill et al. 2004). However, Hill et al. (2004) concluded this substitution would also be expected to reduce patients' life expectancy considerably and, thus, CABG remained the 'gold standard' for treatment of these patients. In addition, Cohn (2004) highlighted the continued relevance of CABG in treating patients with diabetes or chronic total occlusion,³ both of which are extremely common in persons with CHD. As such, it would appear that the degree to which coronary angioplasty with DES will substitute for CABG is currently a matter of debate within the scientific and medical community.

H.7 Conclusion

The introduction of DES demonstrates that new technology can have markedly different uptake in private and public hospitals, largely reflecting the different incentives and constraints faced by doctors in the respective sectors. However, it highlights that rapid diffusion of a technology in the private sector may create pressures for its uptake in the public sector. This is indicated by the strong uptake of DES in Western Australian and Victorian private and public hospitals since TGA approval in June 2002.

DES also raise concerns about how this uptake in the private sector has occurred with widely differing evidence of cost effectiveness and without the use of appropriate and

³ Chronic total occlusion is defined as complete obstruction of a coronary artery.

updated clinical guidelines.⁴ DES underline potential challenges faced by regulatory processes and statistical agencies in adapting to certain types of new technology incorporating both a device and drug with a pre-existing procedure. So far, neither the ABS nor the AIHW are collecting data about this technology, despite its rapid diffusion in the private sector. Implementation of data collection systems such as registries could also contribute to improved assessments of effectiveness and cost effectiveness and identification of side effects associated with DES. Over time, the cost effectiveness of DES may also improve if competition increases the types of DES available and if the technology is targeted at patients most likely to benefit.

⁴ In 1996, clinical guidelines for the management of coronary heart disease were published by the National Health and Medical Research Council (NHMRC). These were not updated for DES. The guidelines were rescinded by the NHMRC in September 2004. In addition, the MSAC review of evidence regarding DES was not completed until March 2005.

I *Trastuzumab* (Herceptin)

I.1 Introduction

Trastuzumab (Herceptin) is a monoclonal antibody aimed at controlling a particular type of breast cancer. In general, breast cancer is caused by uncontrolled or malignant cell division that forms a tumour. Malignant tumours may expand locally by invading surrounding tissue or metastasise and spread via the lymphatic or vascular systems to the rest of the body.

One type of breast cancer that Herceptin was designed to combat, is associated with a genetic alteration in which extra copies of a gene (the human epidermal growth factor receptor-2 (HER2)/neu gene) are generated. The HER2/neu gene produces proteins that regulate breast cell growth. Excessive amounts of the HER2 protein are found in approximately 20–30 per cent of metastatic breast cancers. When compared with HER2-negative tumours, HER2-positive cancers tend to grow faster, are more likely to recur, are associated with shortened survival and are less responsive to standard chemotherapy.

Herceptin targets only those cells that display an excess of HER2 protein, slowing or stopping their growth. It differs from conventional chemotherapy, which is ‘undirected’ — harming both cancer cells and healthy cells with consequent side effects such as nausea, hair loss, low blood counts and mouth ulcers.

Herceptin is currently approved internationally for the treatment of women with advanced metastatic breast cancer whose tumours exhibit excess HER2 protein or extra copies of the HER2/neu gene (gene amplification). The United States Food and Drug Administration (FDA) licensed Herceptin in 1998 and it was approved by the European Union and the Therapeutic Goods Administration (TGA) in 2000. The TGA registered Herceptin for:

the treatment of patients with metastatic breast cancer who have tumours that over-express HER2, as a single agent for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease, or in combination with taxanes for the treatment of those patients who have not received chemotherapy for their metastatic disease (Australian Drug Evaluation Committee, 210th meeting recommendations, meeting number 3, 8–9 June 2000).

Treatments for breast cancer are summarised in figure I.1. Some definitions are included in box I.1.

Box I.1 Definitions of terms

(Neo)adjuvant chemotherapy: chemotherapy given before (neo) or after surgery.

Disease-free survival: the length of time after treatment during which no disease is found.

Docetaxel (Taxotere): a type of taxane (see below).

Incremental cost effectiveness ratios: compare mutually exclusive interventions, for example, the treatment of metastatic breast cancer using Herceptin compared to an alternative treatment for the same disease but without the use of Herceptin. To create an incremental cost effectiveness ratio, the difference in costs of two interventions is divided by the difference in health benefits.

Metastatic breast cancer: breast cancer cells that spread and form cancers in other parts of the body, for example, bone, liver, brain or lungs.

Monoclonal antibodies: proteins which specially recognise and bind to other unique proteins in the body.

Monotherapy: patients receiving a single therapeutic agent for their disease as opposed to a combination of agents.

Paclitaxel (several brand names): a type of taxane (see below).

Response to a drug: refers to the reduction or complete disappearance of clinical evidence of disease. Even if all evidence of disease disappears, microscopic metastases may remain undetected, regrow and become resistant to treatment.

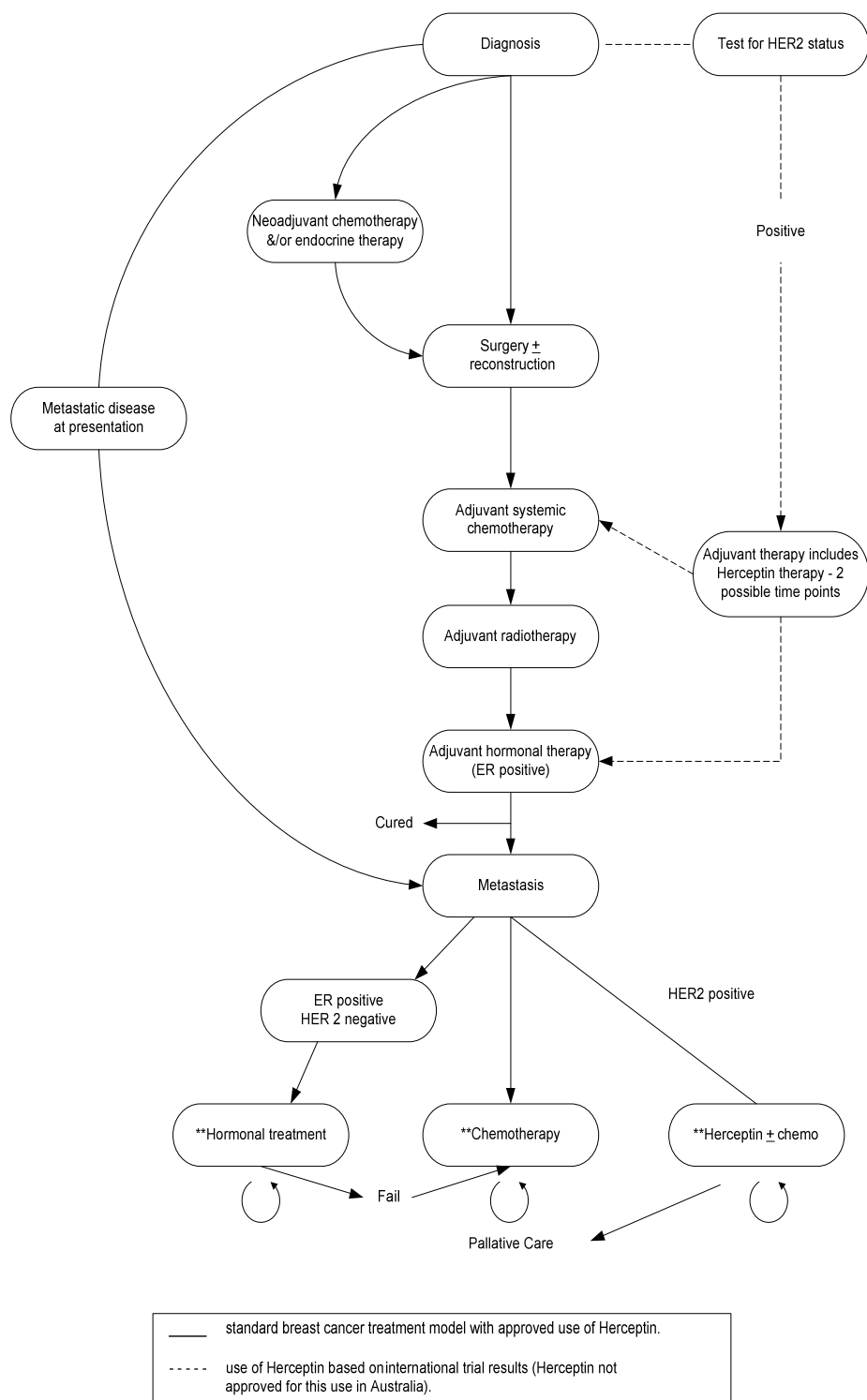
Taxanes: prevent cell division and are a type of chemotherapy not associated with the relatively high levels of heart problems associated with anthracycline chemotherapy and which is synergistic with Herceptin.

Vinorelbine (Navelbine): a type of chemotherapy generally used as monotherapy in the final stages of disease. (There are a number of options used in this setting — another is Capecitabine.)

Once registered in Australia, Herceptin was initially funded by the drug company (Roche) which provided the drug free to patients accepted into clinical trials, and by hospitals. For example, in Victoria, Herceptin was funded through the New Technology Grant Program for public hospitals.

The Victorian Government provided funding of \$750 000 and \$1.1 million in 2000-01 and 2001-02 respectively, for Herceptin prior to its being funded through the Australian Government specialised drugs program. (DHS, sub. PR46)

Figure I.1 **Breast cancer treatment model**



ER is estrogen receptor. ** At these points there are options for several lines (or treatment strategies) — first line, second line, third line. Patients may cycle through these strategies using different agents.

Sources: Adapted from Neyt et al. (2005); pers., comm. Associate Professor Richard Bell, 12 July 2005.

Herceptin was considered several times by the Pharmaceutical Benefits Advisory Committee (PBAC) (NATSEM, sub. 1) but was not judged cost effective and was not therefore approved for listing on the Pharmaceutical Benefits Schedule (PBS). From 1 December 2001, it has been distributed under a separate Australian Government 'Herceptin Program', administered by the Health Insurance Commission (HIC). Under the Program, Herceptin is available free of charge to eligible patients with late stage metastatic breast cancer (box I.2). The HIC reimburses the drug company for the cost of the drug.

As discussed in chapter 8, PBAC deliberations are not publicly disclosed and the decision making processes leading first to its rejection by PBAC, and then to the establishment of the separate Herceptin Program, were not transparent. The lack of information on the public record leads to uncertainty and is not conducive to consistency in the decision processes facing different medical advances or in the treatment of different patient groups.

I.2 Need and use

Breast cancer is the most prevalent type of cancer affecting Australian women. In Australia in 2003, 2713 women died from the disease. While breast cancer also affects men, the incidence is very small. Nine men died from breast cancer in Australia in 2003 (ABS 2003b). Age standardised death rates fell from 17.1 per 100 000 people in 1993, to 14.5 in 1998 to 13.3 in 2003 (ABS 2003b).

The median age at death from breast cancer between 1998 and 2002 was 67 years (AIHW and AACR 2004). Death rates increase with age (table I.1).

Table I.1 **Breast cancer deaths and death rates by age group, 2003**

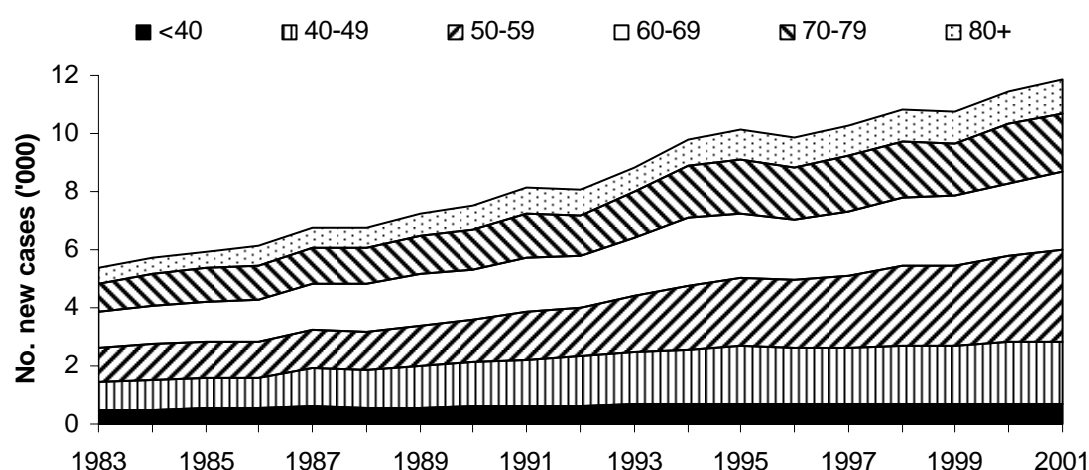
<i>Age group (years)</i>	<i>No. deaths</i>		<i>Rate^a</i>	
	<i>Females</i>	<i>Persons</i>	<i>Females</i>	<i>Persons</i>
25–34	31	31	2.1	1.1
35–44	np	185	np	6.2
45–54	427	427	31.3	15.8
55–64	np	598	np	29.6
65–74	np	517	np	38.3
75–84	578	581	111.3	64.1
85+	383	383	193.3	132.3

^a Deaths per 100 000 of the estimated mid-year population for each age group. **np** Not published by the ABS.

Source: ABS (2003b).

There were 11 886 new cases of breast cancer in 2001 (AIHW 2005b). The incidence of breast cancer is increasing over time (figure I.2), predominantly due to population ageing, but diet, lifestyle and obesity are all considered to be factors.

Figure I.2 Incidence of breast cancer by age, Australia



Data source: AIHW interactive cancer data (2005b).

Nationally, in 1996, breast cancer was the fifth largest contributor to the burden of disease in females and the third largest cause of female mortality (Mathers et al. 1999).

In 2001, more than 28 500 female years of life were lost due to breast cancer — the highest burden of cancer in females. In the same year, for both sexes, breast cancer accounted for the third highest number of person-years of life lost due to cancer, after lung and colorectal cancer (AIHW and AACR 2004).

The Victorian Burden of Disease Study suggests that breast cancer will remain the third leading cause of disability-adjusted life-years (DALYs) in Victorian women between 1996 and 2016, but will become the second most common cause of life-years lost in Victorian females by 2016 compared with the third most common cause of life-years lost in 1996 (VDHS 1999).

State and region

Between 1997 and 2001, age standardised breast cancer incidence rates were highest in the ACT and lowest in the Northern Territory (table I.2).

Table I.2 Annual average incidence of breast cancer, 1997–2001

<i>NSW</i>	<i>Vic</i>	<i>Qld</i>	<i>WA</i>	<i>SA</i>	<i>Tas</i>	<i>ACT</i>	<i>NT</i>
Age standardised incidence rate per 100 000 females							
112.3	114.9	117.2	112.9	117.4	104.1	122.1	97.9

Source: AIHW and AACR (2004).

The link between incidence and prevalence and remoteness is unclear.

- One study found that between 1998–2002, age standardised death rates from breast cancer were somewhat lower in remote or very remote areas than in other regions (over 13 deaths per 100 000 people in major cities and regional areas compared with 11 deaths per 100 000 people in remote and very remote areas) (AIHW and AACR 2004).
- On the other hand, in New South Wales, incidence rates for breast cancer did not appear to differ across regions in 1998–2002 (Population Health Division 2004). Similarly, Draper et al. (2004) found no significant variation across regions in age standardised death rates from breast cancer between 1998–2000.

Socioeconomic group

In 1996, for all malignant cancers, healthy female-years of life lost were 11 per cent higher in women in the lowest socioeconomic areas compared with those in the highest socioeconomic areas (Mathers et al. 1999). Similarly, Draper et al. (2004) found those aged 25–64 years in the most disadvantaged groups were significantly more likely to die from cancer than those aged 25–64 years in the least disadvantaged groups. For those aged 65 or over, males in the most disadvantaged groups were more likely to die of cancer than those in the least disadvantaged groups, but there was no significant difference for females.

This does not necessarily apply for breast cancer, however. Apparent differences in mortality rates from breast cancer across socioeconomic groups depend on the type of classification measure used.

- Based on the index of relative socioeconomic disadvantage (IRSD) (chapter 6), there were no apparent differences between the most and least disadvantaged in mortality rates from breast cancer for those aged 25–64 years or those aged 65 years or over in 1998–2000 (Draper et al. 2004).
- By contrast, during the same time period, across occupational groups for females aged 25–54 years, manual workers (including tradespersons) were more likely to die from breast cancer than clerical workers, and both manual and clerical

workers were *less* likely to die from breast cancer than managers, administrators and professionals (Draper et al. 2004).

Use of Herceptin

Eligibility for Herceptin is outlined in box I.2. According to NATSEM (sub. 1), the projected target population for Herceptin was around 1000 patients in 2001.

Box I.2 Eligibility for Herceptin in Australia

Under the Herceptin Program, Herceptin is currently available free to Australian patients with HER2-positive metastatic breast cancer either:

- in combination with taxanes for patients who have not received chemotherapy for metastatic disease; or
- as monotherapy for the treatment of those patients who have received one or more chemotherapy regimen(s) for metastatic disease.

Herceptin is not approved in combination with Navelbine.

Patients must have:

- immunohistological (IHC) evidence of HER2 protein at the 3+ level; or
- IHC evidence of HER2 protein at the 2+ level, subsequently confirmed as exhibiting HER2 gene amplification by fluorescence in situ hybridisation (FISH); or
- exhibit HER2 amplification by FISH.

Prescribers must register the patient with the HIC for participation in the Herceptin Program and confirm patient registration every six months. To register, the prescriber must provide evidence that the patient is eligible (via faxed pathology reports and verbal confirmation), evidence of patient and prescriber consent, and patient details including patient weight (as dosage is based on weight).

Once eligibility is established, the HIC places an order with the drug company (Roche Products) who delivers the product to the address nominated by the prescriber.

Source: HIC (2005c).

Statistics on the characteristics of the women who received Herceptin prior to the commencement of the Herceptin Program are not available, so it is not possible to depict the pattern of diffusion of the drug from market entry. However, Roche advised that Herceptin was provided to 50 patients between TGA approval and the establishment of the Herceptin Program (pers. comm., Roche, 4 August 2005). Data on the number of public hospital patients receiving the drug during that period are not available. Once subsidised, many more women received the drug. In 2002, 544 women received Herceptin, followed

by 695 women in 2003, 956 in 2004 and 867 to May 2005.¹ These data suggest that it took three or so years after Herceptin was subsidised for its distribution to reach NATSEM's projected target of 1000 patients.

Most Herceptin patients (over three quarters) were aged between 40 and 69 years (table I.3). Over the entire period, 99 women aged between 80 and 89 years and six women aged 90 or over received Herceptin.

Table I.3 Herceptin patients by age, 2002–2005^a

	20–29	30–39	40–49	50–59	60–69	70+	Total
No. women on Herceptin	14	310	776	995	581	386	3062
Female population in each age group	1 347 808	1 490 519	1 428 353	1 144 166	754 958	1 011 843	7 177 647 ^b
Age specific rate (per 100 000 females)	1.0	20.8	54.3	87.0	77.0	38.1	42.7

^a Calendar years. 2005 to May only. ^b Female population aged 20 years or over.

Sources: ABS 2001 unpublished estimated resident population data; HIC unpublished data.

The rate at which women received Herceptin in New South Wales and the ACT was relatively low compared with both the incidence of breast cancer, and the female population aged 20 or over in each State (table I.4). The relatively low rate in the ACT may reflect its comparatively younger population (table I.5). However, the New South Wales rate is low despite the fact that its age distribution is very similar to that in Victoria (table I.5). The Tasmanian average was higher, possibly reflecting its slightly older female population (tables I.4 and I.5).

¹ These figures are based on HIC data and include only subsidised drugs. However, advice from clinical experts and Roche suggest that the HIC data here cover the vast majority of women taking Herceptin for metastatic disease.

Table I.4 Incidence of breast cancer and women on Herceptin by State

	<i>No. women on Herceptin 2002–May 2005 (A)</i>	<i>Annual average new cases of breast cancer, females, 1997– 2001 (B)</i>	<i>Women on Herceptin/ Average annual incidence (A/B)</i>	<i>Number females aged 20 or over, 2001 (C)</i>	<i>Women on Herceptin per 100 000 women aged 20 or over (A/C)</i>
NSW	883	3712	23.8	2 424 243	36.4
Vic	900	2799	32.2	1 809 879	49.7
Qld	598	1995	30.0	1 318 302	45.4
WA	298	991	30.1	686 440	43.4
SA	250	963	26.0	571 064	43.8
Tas	98	261	37.5	174 428	56.2
ACT	15	168	8.9	130 310	11.5
NT	20	54	37.0	62 981	31.8
Total	3062	10 943	28.0	7 177 647	42.7

Sources: ABS 2001 unpublished estimated resident population data; AIHW and AACR (2004); HIC unpublished.

Table I.5 Female population aged 20 years or over — proportion in each age group by State, 2001 (per cent)

	<i>20–29 years</i>	<i>30–39 years</i>	<i>40–49 years</i>	<i>50–59 years</i>	<i>60–69 years</i>	<i>70+ years</i>	<i>Total aged 20+</i>
NSW	18.6	20.6	19.6	15.7	10.8	14.7	100.0
Vic	18.7	21.0	19.5	15.7	10.6	14.5	100.0
Qld	19.4	20.9	20.2	16.3	10.2	12.9	100.0
WA	19.2	21.4	21.0	16.0	10.1	12.3	100.0
SA	16.7	19.3	19.7	16.5	11.2	16.6	100.0
Tas	16.5	19.4	20.4	16.7	11.6	15.5	100.0
ACT	22.0	22.1	21.4	16.7	8.4	9.4	100.0
NT	26.7	27.6	22.3	14.3	5.5	3.6	100.0
Total	18.8	20.8	19.9	15.9	10.5	14.1	100.0

Source: ABS 2001 unpublished estimated resident population data.

In some States, those in regional areas were more likely to receive Herceptin than those in major cities (table I.6). In most jurisdictions, those in remote and very remote areas — with the exception of South Australia and Tasmania — were less likely to receive Herceptin. These patterns probably reflect the female age distribution across regions (table I.7). Females living in remote and very remote areas tend to be younger, and women in inner regional areas tend to be older, than those in other regions.

Table I.6 Receipt of Herceptin by State and region, 2002–2005^{a,b}

	<i>Major cities</i>	<i>Inner regional</i>	<i>Outer regional</i>	<i>Remote and very remote</i>
Rate per 100 000 women aged 20 years or over in each region in each State				
NSW	37.3	32.3	33.5	8.1
Victoria	48.3	52.1	55.3	na
Queensland	48.1	48.8	33.1	14.7
WA	41.4	57.2	44.4	26.0
SA	43.6	40.5	40.8	47.5
Tasmania	na	52.0	56.3	147.4 ^c
ACT	12.8	na	na	na
NT	na	na	35.7	10.2
Total	42.3	44.5	40.0	22.6

^a Calendar years. 2005 to May only. ^b Data not age standardised. ^c Tasmanian data are based on small numbers. **na** Not applicable.

Sources: ABS 2001 Census unpublished population data; HIC unpublished.

Table I.7 Female population aged 20 years or over — proportion in each age group by remoteness area, 2001 (per cent)

	<i>Major cities</i>	<i>Inner regional</i>	<i>Outer regional</i>	<i>Remote</i>	<i>Very Remote</i>
20–29 years	20.1	15.1	16.7	20.4	26.5
30–39 years	21.0	19.4	20.8	24.8	26.5
40–49 years	19.5	20.7	20.7	21.1	20.4
50–59 years	15.6	16.9	16.7	15.7	13.8
60–69 years	9.9	12.2	11.4	9.1	7.1
70+ years	13.8	15.7	13.7	8.9	5.7
Total	100.0	100.0	100.0	100.0	100.0

Source: ABS 2001 Census unpublished population data.

With the exception of the territories, those in the least disadvantaged areas received Herceptin at a higher rate than those in the most disadvantaged areas (table I.8). The difference was most pronounced in New South Wales, where those in the least disadvantaged areas were more than twice as likely to receive Herceptin than those in the most disadvantaged areas. These differences do not appear to be explained by differences in the age structure of the population between the most and least disadvantaged (table I.9).

Table I.8 Receipt of Herceptin by socioeconomic group, 2002–2005^{a,b}

	<i>Socioeconomic group^c</i>						<i>Rate ratio^d</i>	
	1	2	3	4	5	6		
	Women on Herceptin per 100 000 women aged 20 or over						(5/1)	(6/1)
NSW	24.5	35.8	32.5	31.4	40.4	56.1	1.6	2.3
Victoria	37.5	46.4	51.4	46.4	52.6	65.2	1.4	1.7
Queensland	42.4	43.3	40.7	44.1	46.4	53.8	1.1	1.3
WA	24.1	35.1	66.5	31.9	39.5	42.1	1.6	1.7
SA	49.1	51.6	39.9	36.7	26.8	69.5	0.5	1.4
Tasmania	45.1	47.3	72.5	24.2	76.5	67.0	1.7	1.5
ACT	0.0	7.2	31.0	5.3	0.0	0.0	na	na
NT	83.9	7.3	47.9	21.9	25.4	0.0	0.3	0.0
Total	34.7	40.4	43.0	36.8	43.9	55.9	1.3	1.6

^a Calendar years. 2005 to May only. ^b Data not age standardised. ^c Socioeconomic group based on IRSD (chapter 6). A high index score (6) means the area has few families of low income and few people with little training and in unskilled occupations. A high index score reflects lack of disadvantage (ABS 2001). ^d Least disadvantaged over most disadvantaged (rate for group six divided by rate for group one, or rate for group five divided by rate for group one). **na** Not able to be calculated.

Sources: HIC unpublished; ABS 2001 Census unpublished population data.

Table I.9 Female population aged 20 years or over — proportion in each age group by socioeconomic status, 2001 (per cent)

	<i>Socioeconomic group^a</i>					
	1	2	3	4	5	6
20–29 years	20.5	18.2	17.4	18.6	19.8	18.9
30–39 years	21.0	20.6	20.3	21.2	21.4	19.8
40–49 years	18.9	19.6	19.8	20.2	19.9	20.5
50–59 years	15.2	15.7	16.0	16.0	15.8	16.9
60–69 years	11.1	11.4	11.5	10.3	9.6	9.2
70+ years	13.2	14.6	15.0	13.7	13.5	14.8
Total	100.0	100.0	100.0	100.0	100.0	100.0

^a Socioeconomic group based on IRSD (chapter 6). A high index score (6) reflects *lack* of disadvantage — the area has few families of low income and few people with little training and in unskilled occupations (ABS 2001).

Source: ABS 2001 Census unpublished population data.

More than half of the women receiving Herceptin held a health care concession card (table I.10). It is not possible to accurately compare this with similar data for drugs listed on the PBS.

Table I.10 Health care concession card status of women receiving Herceptin

	2002	2003	2004	2005 ^a
No. women with concession	266	379	545	472
Per cent with concession	49%	55%	57%	54%
No. women without concession	278	316	411	395

^a Calendar year to May 2005.

Source: HIC unpublished.

I.3 Expenditure

The Australian Government announced funding of \$38.1 million in 2005-06 and \$41.9 million in 2006-07 for Herceptin in the 2005-06 Budget. Funding beyond 2006-07 will be considered following a further review of the Herceptin Program (CoA 2005). Government expenditure on Herceptin for the calendar years 2002–2004 was \$15.1 million, \$21.2 million and \$30.6 million respectively (table I.11). (These estimates exclude expenditure on the associated diagnostic tests which are discussed below.) Spending grew by over 40 per cent per year and was less than one per cent of annual expenditure on the PBS/RPBS (table I.11). Overall, expenditure on Herceptin depends on the size of the target group (outlined above), and the cost of the drug per patient.

Table I.11 Herceptin — expenditure, patients and vials^a

	Units	2002	2003	2004	2005 ^b
Patients	No.	544	695	956	867
Vials	No.	14 040	22 689	29 603	16 156
Expenditure	Dollars	15 053 827	21 223 132	30 590 619	15 085 558
Expenditure growth	%	na	41.0	44.1	na
Cost per patient	Dollars	27 672	30 537	31 999	17 400
Cost per vial	Dollars	1072	935	1033	934
Herceptin as a % of total PBS/RPBS	%	0.3	0.4	0.5	na

^a Calendar years. ^b Calendar year to May 2005. **na** Not applicable.

Source: HIC unpublished data.

Cost of Herceptin per patient

In each case, the cost of Herceptin per patient depends on the patient's weight (which determines the amount of the drug required per dose), the dosage interval (currently weekly in Australia), and the number of doses required (or the length of treatment). The

currently approved dosing regime for Herceptin in Australia is in box I.3. Patients require one, two or three vials per week depending on their weight.

In Australia, the average cost of a 150mg vial of Herceptin between 2002 and May 2005 was close to A\$1000. In 2001, the National Health Service United Kingdom (NHS) price for a 150mg vial was £407 (around A\$900) (NICE 2002a).²

The appropriate duration of Herceptin treatment has yet to be established but common practice is to provide the drug until disease progression occurs (Stebbing et al. 2000). Some studies are examining whether it is useful to continue taking Herceptin after the disease has progressed (see below). The average duration of treatment in the trials mentioned in Stebbing et al. (2000) for metastatic disease was 34 weeks. NATSEM (sub. 1) suggested the average duration of treatment was 9 months.

Based on HIC data for the calendar years 2002 to 2004, the cost per patient was \$28 000 to \$32 000 (table I.11). NATSEM (sub. 1) suggested a cost per patient of \$32 000 in 2001.

Box I.3 Approved dosages for Herceptin

The HIC restricts prescribing of Herceptin as follows:

- Patients less than and including 75kg require five vials in the initial order (including a loading dose) then four vials per four weeks. The dosage administered is one vial each week.
- Patients over 75kg up to and including 150kg require nine vials in the initial order (including a loading dose) then eight vials per four weeks. The dosage administered is two vials each week.
- Patients over 150kg up to and including 225kg require 13 vials in the initial order (including a loading dose) then 12 vials per four weeks.

Source: HIC (2005b).

Other costs associated with use of Herceptin include testing for HER2 overexpression and testing of cardiac function.

- There are two tests for HER2 overexpression — the IHC (which tests for excess amounts of the HER2 protein) and the FISH test (which tests for excess amounts of the HER2/neu gene). The FISH test is more accurate but significantly more expensive.

² Overseas currencies are inflated to 2002 prices using an implicit GDP deflator for the relevant country, and then converted into Australian dollars using purchasing power parity.

Recommended HER2 testing practice in Australia is to use the FISH test if the IHC results are equivocal (Bilous 2001; box I.2).

- The IHC test is not fully subsidised in Australia. It is listed on the Medicare Benefits Schedule (MBS) for a fee of \$52–\$56 (pers. comm., HIC, 11 July 2005 and pers. comm., Associate Professor Richard Bell, 12 July 2005).³ The same test in the US costs US\$85 (A\$110) (Elkin et al. 2004) and a US licensed HER2 test (the DAKO Herceptest) which is available in Australia (and has been quality tested by the Royal Australian College of Pathologists) costs around A\$120 per test (pers. comm., Associate Professor Richard Bell, 12 July 2005).
- The FISH test does not appear to be listed on the MBS. In the US, the FISH test costs US\$400 (around A\$520) (Elkin et al. 2004). In Australia, it is available from two laboratories (Sydney and Brisbane) and costs A\$350–450 (pers. comm., Associate Professor Richard Bell, 12 July 2005).

The apparent lack of coordination between the subsidy program for Herceptin and subsidies for these diagnostic tests is problematic given the importance of targeting such an expensive drug. The separation of the tests from the Herceptin Program may reflect the separate institutional processes governing decisions about subsidies for drugs and pathology. The latter are generally the responsibility of committees related to the Medical Services Advisory Committee (MSAC), whereas drugs are the concern of PBAC.

- Estimates of expenditure on Herceptin should also include the costs of cardiac testing. Herceptin has been associated with heart problems including heart failure, and cardiac testing is recommended during treatment with Herceptin. National Institute for Health and Clinical Excellence (England and Wales) (NICE) data suggest that a set of cardiac tests was £580 (around A\$1300) in 2002.

I.4 Benefits

Metastatic disease is generally incurable, but in clinical trials, Herceptin has been shown to prolong the survival of women with advanced metastatic breast cancer that is HER2-positive. NICE (2002a) noted that:

³ MBS item number 72848 covers the following: Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen — one to three of the following antibodies: oestrogen, progesterone and c-erb-B2 (HER2) (Item is subject to rule 13). Fee: \$51.55. Benefit: 75%=\$38.70, 85% = \$43.85 (pers. comm., HIC, 12 July 2005).

... improvements in survival of this magnitude due to therapeutic intervention have rarely been recorded in women with metastatic breast cancer. (p. 7)

The addition of Herceptin to a standard chemotherapy regimen for those who had not previously received chemotherapy for metastatic disease was shown in trials to control the cancer for longer (by around 3 months more than chemotherapy alone) and provide a survival advantage of around 5 months over chemotherapy alone. (Although according to NICE (2002a), this probably underestimates the survival benefit as trial patients receiving chemotherapy alone were given Herceptin after disease progression.) Those with greater levels of HER2 protein overexpression were more likely to benefit from Herceptin. Patients on Herceptin were also in less pain and suffered less shortness of breath. Side effects of Herceptin included cardiotoxicity (the likelihood of congestive heart failure was higher in women receiving the combination treatment compared with chemotherapy alone) and infusion related reactions.

Used as monotherapy in women who had already received chemotherapy, Herceptin was shown to reduce tumour size in 15 per cent of women tested. The positive response lasted around nine months (compared with around five months for the patients' previous chemotherapy regimens). Median duration of survival in the various monotherapy studies ranged from around 13 months (second or third line) to 22 months (first line) (pers. comm., Associate Professor Richard Bell, 12 July 2005). There were infusion related side effects, and some patients experienced cardiac dysfunction. However, these data are based on phase II studies and not on randomised controlled trials comparing Herceptin monotherapy with alternative treatment.

Many studies have shown that the combination of Herceptin plus Navelbine is effective with high response rates of 60–80 per cent. No comparative studies have been conducted and Herceptin has not been approved for this use (box I.2) (Breastcancer.org 2005a).

I.5 Cost effectiveness

Australian cost effectiveness studies

As mentioned earlier, the PBAC decided Herceptin was not cost effective. Since PBAC submissions and decisions are not publicly available (as discussed in chapter 8) it is not possible to refer to the Australian data here. However, the Medical Oncology Group of Australia (MOGA 2002) summarised the PBAC decision as follows:

Although the TGA accepted the effectiveness of Herceptin, the drug was rejected for listing by the PBAC on three occasions on the grounds that the high cost of the drug and the duration of therapy led to an unacceptably high cost effectiveness ratio. (p. 5)

According to NATSEM,

One problem that the PBAC apparently worried about was the cost-effectiveness ratio in that there was no definite end-point to treatment, other than treatment stopping when there was no sign of cancer or the disease progressed. (sub. 1, p. 50)

Both NATSEM and MOGA argued that patients likely to respond to biologically targeted therapies can be clearly identified, so leakage (prescribing of drugs outside the indications approved by the relevant authority) is unlikely to be a problem.

Although new biologically targeted cancer drugs are often expensive in unit terms, they are usually used in limited populations, so the overall cost is relatively low. In addition, the most appropriate population for treatment can often be identified through testing of a gene defect or receptor on the cancer cell, so prescribing criteria can usually be well-defined. (MOGA 2002, p. 3)

International cost effectiveness studies

NICE (2002a) concluded that both combination and monotherapy were cost effective.⁴ The NICE analysis along with that of two other studies is summarised below.

The NICE (2002a) decision on combination therapy was based on data drawn from a study comparing combination Herceptin and Paclitaxel (a type of chemotherapy agent) with Paclitaxel alone. For patients with high levels of HER2 (HER2 3+), the estimated incremental cost effectiveness ratio was £37 500 (around A\$82 400) per quality-adjusted life-year (QALY) gained (substantially less per life year gained). The costs included HER2 testing (£21 (A\$50) for a single test) and cardiac testing (£520–640 (A\$1140–1410) for four tests). The survival advantage was assumed at around 10 months, to account for ‘cross over’ (whereby trial patients who initially received chemotherapy alone ‘crossed over’ or were then given Herceptin after their disease progressed). NICE (2002a) noted that another study comparing combination Herceptin and Docetaxel (another type of chemotherapy) with Docetaxel alone found a survival advantage for combination therapy equal or better than for the Paclitaxel comparison.

The NICE (2002a) decision on Herceptin monotherapy was based on a comparison with Navelbine monotherapy. The estimated incremental cost effectiveness ratio was around

⁴ NICE foreshadowed the development of a guideline on breast cancer later in 2005, which will include a review of the guideline on Herceptin.

£7500 (A\$16 500) per life year gained if Herceptin was used instead of Navelbine (assuming the additional survival attributable to Herceptin monotherapy was 8 months). The cost per QALY was estimated by manufacturers for the NICE study at £19 000 (A\$41 750) assuming that the 8 months of additional survival was equivalent to 2.6 quality adjusted months. NICE expressed reservations about the lack of controlled studies for Herceptin monotherapy, but decided that such concerns would not raise the cost per QALY by enough to reverse its decision on cost effectiveness.

A more recent study in Belgium assessed the incremental cost effectiveness of using Herceptin monotherapy after previous chemotherapy treatments for the treatment of metastatic breast cancer in hospital (Neyt et al. 2005). The comparator was Navelbine monotherapy. Herceptin monotherapy was associated with an extra cost to the hospital of around €47 777 (A\$69 844) per additional year of life. This included the cost of the FISH test (box I.2).

Identification of potentially responsive patients is an important influence on the cost effectiveness of biologically targeted interventions such as Herceptin (Elkin et al. 2004) and diagnostic testing needs to be incorporated into cost effectiveness analyses for these agents. According to Elkin et al. (2004), the diagnostic performance of the tests for HER2 overexpression:

... had considerable influence on cost effectiveness, independent of test cost, due to the high cost of treating patients with false positive test results and the missed opportunity for patients with false negative results to benefit from Trastuzumab. (p. 861)

As noted above, the IHC test is cheaper but less accurate than the FISH test. Elkin et al. (2004) compared a base case of no testing and chemotherapy alone with various testing strategies followed by combination Herceptin and chemotherapy for HER2-positive patients, or chemotherapy alone for HER2-negative patients. They found very high cost effectiveness ratios in the range US\$125 000 to US\$145 000 (A\$161 300 to \$187 000) per QALY gained and concluded that at this price, it was worth using the most accurate — if more expensive — test to ensure that the drug was targeted properly. However, as discussed previously, neither test is fully subsidised in Australia or included with administration of the Herceptin Program.

I.6 Future Developments

Use of Herceptin at earlier stages of disease (adjuvant Herceptin)

Results have been released recently (April 2005) from several large scale international trials involving more than eight thousand patients showing that Herceptin in combination

with adjuvant chemotherapy significantly improves disease-free survival⁵ for women with *early* stage HER2-positive breast cancer. Patients who, after surgery, received Herceptin in combination with chemotherapy, had statistically significant improvements in rates of disease recurrence and overall survival. The studies also found, however, that women receiving Herceptin had a significant increase in the risk of congestive heart failure compared with chemotherapy alone. The trials will continue for a number of years to assess long-term survival and recurrence rates. The manufacturer of Herceptin, Genentech Inc, is planning to seek approval from the FDA for use of Herceptin for early stage disease. Roche will seek approval in non-US markets.

Adjuvant Herceptin is a complement to other existing treatments (figure I.1). However, as adjuvant use has been shown to reduce recurrence of disease, it will substitute for later use in some patients who may otherwise have developed metastatic cancer. Further, adjuvant patients relapsing on Herceptin by definition have Herceptin resistant tumours and would not therefore be placed on Herceptin therapy once their disease progressed (pers. comm., Associated Professor Richard Bell 13 July 2005).

Each year, it is estimated that around 1700 women could benefit from adjuvant Herceptin,⁶ (in addition to the 1000 or so women with HER2-positive metastatic disease). The length of adjuvant Herceptin treatment is currently one year.⁷ This implies that adjuvant Herceptin could increase expenditure by at least \$105 million per year⁸ — or around 2 per cent of PBS/RPBS spending in 2004.

Other issues

- In future, the Herceptin treatment period for metastatic cancer may lengthen. Current practice is to treat patients with Herceptin until the disease stops responding and the cancer starts to progress. There is however some evidence that it is beneficial to continue Herceptin after disease progression (for example, Bell 2002). The terminal phase of cancer might be three months (Neyt et al. 2005). Based on NICE (2002a) data for three months of Herceptin monotherapy, the additional cost per patient could be £5300 (A\$11 640).

⁵ Disease-free survival refers to the length of time after treatment during which no disease is found (box I.1).

⁶ This is around 17 per cent of new cases of breast cancer — those that are HER2-positive and non-metastatic (pers. comm., Associate Professor Richard Bell, 12 July 2005).

⁷ One trial is comparing one year of treatment with two years, but the results will not be available until 2008.

⁸ For patients under 75kg, one year of Herceptin, including loading, is around \$62 000 per patient (pers. comm., Associate Professor Richard Bell, 12 July 2005).

-
- There is some evidence that a change in the dosage interval from one week to three weeks for women with HER2-positive metastatic cancer would not compromise the safety or efficacy of the drug, but would improve patient convenience and reduce waste (Baselga et al. 2005; Lleyland Jones et al. 2003). Under the current weekly dosage regime, vials are only partly used for women who weigh more than 75kg because the standard vial size is 150mg. However, the currently available evidence supporting three weekly dosage may not be of a standard acceptable to the TGA (which requires phase III evidence). A phase III trial comparing the efficacy of different dosage regimes may not be a priority for the drug company, in part given the limited pool of patients available for the trials already underway.
 - Population ageing is likely to further increase the pool of breast cancer patients and spending on drugs such as Herceptin.
 - The Australian patent for Herceptin expires on 14 September 2015 (pers. comm., Roche, 18 July 2005) so competition from generics (depending how difficult it is to replicate Herceptin) will not affect the price for at least another ten years. The patent for Herceptin in the US expires April 2017.

I.7 Conclusion

Herceptin is a significant technological advance associated with improvements in survival times for some women with breast cancer. However, as a supplement to existing treatments for advanced metastatic breast cancer, Herceptin unequivocally adds to health expenditure. It is an expensive drug and is not associated with cost savings elsewhere in the health system. In addition, the QALYs gained are relatively few, so the incremental cost effectiveness ratio for Herceptin is relatively high.

The deliberations behind the Australian Government's decision to subsidise Herceptin are not on public record. However, decisions about subsidising expensive but life prolonging agents are highly controversial and are likely to benefit from increased transparency, in part to promote consistency of treatment across patient groups. In addition, the separate administration and subsidisation of drugs outside the PBS (such as through the Herceptin Program) may increase uncertainty, and lead to discrepancies in regulatory arrangements across drugs, and proliferation of processes for scrutiny and review.

The diagnostic performance and costs of testing need to be included in cost effectiveness analyses in the case of expensive drugs like Herceptin and other biologically targeted therapies, to ensure the drug is targeted properly. In Australia, the diagnostic tests for

Herceptin are not fully subsidised and not included with administration of the Herceptin Program. The institutional arrangements governing subsidisation of pathology tests are separate from those of drugs and this may impede concurrent consideration of drugs with associated tests. Pathology tests are generally the responsibility of committees related to MSAC, whereas drugs are the concern of PBAC.

It took three years or so after Herceptin was subsidised for the quantity supplied to match initial estimates of need. Data on the distribution of the drug suggest that women living in the most disadvantaged regions were less likely to receive Herceptin than those in least disadvantaged regions. However, distribution of the drug by remoteness appeared consistent with the different female population age profiles across different remoteness areas.

In future, there is a high probability that Herceptin will be approved in the Australian market as adjuvant treatment for early stage breast cancer, based on trials showing considerable benefits, including reduced recurrence of disease. The associated addition to expenditure if the drug is listed for this indication could be over \$100 million per year.

J PSA tests for prostate cancer

J.1 Introduction

The prostate specific antigen (PSA) test was a significant advance in the diagnosis of prostate cancer in the late 1980s. Unlike methods available before this time, namely digital rectal examination (DRE) and the prostatic acid phosphatase (PAP) blood test, the PSA test is capable of indicating the possibility of prostate cancer at early stages of development. PSA tests are either used alone or they are used together with the less expensive DREs (Girgis et al. 1999), and have largely replaced PAP tests (Smith and Armstrong 1998).

In addition to diagnosis of prostatic disease, PSA tests are also used to monitor disease progression and to evaluate the effectiveness of treatments for prostate cancer and benign prostatic hyperplasia (BPH), the non-cancerous enlargement of the prostate gland.

The major limitation of the PSA test is its inability to distinguish between prostate cancer, BPH and other diseases of the prostate. Consequently, a positive diagnosis from a PSA test must be confirmed by a biopsy. Biopsies are more expensive (DoHA 2004e) and much more invasive than PSA tests, but are necessary to determine the stage of disease progression (Turini et al. 2003). Even once a positive diagnosis has been established, treatment is not necessarily the recommended course of action for all patients (box J.1). It is for these reasons that the use of PSA tests to detect prostate cancer in asymptomatic men has been controversial.

In Australia there is no nationally coordinated screening program for prostate cancer. The Urological Society of Australasia, the Prostate Cancer Foundation of Australia, the Cancer Council Australia and the Clinical Oncological Society of Australia do not support the use of PSA tests for this purpose. They recommend ‘informed consent’ — in other words, PSA tests should only be used to test asymptomatic men after they have been fully informed of the advantages and disadvantages of PSA testing (Cancer Council Australia and the Clinical Oncological Society of Australia, sub. 32; Prostate Cancer Foundation of Australia, pers. comm., 16 August 2005; Urological Society of Australasia 2005b). The Cancer Council Australia and the Clinical Oncological Society of Australia recommended that ‘GPs receive adequate

information about the advantages and disadvantages of prostate cancer screening, enabling at-risk men to make an informed choice' (sub. 32, p. 17). The Urological Society of Australasia echoes these views:

... men should have the benefit of making their own decision about screening, rather than the two extremes of universal community screening, or total opposition by committees of people not aware of each individual's perception of the relative risks. (2005b, p. 5)

However, the PSA test appears to have been used extensively to test men who do not have symptoms indicative of prostatic disease.

Box J.1 Diagnosis and treatment options for prostate cancer

Diagnosis

- Prostatic acid phosphatase (PAP) blood test. This was the first available blood test for prostatic disease. PAP tests are now uncommon and are mostly used to monitor disease progression.
- Prostate specific antigen (PSA) blood test. The PSA test determines the level of a particular protein in the blood that is only produced by the prostate gland. Abnormally high levels of this protein are an indication of prostatic disease. It is used to diagnose and also to monitor prostatic disease.
- Digital rectal examination (DRE). The major limitations of this technique are that it is difficult to assess the whole prostate and it is difficult to detect early changes.
- Biopsy. This is usually aided by a transrectal ultrasound. Possible side effects include infection and bleeding.

Treatment

- Watchful waiting, or active monitoring. In other words, no treatment, but monitoring progress of the cancer with the use of diagnostic techniques.
- Androgen deprivation therapy. This therapy is used for advanced prostate cancer and aims to deprive the prostate of the hormones that support its growth. Traditionally, this was achieved through the removal of the testes, but it is becoming more common to use drugs instead.
- Radiotherapy. Traditionally, this is delivered with an external beam of radiation to kill cancer cells. A recent advance in this area is brachytherapy — the implantation of radioactive seeds directly into the prostate gland — which may be associated with lower rates of urinary incontinence and impotence compared with other treatments.

(Continued next page)

Box J.1 (continued)

- Cryotherapy is a relatively new technique which involves freezing cancerous cells in the prostate gland.
- Prostatectomy involves removal of the prostate gland and sometimes the removal of surrounding tissues and nerves. Possible side effects are urinary incontinence and impotence. Techniques include:
 - Open prostatectomy. This is the more traditional and most invasive technique. Though still widely performed, its use is declining.
 - Laparoscopic prostatectomy. This procedure is relatively common, but because it is performed through small incisions, requires advanced skills.
 - Robot-assisted prostatectomy. This technique has only been used in the last couple of years and is still in development. It is very expensive, but it is claimed to offer potential benefits over other techniques such as faster recovery times and lower rates of complication.

Sources: ASERNIP-S (2004); Harris and Lohr (2002); Linton and Hamdy (2003); Oncology Business Week (2005); Smith and Armstrong (1998); Turini et al. (2003); Urological Society of Australasia (2005a); Urological Society of Australasia (2005b).

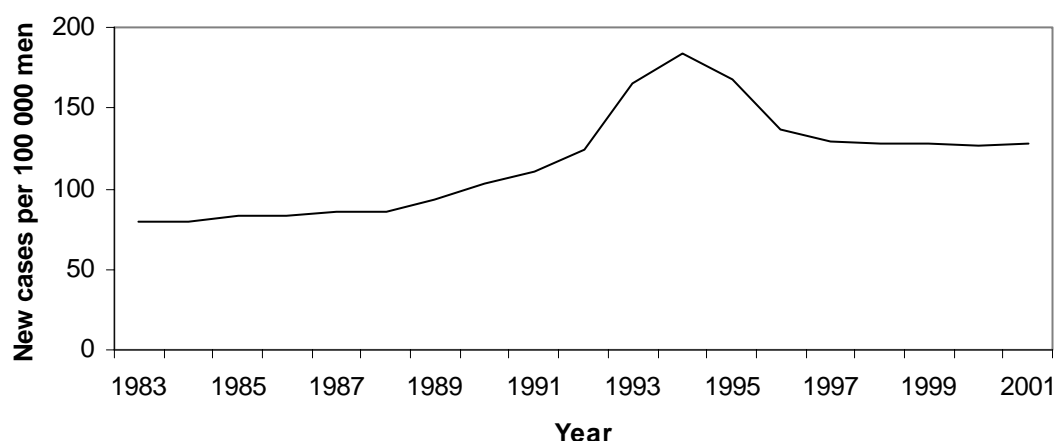
The availability of PSA testing has been correlated with rapid increases in the reported incidence of prostate cancer in Australia and many other countries including the United States, New Zealand and the United Kingdom (AIHW and AACR 2004; Harris and Lohr 2002). Between 1989 and 1994 the reported incidence of prostate cancer in Australia almost doubled, reflecting the diagnosis of a number of previously undetected cases (figure J.1). The reported incidence of prostate cancer reached a peak in 1994, declined between 1994 and 1997, and then stabilised. Although not as high as in the mid 1990s, the diagnosed incidence of prostate cancer is still considerable — in 2001 it was the most frequently diagnosed cancer in men (excluding non-melanoma skin cancers), with over 11 100 new cases (AIHW and AACR 2004). The Australian diagnosis rate is low in comparison with the United States and New Zealand, but high compared with the United Kingdom (AIHW and AACR 2004). International differences in the diagnosis rate of prostate cancer can be partly explained by differences in the rate of uptake of PSA testing.

It has been suggested that the ageing of the population is partly responsible for the rising incidence of prostate cancer (Linton and Hamdy 2003; Turini et al. 2003), as the risk of developing prostate cancer increases with age (figure J.2).¹ By conducting autopsies on younger men, a US study found that over one-quarter of men aged 30 to 39 and over

¹ A family history of prostate cancer also increases the risk that a man will develop prostate cancer. Risks of developing prostate cancer differ between ethnic groups (Urological Society of Australasia 2005b).

one-third of men aged 40 to 49 had some cancerous cells in their prostate gland (Sakr et al. 1993 cited by Thompson and Optenberg 1995). Autopsy results have also indicated that nearly all men who live to the age of 100 will show signs of prostate cancer (Berg 2003).

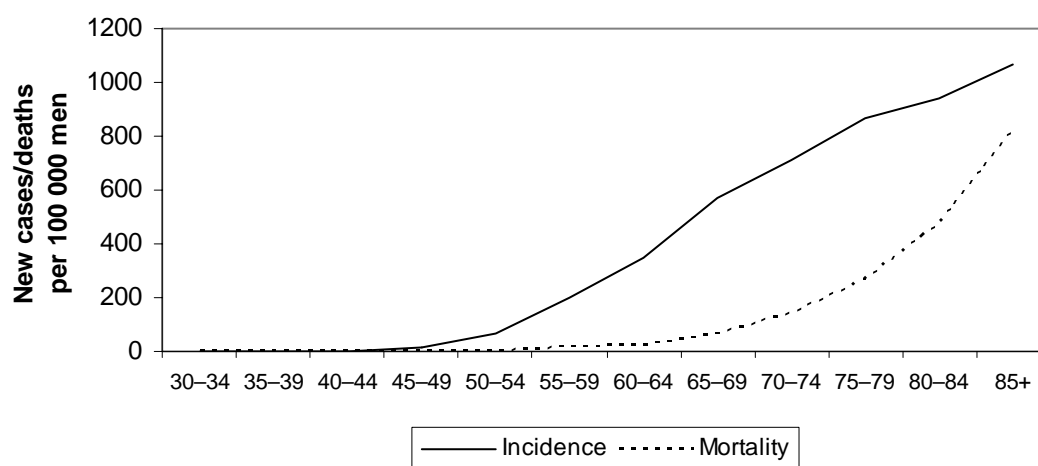
Figure J.1 Prostate cancer incidence from 1983 to 2001^a



^a Rates are age standardised to the Australian population in 2001.

Data source: AIHW (2005a).

Figure J.2 Age-specific incidence and mortality rates from prostate cancer, 2001



Data sources: ABS (2004b); AIHW and AACR (2004).

For men aged 69 or younger, the reported incidence of prostate cancer is much higher than the mortality from prostate cancer (figure J.2). This is reflected in the rates of prostate cancer mortality and incidence for the whole male population. In 1993, the

age-standardised incidence rate was around 165 new cases per 100 000 men, while the age-standardised mortality rate was around 44 deaths per 100 000 men. By 2003 the mortality rate had fallen to around 34 deaths per 100 000 men (AIHW 2005a).

The survival rate is high because not all prostate cancers are fast growing and not all cancers spread to other areas of the body (although the aggressiveness of prostate cancers varies significantly) (Neal and Donovan 2000). In 2001 around 30 per cent of the men who died with prostate cancer died as the result of another cause. Across all cancers, the proportion who died from another cause was considerably lower at around 11 per cent (AIHW and AACR 2004). Prostate cancer therefore compares favourably to most other cancers in this regard. Lung cancer is a case in point. In 2001 there were fewer new cases of lung cancer (around 5400) than prostate cancer (over 11 100) amongst men, but more deaths directly attributable to the cancer (around 4700 compared with 2700 for prostate cancer) (AIHW and AACR 2004).

The five-year survival rate has significantly improved since the introduction of PSA testing — from 59 per cent in 1982–86 to 83 per cent in 1992–97 — however, this improvement is probably largely artificial (AIHW and AACR 2001). Prior to PSA testing, early stage cancers went largely undetected, and therefore the mortality rate reflected deaths of men with more advanced cancers (AIHW and AACR 2004).

A recent US study by Steenland et al. (2004) suggests that men of higher socioeconomic status may have a higher rate of survival from prostate cancer. They found that men without post secondary education had a higher mortality rate than men with at least a college education. However, the difference in mortality rates was only partly attributable to the stage of the cancer at the point of diagnosis and access to PSA testing.

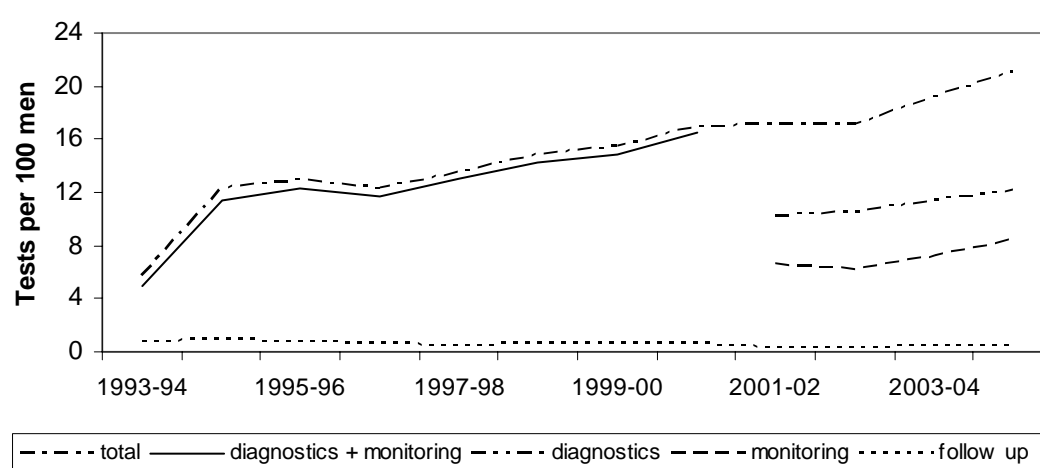
In comparison to other cancers, such as lung and colorectal cancers, the mortality burden of prostate cancer constitutes a smaller proportion of its total disease burden (Mathers et al. 1999). This is due to the considerable morbidity associated with prostate cancer — prostate cancer is associated with sexual dysfunction, difficulty with urination, and bone pain (American Urological Association 2000). In 1996, prostate cancer was ranked the sixth most common cause of disease and injury burden in men aged 65 years or older, and the fourteenth cause of disability burden for all men in that year (Mathers et al. 1999). The Victorian Department of Human Services (1999) projected an increase in the age-standardised burden of prostate cancer of 22 per cent between 1996 and 2016.

J.2 PSA use and expenditure

The PSA test first appeared on the Medicare Benefits Schedule (MBS) in 1989 (Smith and Armstrong 1998). Since that time there have been several changes to its listing, including in 2001, when there was a restructure to promote appropriate use (HIC 2001a). Currently, there are three items for PSA tests on the MBS — one for testing men with or without symptoms, the second for monitoring men with diagnosed prostatic disease (this presumably includes post-treatment evaluation), and the third for following up unclear results from a previous PSA test. Tests for diagnosis and follow up are restricted to one per 12-month period (DoHA 2004e).

The rate of PSA testing has increased since 1993-94 when Medicare data were first available (figure J.3). The biggest jump was between 1993-94 and 1994-95 when the rate of testing (for both diagnosis and monitoring) more than doubled. The restructure of the MBS items for PSA tests in 2001 resulted in the rate of services reported for disease monitoring falling and the rate of services reported for diagnosis increasing. The rate of testing for diagnosis has continued to increase since 2000-01, and currently outweighs the rate of testing for monitoring the progression of the disease. In 2004-05, around 12 per cent of men aged 35 or older had a PSA test for diagnosis, and around 8 per cent had a PSA test for monitoring (although currently there are no restrictions on the number of tests for monitoring that a man can have) (HIC 2005a). Tests for the clarification of equivocal results are relatively uncommon and the rate of such tests was relatively stable over the period.

Figure J.3 Use of PSA tests from 1993-94 to 2004-05^{a,b,c}



^a Prior to May 2001 PSA tests for diagnostic and monitoring purposes were represented by one MBS item number. ^b Data prior to May 2001 reflect PSA tests and PAP tests. However, by the mid-1990s the ratio of PAP tests to PSA tests was small (Smith and Armstrong 1998). ^c Based on the male population aged 35 or older at the start of each financial year.

Data sources: ABS (2004b); HIC (2005a).

Two studies (Girgis et al. 1999; Smith and Armstrong 1998) have suggested that the PSA test is being used as a screening device in Australia. According to Smith and Armstrong (1998), between January 1995 and December 1996, the vast majority of men aged 30 or older (over 70 per cent) had had just one PSA test. This indicates that the tests were used to test for cancer and not to monitor progression. Further, from 1990 to 1995, the ratio of tests for prostate cancer to positive diagnoses increased dramatically from around 19:1 to 45:1. Another study by Slevin et al. (1999) (cited by Gattellari and Ward 2005) has indicated that men are infrequently adequately informed of the potential benefit and harm resulting from PSA screening. Gattellari et al. (2003) (also cited by Gattellari and Ward 2005) indicate that GPs tend to order PSA tests ‘opportunistically’ — in other words, they order PSA tests at the same time as they order other blood tests.

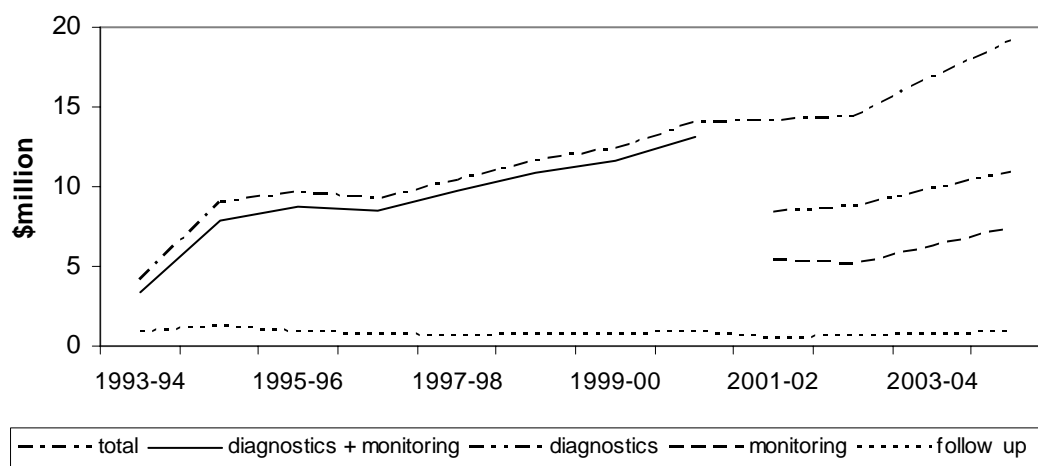
According to the Australian Institute of Medical Scientists, widespread consumer awareness has been an important driver of demand for PSA testing:

The influence of public will and sentiment for advanced and sometimes unproven technology or diagnostics may often override any evidence of community benefit as is the case with PSA testing... (sub. 3, p. 1)

There is some evidence in Australia to indicate that the threat of litigation is influencing the decisions of GPs with regard to screening men in low risk groups (Girgis et al. 1999; Pinnock et al. 1998 cited by Girgis et al. 1999). In a survey of over 200 GPs in NSW, around 60 per cent perceived a risk of litigation if they denied PSA testing of asymptomatic men, while only 15 per cent were concerned about the risk of litigation arising from complications following PSA testing (Girgis et al. 1999).

Currently, the schedule fees for diagnosis, monitoring and treatment evaluation are each \$20.50 and the schedule fee for follow-up tests is \$37.80 (DoHA 2004e). In 2004-05, the Australian Government spent over \$10.8 million on diagnostic PSA tests, and around \$7.4 million on monitoring, totalling around \$18.2 million (figure J.4). For the 2003-04 financial year (when data on total MBS expenditure became available) diagnostic PSA tests and PSA tests for monitoring accounted for almost 0.2 per cent of total MBS expenditure (DoHA 2004g; HIC 2005a). These figures do not incorporate the costs of general practitioner consultations (each around \$30 or more), or the costs of resulting negative biopsies — a transrectal needle biopsy and ultrasound attracts MBS fees of around \$350 (DoHA 2004e) — and their associated side effects, including infections or bleeding, are also excluded.

Figure J.4 **Government expenditure on PSA tests from 1993-94 to 2004-05^{a,b}**



^a Prior to May 2001 PSA tests for diagnostic and monitoring purposes were represented by one MBS item number. ^b Data prior to May 2001 reflect PSA tests and PAP tests. However, by the mid-1990s the ratio of PAP tests to PSA tests was small (Smith and Armstrong 1998).

Data source: HIC (2005a).

Benoit and Naslund (1997) and Turini et al. (2003) indicate that it is more expensive to treat prostate cancer when it is detected earlier rather than later. Aggressive and expensive treatments such as radical prostatectomy and radiation are more widely used to treat early stage cancers than advanced cancers. Advanced cancer is usually treated with less expensive technologies, for example, androgen deprivation therapy. Further, older men are more likely to be diagnosed with advanced cancer and are more likely to be monitored rather than treated. This of course is only one side of the equation. The benefits of earlier detection and treatment need to be considered as well (see below).

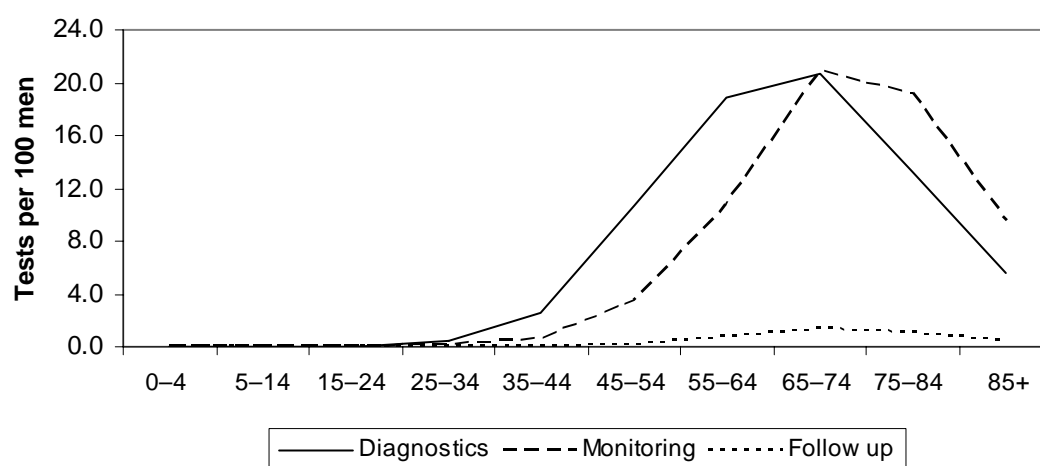
Profile of use

In 2004-05, the number of tests per 100 men increased with age up to the 65–74 age group when the number of tests began to decline. As figure J.5 indicates, men in the 55–64 age bracket or younger had diagnostic tests more commonly than tests to monitor disease progression. The reverse was true for men aged 75 or older, while men aged between 65 and 74 had roughly equal rates of PSA tests for diagnosis and monitoring. A large proportion of the male population was tested for prostate cancer — around one in ten men aged 45–54, and around one in five men aged 65–74 had at least one PSA test within this 12-month period.

Of men in the 75–84 age group, around 19 in 100 had a PSA test for monitoring (although this figure is likely to be inflated because there are no restrictions on the number of PSA tests a man can have for monitoring the progression of cancer), and approximately 13 in 100 had a PSA test for diagnosis. According to the Urological Society of Australasia (2005b), screening is ‘most likely to be beneficial’ to those who are expected to live for at least ten years.

Testing rates differ across the States and Territories. In 2004–05, across all age groups, South Australia had the highest rate of testing for diagnostic purposes, and the Northern Territory had the lowest. However, these are not age-standardised rates (HIC 2005a).

Figure J.5 **PSA tests, by type and age group 2004–05^{a,b}**



^a National average. ^b PSA tests for diagnosis and follow up are restricted to one in a 12-month period. There are no restrictions on PSA tests for monitoring.

Data source: HIC (2005a).

Coory and Baade (2005) examined regional differences in age-standardised rates of PSA testing, of radical prostatectomy, of incidence of prostate cancer and of prostate cancer mortality between 1985–87 and 2000–02. They found that men in regional and rural areas had fewer PSA tests, lower reported incidence of prostate cancer, fewer prostatectomies and higher mortality than men in capital cities. Over time, the difference across regions in rates of PSA testing, reported incidence and radical prostatectomies diminished, but the difference in mortality rates increased. This finding was supported by the AIHW and AACR’s *Cancer in Australia 2001* report (2004), which indicates that between 1998 and 2002 the age-standardised average annual death rate from prostate cancer was appreciably higher in other areas of Australia compared with capital cities.

J.3 Benefits of PSA testing

Most of the claimed benefits of PSA testing are associated with its ability to detect cancer at an earlier stage than is otherwise possible. Early detection is argued to improve prognosis, chance of cure, and allows for a greater choice of treatment options because the cancer is more likely to be contained to the prostate gland (Benoit and Naslund 1997; Urological Society of Australasia 2005b). Further, there is some evidence to indicate that PSA testing reduces anxiety through reducing uncertainty — this may hold true even when men are initially given false positive diagnoses (Essink-Bot et al. 2003).

PSA tests to screen for prostate cancer are able to detect cancer in around 70 to 80 per cent of cases (American Urological Association 2000), but DREs ‘can only detect cancers which are relatively large’ (AHTAC 1996, p. 5). Whilst biopsies are also capable of diagnosing early stage prostate cancer, they are less suited for this purpose due to their more invasive nature and greater cost (AHTAC 1996).

Early diagnosis can help to avoid the significant morbidity and costs associated with advanced prostate cancer (Benoit and Naslund 1997; American Urological Association 2000). However, as noted by the Cancer Council Australia and the Clinical Oncological Society of Australia, ‘the question remains whether measurement of PSA provides benefits to patients in terms of treatment and quality of life outcomes’ (sub. 32, p. 16). Therefore, the net impact that PSA testing has on morbidity across all men who are tested is unknown.

PSA tests offer benefits in addition to that of early diagnosis. The tests are also used to monitor the progression of cancers that are contained to the prostate gland (Smith and Armstrong 1998). This can be in conjunction with DREs. The ‘watchful waiting’ approach can avoid or delay unnecessarily aggressive treatments, including prostatectomy, that have associated risks (box J.1). If patients opt for treatment rather than watchful waiting, PSA tests can also be used as a measure of its success — PSA levels are much lower following a successful treatment of BPH or prostate cancer (American Urological Association 2000).

There is weak evidence that links prostate cancer screening with a reduction in prostate cancer mortality. A widely-cited Scandinavian study by Holmberg et al. (2002) reported that treatment of early stage prostate cancer lowers disease-specific mortality. Holmberg et al. (2002) randomly assigned patients who were diagnosed with early stage prostate cancer to two groups — those who would be actively monitored (the watchful waiting approach), and those who would have radical prostatectomies. In terms of overall survival rates, there was no statistically significant difference between the two groups, but there was a statistically significant difference in terms of mortality due to prostate cancer specifically. After five years, patients had a 6.6 per cent lower risk of death from prostate cancer when

they had their prostate removed than if they were actively monitored. But the study was devised and begun in the late 1980s, before PSA tests were widely used to screen for prostate cancer. Holmberg et al. stated that:

In men with cancer detected by screening, the baseline risk of death from prostate cancer may be even lower, and thus the absolute benefit of radical treatment may be even less pronounced than in this study. Moreover, the lead time in screening — which may be many years (Pearson et al. 1996) — would add to the time before the benefit emerges. (2002, p. 788)

In Australia and other countries, the widespread use of PSA testing as a screening device has coincided with a drop in prostate cancer mortality rates. Murphy et al. (2004) suggest that the reduction in the US prostate cancer mortality rate between 1993 and 2003 can be largely attributed to screening for prostate cancer, although they acknowledge that advances in the treatment of prostate cancer also occurred in this period. However, the mortality rate has fallen in other countries where prostate cancer screening is not as common (Oliver et al. 2001 cited by Makinen et al. 2003). Also, Harris and Lohr (2002, p. 917) contend that, ‘no conclusive direct evidence shows that screening reduces prostate cancer mortality’. Further, according to Linton and Hamdy (2003), the fall in mortality rates occurred too soon after the introduction of PSA tests to be the result of screening for prostate cancer.

J.4 Cost effectiveness of PSA testing

As discussed above, the PSA test is apparently being used in Australia to test asymptomatic men for prostate cancer. In other words, the test is being used as a screening device. It is unclear whether this constitutes cost-effective use. Currently, there are two large-scale trials underway that are evaluating the appropriateness of prostate cancer screening: the US Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial; and the European Randomised Study of Screening for Prostate Cancer. These trials should be completed in 2006 and 2008 respectively (The Cancer Council Australia 2005).

The cost effectiveness of population screening for prostate cancer using PSA tests has been questioned because:

- PSA tests cannot correctly identify with sufficient accuracy those patients who are, and those who are not, likely to have prostatic disease. This is partly because the ‘upper limit of normal’ of PSA levels (4 ng/ml) has been widely adopted without strong evidence to indicate that this represents an effective benchmark for the presence of disease (Hernandez and Thompson 2004). A significant proportion of men, particularly older men, are given false positive results (Atkins et al. 2005). Of the men with PSA

levels above 4 ng/ml, but below 10 ng/ml, only one in four will be diagnosed with cancer after a biopsy (Urological Society of Australasia 2005b). The costs associated with false positive results from PSA screening are unnecessary anxiety, biopsies and treatment.

- With currently available diagnostic tools, clinicians are unable to distinguish tumours that warrant treatment and those that can be left alone (Makinen et al. 2003). As a result, some men opt for radical treatment when watchful waiting might be more appropriate. This happens because some men are more concerned about the consequences of doing nothing than they are about having unnecessary treatment (Atkins et al. 2005). Even once a man decides to have treatment it is unclear which treatment he should have, as there is no consensus amongst clinicians as to which treatments are best (Turini et al. 2003).
- Complications can result from treatment and, for some patients, treatment may increase the morbidity and the mortality burden of disease. A study by Harris and Lohr (2002) indicates that bowel problems, erectile dysfunction and urinary incontinence are relatively common complications of prostate cancer treatments.

Overall, it is not clear that the benefits that accrue to a subgroup of the screened population outweigh the significant costs of screening, and of unnecessary tests and treatments, which may have significant side effects. This is partly because there has been limited research into the cost effectiveness of PSA tests for screening purposes. Nonetheless, Benoit et al. (2001) estimated that for men aged between 50 and 70 years, the cost per life year saved from PSA screening was between US\$3800 and US\$5000. Thompson and Optenberg (1995) also found the use of PSA tests (in conjunction with DREs) to screen for prostate cancer to be cost effective for this age group — at a cost per quality-adjusted life-year in the range of US\$8700 to US\$23 100. However, the authors also noted that:

Due to a lack of prospective, randomized studies of screening for prostate cancer, the impact of screening on prostate cancer morbidity or mortality cannot be determined. (Thompson and Optenberg 1995, p. 144)

Others (Benoit and Naslund 1997; Turini et al. 2003) have also highlighted the need for reliable information on the effects of prostate cancer screening, including the need for data relating to quality of life impacts.

To date, no studies have evaluated the cost effectiveness of PSA tests for the purpose of diagnosing men who have symptoms of prostatic disease, monitoring disease progression or for evaluating the effectiveness of treatment.

J.5 Future developments

It is likely that in the near future there will be a number of improvements in the diagnosis and treatment of prostate cancer. There are several diagnostic tools that are in development or are already in use overseas. A genetic urine test with reportedly lower rates of false positive and false negative results than the PSA test is in use overseas, and two other tests for prostate cancer are in the latter stages of development (Johns Hopkins Medicine 2005; Miraculins 2005; PSA Rising 2003). At least initially, these tests are likely to be used to clarify conflicting or inconclusive PSA tests and prostate biopsies. They would therefore add to the costs of diagnosis, but they also have the potential to reduce the cost of unnecessary treatments.

Advances in biopsy technology also have the potential to assist clinicians to determine an appropriate treatment plan. One recently announced study will investigate a new biopsy technique that will enable a series of markers for prostate cancer to be investigated. It is thought that examining the specimen for a large number of markers will help to distinguish the high risk from the low risk tumours with greater certainty (Hawkes 2005).

New pharmaceuticals for the treatment of prostate cancer can also be expected. Two examples are Provenge and Aplidin. Provenge is designed to stimulate the body's immune response, and is in phase III clinical trials (chapter 11). It is potentially beneficial for the treatment of end stage and also some early stage cancers (Dendreon 2005). Aplidin is being developed for the treatment of cancers that are unresponsive to androgen deprivation therapy or to chemotherapy, and it is in phase II clinical trials (PharmaMar 2005).

Finally, advances in surgical treatments are also likely. High intensity focused ultrasound (HIFU) is a promising example. HIFU is in phase II clinical trials in Europe (Cancer Research UK 2005). It is a minimally invasive procedure that uses intense heat to kill cancer cells. Early results indicate that it is less frequently associated with complications and it is potentially cheaper than the surgical procedures currently in use (Derbyshire 2004).

J.6 Conclusion

The PSA test was a significant advance in the early diagnosis and monitoring of prostate cancer. Over the past decade, the use of and expenditure on PSA tests have steadily increased — in 2004-05 the Australian Government spent over \$18 million on PSA testing. There is evidence to suggest that PSA tests have been used to screen much of the male

population above 45 for prostate cancer despite equivocal evidence of the benefits. The Urological Society of Australasia, the Prostate Cancer Foundation of Australia, the Cancer Council Australia and the Clinical Oncological Society of Australia do not support the use of PSA testing for screening.

Prostate cancer screening is believed to benefit a subgroup of the screened population, but it is unclear whether these benefits outweigh the associated costs. While the test was introduced onto the MBS in 1989, no reliable cost-effectiveness studies are yet available. It is therefore unknown whether the combination of PSA testing and prostate cancer treatment is ultimately cost effective. However, there seems little doubt that PSA testing has increased overall costs. In future, the benefits of PSA testing may be enhanced by advances in diagnostic technologies and in treatments for prostate cancer.

K Information and communications technology

The terms of reference define medical technology to include the ‘knowledge and support systems within which healthcare is provided’. An increasingly important aspect of these are general technologies, such as information and communications technology (ICT), that can have medical applications. The actual and potential impacts of advances in ICT in health-related settings are the focus of this appendix.

K.1 ICT and health — the context

ICT refers to the range of technologies (physical devices and networks) involved in the digital and/or electronic collection, retrieval, dissemination and processing of data and/or information. It includes information technologies, such as computers and software, and telecommunications technologies, such as phones and satellites.

Significant advances in both information and communications technologies have occurred over time — computers becoming more powerful, compact and mobile, and telecommunications moving from landlines to satellites, and from analogue to digital, for example. The two technologies converged in the late-1980s to 1990s to become ‘information and communications technology’ (PC 2004b), with their range of applications and business uses broadening. These developments:

... have progressively reduced the costs of gathering, storing, retrieving, processing, analysing and transmitting information. In these ways, they have provided firms with cheaper and readier access to more accurate, timely and useful information. (PC 2004b, p. 2)

The availability of information is of great importance in a range of medical settings — from the provision of healthcare, to administration and research (GAP 2004b; Victorian Department of Human Services (VDHS), sub. 24; Department of Health and Ageing (DoHA), sub. 34). Fujitsu Consulting (2004a, p. 27) noted information availability can be the ‘difference between life and death’ in clinical settings, while Chandra et al. (1995) identified information as the key to improving productivity.

Hence, ICT advances are especially important to the healthcare industry. These advances have applications beyond basic information management (table K.1), and can facilitate and

promote medical advances in diverse areas, with implications for a variety of users (boxes K.1 and K.2).

Table K.1 Some healthcare applications of ICT

<i>Administrative applications</i>	<i>Clinical applications</i>
Computerised admission data, accounting, billing	Medical imaging and signal processing
Automated hospital information systems	Knowledge-based systems in clinical decisions
Managerial decision support systems	Clinical intelligence support
Electronic patient records	Linkage to computerised patient records
Automated referral and training	Automated clinical training and education
Electronic mail, other automated communication	Telehealth and telemedicine
Automated linkages with other databases	Smart cards
Electronic networking with suppliers and regulators	Neural networks and pattern recognition

Source: Geisler (1999).

Box K.1 End-user applications of ICT

	Public Public information ^a	Providers Provider information ^a	Administrators	Researchers	Policymakers
General information provision					
Administration	Patient administration system		Human resources Procurement Asset management Performance management Finance		
Integration and communication	Claims and billing	Telehealth/telemedicine ^a Secure messaging and data transfer			
Clinical event management	Data capture and translation	Electronic Decision Support ^a Clinical information system ^a			
Monitoring and research	Electronic health records ^a			Population surveys Statistical information analysis	
			Data warehousing Registries and disease surveillance		
Patient and provider directories					
Authentication and access control					

^a Specific examples of these applications are discussed in more detail below.

Source: BCG (2004, p. 30).

Box K.2 **Some definitions**

Clinical information system. System designed to collect, store, manipulate and make available clinical information important to the delivery of healthcare at the institutional level. Includes specialised systems, primary care clinical record systems, and community-based care management systems.

Electronic health records. Centralised longitudinal records (collection of an individual's health information/medical history), stored electronically/digitally. They may contain details such as healthcare events, pathology and diagnostic test results, current medications, allergies, immunisation information, illnesses, surgery and other treatments. They do not, however, include detailed encounter information (clinical notes). They contain only a subset of the information held in an individual's (electronic) medical record, kept in the doctor's office or hospital department.

(Clinical) decision support system. System that uses best practice information to guide clinical decisions by providers, either when requested or when patient data suggests it is necessary. When these systems provide evidence-based information electronically, facilitating patient and practitioner access at the time a clinical decision needs to be made, they are known as Electronic Decision Support Systems.

Patient administration system. Information system used for patient management and transfers, facility management, resource scheduling, bill calculation and storing patient demographic and personal details.

Patient and provider directories. Applications that maintain sufficient basic patient and provider identification to distinguish between individuals.

Sources: BCG (2004); GAP (2005).

The National Office for the Information Economy (NOIE 2002e) noted that health professionals have used 'a range of computer and telecommunications applications to deliver improved health outcomes and reduce costs for over twenty years'. However, ICT advances have broadened the potential applications. More and McGrath (2000, p. 16), for example, pointed to the internet as making possible applications 'that would have been either prohibitively expensive or totally impractical several years ago'.

Investment in ICT is also seen as a fundamental component of overall health system reform (BCG 2004). However, although the potential benefits of ICT adoption are significant, so too are the barriers to its uptake. As noted by Philipson, the complexity and diversity of the healthcare industry — due to the range of activities, people and organisations involved — mean that it:

... more than any other area of human activity, should be able to benefit greatly from the effective use of IT. But that complexity and diversity also means there are many problems. (2005, p. 5)

This appendix investigates the benefits and costs of ICT, and issues (including obstacles) surrounding its uptake, in the Australian health sector. It does this both at the broad level and for particular applications (primarily in relation to the delivery of healthcare), specifically:

- administration and support systems (such as electronic health records (EHR) and computerised medication management) — part of the clinical event management and administration applications referred to in box K.1; and
- telehealth and telemedicine.

Quantifying the actual overall costs and benefits of these examples is problematic.

- Many ICT applications are still in relatively early stages of development. This means that, in many cases, more is known about upfront costs (which can be high), than about longer-term, often intangible, benefits.
- ICT is applied in many diverse localised settings and, unlike medicine-specific technologies, has not been subject to formal common health technology assessment processes. These two factors make it difficult to obtain generalisable data to examine the (potential) overall impact of ICT advances.
- Few Australian studies exist. International data are also often scarce, and even where available may not be applicable to the Australian context.

K.2 Health ICT in Australia — the big picture

... a vision for a connected health system ... is far from today's reality. Healthcare is largely delivered by independent institutions and providers; consumers have to navigate a complex, often difficult to understand, system; records and information are still primarily paper-based; and researchers, administrators and policy makers often struggle to locate, interpret and validate the information they need to manage the system and enhance outcomes for consumers. (BCG 2004, p. 22)

Since the National Health Information Agreement was signed in 1993, various committees, plans, strategies and trials have been initiated for health ICT. These have been undertaken at local, State and Territory, and national levels (table K.2), addressing diverse areas including standards development, EHR and supply chains.

Although ICT does not currently account for a large proportion of total healthcare expenditure in Australia — estimates varying from no more than 1 per cent up to about 3 per cent of expenditure (DoHA, sub. 34; GAP 2005; HealthConnect Program Office 2003a) — this is still a large amount of money (about \$0.7–\$2 billion per year). This proportion is, however, lower than in a number other countries, such as the United Kingdom and United States, where health ICT expenditure is estimated to be around 4–5 per cent of healthcare costs.

Table K.2 Australian health ICT — some national developments

1993	National Health Information Agreement signed, laying foundation for collection of consistent health data sets and National Health Data Directory. National Health Information Management Group established to oversee development of national standards.
1995	National Health Information Development Plan agreed.
1998	National Health Information Management Advisory Council (NHIMAC) established to supervise national projects and standards development in health ICT.
1999	National Electronic Health Records Taskforce (NEHRT) established by NHIMAC to develop a coordinated approach to electronic health records in Australia. NHIMAC releases <i>Health Online: A Health Information Action Plan for Australia</i> (second edition released 2001). National Public Health Information Development Plan released.
2000	National Supply Chain Reform Task Force established. NEHRT report, <i>A Health Information Network for Australia</i> , released (July), recommending a national health information network be created (this became HealthConnect). Health Ministers agree to jointly fund two years' research to assess the value and feasibility of a longitudinal health record (HealthConnect) (November). National Health Privacy Working Group established.
2001	National Health Data Dictionary and Management Process Review. Establishment of Health eSignature Authority, an independent registration company, to facilitate the introduction of Public Key Infrastructure in the health sector. <i>Setting the Standards: A National Health Information Standards Plan for Australia</i> released.
2002	Release of <i>National Action Plan to Facilitate the Uptake of e-Commerce in Australian Hospital Supply Chains</i> . National Electronic Decision Support Taskforce established. Broadband Advisory Group announced, to develop advice on broadband development, with health as one of the sectors of greatest interest in terms of productivity effects. HealthConnect trials start in Northern Territory and Tasmania.
2003	MediConnect field tests in Launceston and Ballarat announced. Draft National Health Privacy Code circulated for public consultation. Draft Standards Plan, <i>Foundations for the Future: Priorities for Health Information Standardisation in Australia, 2004–2008</i> , released. Governance arrangements for Information Management (IM) and ICT merged, leading to creation of National Health Information Group (NHIG) and Australian Health Information Council (AHIC). NHIG represents the jurisdictions, providing advice on national health information and related technology planning and management requirements; and managing and allocating resources to projects and working groups that involve joint Commonwealth and State/Territory resources. AHIC is an expert advisory group that advises Health Ministers via the Australian Health Ministers' Advisory Council (AHMAC) on how to address current/emerging needs in healthcare delivery, management and planning through IM&ICT.
2004	Funding for next phase of HealthConnect announced (March). Health Ministers endorse in-principle establishment of national entity to drive national health IM&ICT priorities (April). AHMAC recommends establishing transition team to progress urgent priorities and finalise creation of new entity. Health Ministers endorse immediate establishment of transition arrangements, with the transition team known as the National E-Health Transition Authority (NEHTA) (July).
2005	NEHTA established with three-year work program (January).

Sources: BCG (2004); HealthConnect Program Office (2003a); NEHTA (2005a); NOIE (2002d).

This partly reflects the fact that the Australian healthcare industry has generally been relatively slow to take full advantage of potential advances in ICT (DoHA, sub. 34). It has been estimated, for example, that of the 40 000 to 50 000 'health environments' in Australia (hospital services, general practitioners (GPs), allied health professionals, nursing homes, etc), 'many thousands' have no information technology capability (GAP 2005, p. 9). Many hospitals have primitive ICT administrative systems compared with other businesses of comparative size.

Moreover, implementation has tended to be undertaken in a localised, uncoordinated and fragmented manner. A study in Victoria in the 1990s found that even within the same hospital, different areas used different systems that did not 'talk' to each other (Moncrief 2005). The ICTeHealth project, which began in 2001 in New South Wales, also found 'no demonstrated interoperability' between systems within hospitals (Australian Electrical and Electronic Manufacturers' Association (AEEMA), sub. PR49, p. 11).

In its review for the NHIG and AHIC, the Boston Consulting Group (BCG) (2004) identified 363 current or planned health ICT initiatives in Australian public and academic sectors, involving 21 different jurisdictions and health entities.¹

- The average size of these projects was very small — around 70 per cent having a total budget of less than half a million dollars — with some projects possibly too small to deliver desired outcomes.
- There was duplication in some areas of activity that 'would be more efficiently and effectively performed at a national level' (BCG 2004, p. 43).
- A large number of projects were in areas such as patient and provider directories, which BCG (2004, p. 43) argued 'suggests that stakeholders are trying to meet their immediate needs in the absence of a national solution'.
- Most State and Territory expenditure (more than \$350 million over two years) was for clinical information systems (CISs), patient administration systems (PASs) and EHR in their hospital systems, accounting for most new project expenditure.
- Little funding (about \$7 million over two years) was allocated to developing standards.
- A relatively low priority was attached to electronic decision support (EDS) and broadband rollout.

¹ It also identified some private sector projects, but did not capture these in a comprehensive way because of the fragmented nature of funding and provision, and commercial issues that limited information availability. It noted, however, that private sector ICT investment is significant in radiology, pathology and private hospitals.

Importantly, fewer than half of the reported initiatives had scoped a business case, with only a handful of those identifying quantifiable financial, clinical or outcomes-based benefits to be achieved in a certain timeframe.

BCG (2004) also identified various factors that have contributed to the lack of progress in health ICT implementation.

- *Resourcing and governance arrangements.* Many of the initiatives identified by the BCG involve part-time or intermittent participation of people in committees and working parties. Moreover, under current governance arrangements, committees often have unclear decision making authority and ‘are often incapable of resolving the critical commercial and other trade-offs required’ (BCG 2004, p. 53).
- *Lack of standards in key areas.* Crucial to system interoperability, standards are seen to be necessary in areas such as software engineering processes and system operability (messaging, data definitions and domains); terminology and coding; identifiers (for patients and service providers); and legislation. ACT Health (sub. 11, p. 2) observed, for example, the concerns of some ‘that disparate data formats and the subsequent need for translation programs could increase communication problems that this technology is supposed to reduce’.
 - The BCG (2004, p. 50) suggested that the importance of standards is not reflected in investment plans for their development in Australia (contrasting this with the situation in the United Kingdom and Canada (box K.3)).

Box K.3 Overseas funding for standards development

‘This misalignment [between the priority attached to, and expenditure on, developing standards] in Australia is reinforced when compared with the approaches adopted by the UK and Canada. The Canada Health Infoway plans emphasise standards development and adoption. Infoway has committed between C\$190m and C\$240m (approximately 20% of its budget) to the development of architecture and standards over 4 years. The UK NHS [National Health Service] Information Authority, which is tasked with coordinating national investment in an arguably less complex environment, has an annual budget of approximately A\$240m — A\$55m of which is committed to setting and agreeing standards, service support and health informatics development.’

Source: BCG (2004, p. 51).

- *Inadequate attention to change management.* BCG (2004, pp. 56–7) observed the need to engage ‘‘time poor’ clinicians and health professionals’ to encourage their use of ICT, and to overcome their scepticism about the direct benefits of new technologies. It noted that the failure of ‘many past health projects can largely be attributed to insufficient investment in training and change management’.

-
- *Nature of public funding arrangements.* The NOIE (2002d) commented, for example, that the use of ICT by healthcare providers has been discouraged where funding arrangements favour traditional service delivery mechanisms (that is, by providing reimbursement for using traditional inputs but not for ICT investment and services).
 - *Generally insufficient funding.* DoHA (sub. 34) noted the underinvestment in health ICT to date, while BCG (2004) also observed significant underinvestment by the States/Territories in the past. It can also be difficult to develop business cases to convince funding agencies (such as Treasuries) of the merits of health ICT initiatives, because of the fragmented, diffuse, less visible and longer-term nature of their benefits relative to some other initiatives (BCG 2004).
 - *Inadequate access to technology,* especially broadband networks, but also computer terminals on site. Broadband refers to high speed, ‘always on’ access to the internet, which has the capacity to transfer large amounts of information or graphics (DoHA 2004j). This makes it especially important in many health applications where ‘reliability and synchronous transmission are essential’ (NOIE 2002c). A lack of infrastructure to support broadband was one reason suggested for the ineffectiveness of an attempt to link Melbourne’s Alfred Hospital to facilities in Gippsland (AHA, sub. 25).

The fragmented nature of the Australian health system has also been suggested as a factor inhibiting health ICT uptake (Philipson 2005).

K.3 Major ICT administrative and support initiatives

Administration and support systems encompass the procedures, processes and protocols that facilitate the management and delivery of healthcare to consumers. This section outlines some of the various health ICT administrative and support initiatives that have been implemented at national, and State and Territory levels in Australia, as well as the uptake of ICT by general practitioners (GPs) and hospitals.

Initiatives at the national level

BCG (2004) found that a more strategic nationally-coordinated response was needed in some areas to overcome the lack of progress in implementing health ICT. To this end, national solutions are being pursued, some involving cooperation between the Australian and State/Territory Governments, in areas such as standards, EHR and broadband access.

The National E-Health Transition Authority (NEHTA)

Based on a collaborative approach, NEHTA is jointly funded and governed by all Australian jurisdictions, with an overarching role to facilitate cooperation in developing e-health foundations. NEHTA will develop the specifications, standards and infrastructure necessary for an interconnected health sector, and is responsible to the Australian Health Ministers' Advisory Council (AHMAC) and Health Ministers. An Advisory Committee of experts and jurisdictional representatives has been established to provide guidance (NEHTA 2005a, 2005b).

Its arrangements were formalised in January 2005, with \$18.2 million allocated to it over the three years from 2005-06, to fund its core activities. This was in addition to the \$9.5 million already committed for 2004-05 priorities (box K.4). It will seek to leverage existing projects to progress its work.

Box K.4 Priorities of the National E-Health Transition Authority 2004-05

In July 2004, the Australian Health Ministers Advisory Council endorsed the establishment of NEHTA, agreeing to a specific 12-month work program and deliverables for the Authority. This focused on finalising the design and transition to the new e-health entity and progressing the 12-month national health IM&ICT priorities:

- clinical data standards and terminologies;
- patient, provider and product identification standards;
- patient, provider and product directories;
- supply chain;
- consent models;
- secure messaging and information transfer; and
- technical integration standards.

Sources: NEHTA (2005a, 2005b).

In July 2005, NEHTA commissioned a consultancy to review standards being developed internationally and to make recommendations about local adoption. In August, it published an updated work plan for 2005-06, and a new framework for interoperability. The framework represented a 'high-level description of the interoperability task at the organisational, technical and information levels', and is to be updated regularly (Dearne 2005m, p. 30).

Although its work is widely acknowledged as important (Woodhead 2005c), some concerns — including about its likelihood of success, approach and the nature of its work — have been expressed.

Since its establishment in late 2004, NEHTA's focus has changed from one of 'exhaustive testing [of] applications to letting different states and health providers introduce their own electronic health systems while it tries to develop standards which it hopes will allow the different systems to work together' (Stafford 2005d, p. 6). The standards focus has led to some concern about possible overlap between NEHTA's work and that of Standards Australia, particularly its IT-014 Health Informatics Committee (AEEMA, sub. PR49; Dearne 2005k).

These concerns were highlighted by the reaction to the July 2005 release of NEHTA's first draft clinical data specification (for pathology and imaging). Some medical and industry observers believed this appeared to be 'a rework of existing standards developed by the Standards Australia pathology messaging working group, which are in widespread use' (Dearne 2005k).

The Chief Executive of NEHTA (cited in Dearne (2005k)) countered that 'we will use the work that has already been done as a reference point in the work we will undertake, but in a number of areas in clinical information specifications there's no existing body of work'. Seagrave (2005), of Standards Australia, also argued that the relationship between NEHTA and Standards Australia was clear — NEHTA responsible for developing specifications for national public e-health initiatives in the public health system (represented by Australian and State/Territory Governments), and Standards Australia responsible for developing Australian standards with a consensus-based approach.

HealthConnect

Australia's proposed health information network, *HealthConnect*, is a joint initiative of the Australian and State/Territory Governments, endorsed by Health Ministers. Initiated as part of the national e-health strategy, it was the result of a recommendation by the National Electronic Health Records Taskforce in 2000. The concept involves the collection (subject to patient consent), storage and exchange of health-related information in the form of an 'event summary', in a standardised electronic format. It will allow a summary to be accessed from *HealthConnect* by healthcare providers for future episodes of care, regardless of location, with consumers having access to their summary via the internet.

Trials have been used to test the concept's feasibility in a 'live' setting, with each trial site focusing on a specific health issue or population group where benefits are thought to be especially likely. The first sites were Tasmania (diabetic patients in Clarence, then expanded to almost all providers in southern Tasmania), followed by the Northern Territory (remote Aboriginal communities in Katherine). Further trials are underway in, or planned for, Queensland and New South Wales, with Western Australia and Victoria also

possibilities. The New South Wales trials draw on pilots undertaken in Greater Western Sydney and the Hunter as part of that State's EHR system, Health e-link. (DoHA, sub. 34; Fujitsu Consulting 2004b; GAP 2005; HealthConnect Program Office 2004a, 2004b, 2003a)

HealthConnect will also incorporate MediConnect, the national electronic medication record system, field trials of which were conducted in Launceston (Tasmania) and Ballarat (Victoria) in 2003-04. It will be the medicines component of HealthConnect, aiming to improve medication management and to reduce adverse events.

Full implementation of HealthConnect was to begin in 2005 (for a 2006 completion), in all of Tasmania, an extended area of the Northern Territory, and in South Australia, which has an integrated hospital information network that feeds into HealthConnect. Following a review of the trials (HealthConnect Program Office 2005a), concerns about legal issues (HealthConnect Program Office 2005b), and release of a new implementation strategy, these plans were modified, with delays of up to six months expected by some (Dearne 2005j; Crawford 2005). The Tasmanian rollout, for example, is scheduled to start in November 2005, with a project standardising electronic clinical messaging from Launceston General Hospital to GPs in the surrounding area (Dearne 2005n).

Financial incentives

As noted above, the availability of suitable broadband technologies is constrained, particularly in rural and remote areas. In a survey of ICT use in general practice (DBI 2004), 49 and 23 per cent of respondents said improved affordability and availability respectively would make them consider broadband connection.

Thus, the Australian Government has provided incentives to encourage the uptake, not only of specific ICT applications by GPs (box K.5), but also of broadband by GPs, Aboriginal Health Services and pharmacists (box K.6). It has also established a 'Reference Site' in Western Australia to test, measure and demonstrate the benefits to healthcare providers of 'high-speed, continuous, high-quality broadband connectivity' (box K.6).

Apart from offering potential benefits to providers, improving broadband access is seen as important to support broader health ICT initiatives. DoHA (2005a) noted, for example, that broadband can support various activities including HealthConnect. In combination, the GP and pharmacy initiatives also offer the potential to improve connectivity between GPs and pharmacies.

Box K.5 Practice Incentives Program (PIP)

The PIP aims to compensate for limitations in fee-for-service arrangements, with payments focusing on aspects of general practice that contribute to quality of care. Payments are provided based on patients' ongoing healthcare needs, not service volumes, and aim to promote activities including the use of electronic information management systems. It also provides incentives for the establishment of consumer registers and recall systems for patients with diabetes (including a one-off payment for establishment and activation, and a service incentive payment for annual completion of minimum care requirements).

All practices receive \$3 annually per standardised whole patient equivalent (SWPE) (the average GP sees 1000 SWPEs annually) for providing data to the Australian Government (on application and in response to other requests).

Specific incentives to encourage computerisation of practices under the PIP Information Management, Information Technology program are:

- \$2 annually per SWPE for the use of *bona fide* electronic prescribing software to generate the majority of prescriptions; and
- \$2 annually per SWPE for the use of computer systems to send and/or receive clinical information.

PIP practices covered around 80 per cent of Australian SWPEs in May 2004.

Sources: DoHA (2001b); HealthConnect Program Office (2003b); SCRGSP (2005).

State and Territory Government initiatives

For the most part, State and Territory initiatives involve the development of interoperable systems, such as PASs and CISs, within their public hospital networks, and the development of statewide EHR. Victoria, for example, launched its whole-of-health strategy, HealthSMART, to modernise the State's public health system ICT in 2003, allocating \$323.5 million over 10 years to the project. It involves six major areas: resource and patient management systems, and electronic medication ordering across health services; clinical systems, including access to results and an initial structure for EHR; and a technology 'refresh' plan and governance structure for shared ICT services (VDHS, sub. 24).

In other cases, health ICT projects are leveraging off broader ICT initiatives. Rollout of a web content management system to New South Wales area health services, for example, was to follow the full installation of that State's statewide broadband initiative (Foreshaw 2005). The project aims were to deliver common content and authorisation processes, streamline processes and facilitate staff access to information, as well as provide 'substantial cost savings' (Foreshaw 2005).

Box K.6 National health broadband initiatives

Broadband for health

Announced in July 2004, this three-year \$35 million initiative aims to support the uptake of broadband services to general practices and Aboriginal Community Controlled Health Services (ACCHSs) across Australia. It brings together the second Practice Incentives Program (PIP) EHR payment and Access to Broadband Technology funding.

It involves a two-stage implementation. The first, from August 2004, supports the immediate uptake by approximately 5500 Australian general practices and 200 ACCHSs of 'health business-grade broadband' services that meet specified service standards. The second will involve facilitating uptake of advanced broadband arrangements, allowing access to services including Virtual Private Networks, Voice over internet Protocol and videoconferencing.

Broadband for health: Pharmacy

Announced in February 2005, this one-year \$14.5 million initiative aims to support the uptake of broadband internet services for 5000 community pharmacies across Australia. It is expected to provide about \$1700 per pharmacy. It uses funding from the Third Community Pharmacy Agreement, and builds on the Broadband for Health program for GPs and ACCHSs. Suggested benefits to pharmacists include the ability to access Continuing Pharmacy Education material online, conduct online banking and ordering and, in the future, send Pharmaceutical Benefits Scheme (PBS) claims to the Health Insurance Commission via PBS Online.

Eastern Goldfields Regional Reference Site

This Site is being established in an area of Western Australia including Kalgoorlie-Boulder, Wiluna and Esperance. It will 'test, measure and demonstrate the value' of some key health services and applications that can be delivered by advanced broadband. It is expected to inform future connectivity plans and provide practical experience in the adoption of broadband across the Australian health sector and other sectors. GPs, local specialists, Aboriginal medical services, radiology, pathology, the local division of general practice, and regional and district hospitals were invited to participate, with work being conducted to extend the site to pharmacies, aged care facilities and rural clinical schools.

Sources: DoHA (2005a, 2005e, 2004d); Riley (2005).

GPs and ICT

GPs are an important link in overall healthcare delivery, being the first point of contact with the health system for many patients, and providing ongoing support for those with chronic conditions.

GP use of ICT in Australia has increased in recent years, but uptake varies across uses (box K.7) and settings. Up to 90 per cent of Australian GPs are estimated to have desktop computers (GAP 2004b; 2005). A survey conducted in 2003 (DBI 2004) found that GPs most commonly used computers to write prescriptions, access health information, and for clinical records (with 81, 77 and 75 per cent using these applications respectively). More than half the respondents also used computers to access knowledge, for patient recalls and to write letters. In addition, over 90 per cent of practices used a computer at reception (for tasks such as word processing, appointments and practice management).

Box K.7 Some clinical ICT applications used in general practice

Electronic Decision Support Systems (EDSSs). EDSS software allows GPs to enter information directly into the system during each visit. EDSSs can provide functionality including the ability to calculate a patient's risk scores for particular diseases, provision of comprehensive profiles that can be recalled in future visits, access to clinical guidelines and evidence-based management plans, and electronic prescribing. They are seen as a key to the delivery of safe and good quality healthcare, especially as much of the rapidly increasing volume of medical knowledge is stored electronically. Consultations can be conducted more interactively — the doctor can show risk score calculations as they are done, and present embedded information resources and videos as a basis for discussing treatment and disease management options. In this way, patients can be made more active and knowledgeable participants in their care.

Electronic prescribing involves GPs using a software program, several of which are available, to issue prescriptions. Most packages incorporate decision support features such as prompts and warnings, and links to further information. Potential benefits of such systems include clear and legible prescriptions, decreased risk of prescribing errors, fast access to patient records and enhanced prescribing safety.

Sources: Ahearn and Kerr (2003); Beilby et al. (2005); Coombes et al. (2004); Newby et al. (2003).

Electronic prescribing was used by 92 per cent of PIP practices in November 2004, with 91 per cent of these practices having the capacity to send and/or receive clinical information through computer technology (HIC 2005g). This represented a substantial increase on the adoption rates — of 52 and 70 per cent respectively — that existed when the PIP incentives were introduced in August 1999. Most of the growth in use occurred during the first years of the incentives. Use in 2004 was highest in the ACT, and lowest in the Northern Territory. Practices in rural areas were the most likely to use ICT solutions, with those in remote areas least likely to use electronic prescribing (SCRGSP 2005).

Some GPs are using ICT to replace traditional modes of service delivery. A software program established in Sydney, for example, is used by 60 GPs to conduct secure email

consultations with over 1400 patients across Australia (Bryan 2004a). It is to be offered to other GPs and other health professionals to share care plans of heart failure patients in Sydney's inner western suburbs (Bryan 2004a). Nonetheless, participation by this number of GPs represents only a small proportion of the 25 000 registered GPs in Australia (Jay 2004).

ICT in hospitals

General advances in ICT have allowed many changes in the way healthcare is delivered in hospitals, including in the way patients are monitored. Typical applications include those that aid electronic medication management, and patient administration and clinical information systems. There have also been various trials of EDS tools within hospitals across Australia, aided by the use of new technologies such as palm pilots (see, for example, Woodhead 2004a, Dearne 2005d and Litster 2005). Three Victorian hospitals and some private specialists in Queensland have, for example, adopted personal digital assistants (PDAs), which have been used by anaesthetists in 38 000 operations in Australia in two years (Heaney 2005). Expansion to other medical disciplines is also in progress. Other applications, yet to widely used, include systems for Radio Frequency Identification (RFID) (based on electronic identification technology that transmits information via radio waves) (Lewin Group 2005; Martin 2005), pain management (Cadden 2005), and resource management (using mathematical models to help chart, monitor and predict the flow of patients through a hospital) (Cronin 2005; University of Melbourne 2005).

Most of the more advanced administrative and clinical ICT applications are in development and/or trial stages. Many of these are being driven by initiatives and funding of State/Territory Governments which, given their role in the provision of public hospital services, have been more directly involved in hospital-based, than in GP-focused, solutions.

Some projects and trials have also been initiated at the hospital-level, including in the private sector. The Wesley Private Hospital in Brisbane, for example, spent about \$10 million and nearly three years testing clinical software and EDS tools, which will now be deployed in all Uniting Health Care private hospitals in Queensland (Dearne 2005d). In Melbourne, activities ranging from patient management to prescribing will be electronic in Australia's first 'wireless' hospital, the \$85 million Epworth Eastern private hospital, which opened in August 2005 (Mitchell 2005).

Hospitals are also using ICT to enhance links with other hospitals, suppliers and other organisations. In Victoria, for example, the South West Alliance of Rural Hospitals (SWARH), an alliance of public health agencies comprising 12 hospitals and 33 sites, built

its own \$9.8 million internet-based communication system — SWARH*Net (NOIE 2002a). This included expanding its existing network to make broadband available at much lower cost than previously. A similar model has been established by the New England Area Health Service in New South Wales, following the joint opening of an \$11 million communication facility linked to the region's hospitals and healthcare providers, the University of New England and the Institute of Technical and Further Education (Dearne 2004a).

K.4 Potential benefits of ICT initiatives

The range of possibilities provided by ICT advances has led some to see ICT as the solution to many problems currently confronting hospitals and the healthcare sector in general. Such problems include staff and other resource shortages; administrative waste; errors in the prescribing, administration, dispensing and documentation of medication; and the slow movement of information through the system (such that patients are often discharged from hospitals before all test results are known). The ultimate aims of adopting ICT are, therefore, to increase efficiency and improve quality of care.

Hospitals

The benefits (as well as the costs) of ICT in hospitals depend on what is implemented and how. A study of US hospitals (cited by DoHA, sub. 34) found CISs provided:

- 13 examples of cost savings (including in relation to reduced medication errors, communication of clinical care documentation, test reporting, staffing, records storage, and information processing);
- administrative benefits in terms of documentation and improved capture of charging codes; and
- clinical benefits in terms of improved quality of care and improved communication between providers, resulting in more responsive patient care.

DoHA (sub. 34) has argued that the major impact of ICT was likely to be on quality of care, although few formal available studies link the two (Cochrane 2005).

Other US studies have shown electronic medication management systems reduce the rate of adverse drug reactions and prescription errors by 40.9 and 99.4 per cent respectively (cited by the AHA, sub. 25). The systems can also be used to order X-rays, pathology, special diets and other patient services.

Similar and other benefits have been demonstrated in various Australian trials.

- An electronic medication management trial conducted in the Northern Territory resulted in a 67 per cent reduction — from one hour to 20 minutes — in the duration of nurse drug rounds (DoHA, sub. 34).
- Wireless networking and internet telephony systems installed by private health insurer NIB at the Newcastle Private Hospital resulted in a significant reduction in doctor and nurse response times to emergencies, aided by the wiring of bedside emergency call buttons directly into the system; and easier access to key staff regardless of their location, with staff able to receive pages and messages on mobile phones (Woodhead 2004c).
- The use of Palm Pilots (handheld computers or PDAs) by staff in a wireless trial at Melbourne's St Vincent's Hospital (Cochrane 2005) gave them access to applications (such as drug and medical databases, and the hospital intranet) while on rounds. The trial resulted in reduced: transcription errors; transcription times (by 13 minutes a day); and 'breakouts' (the time staff had to leave a patient's bed to access reports) by 46 per cent, although the duration of ward rounds was unchanged (Cochrane 2005).
- The use of PDAs in trials among training anaesthetists resulted in 98 per cent of adverse incidents being reported, compared with the usual 40 per cent (Cresswell 2005). It is hoped that better reporting will help to identify areas in need of improvement, thereby eliminating 'the vast majority' of adverse events in hospitals. These have been estimated to cost up to \$5 billion a year (Cresswell 2005).
- The use in Victoria of an electronic bed tracker, which provides bed availability data online, removed the need for emergency department staff to ring around wards to find an available bed. It resulted in 30 per cent more patients being moved to beds within 12 hours (Jakubowski 2005).
- As part of its system to capture and record information about surgical implants at Canberra Hospital, ACT Health has installed a point-of-use data capture tool (handheld computer plus barcode scanner) that interfaces with its inventory management system (Dearne 2004b). This allows it to ensure its product data are up-to-date and to track expenditure by surgeon (which can in turn be used to provide feedback to doctors and managers) (Scott 2005). The long-term aim is to fully integrate the system into patient and revenue management systems, and link these directly with the hospital's suppliers (Scott 2005).
- Although lower than expected, the SWARH*Net system (section K.3) resulted in cost savings of 30 per cent and 70–80 per cent on telephone and videoconferencing costs respectively by 2002. There were additional savings due to the reduced need to travel because of the increased use of videoconferencing. (NOIE 2002a; VDHS, sub. 24). The

network's establishment also provided the potential for expanded uses (such as wireless handheld devices and record sharing between GPs and hospitals), and for enhanced access to clinical services for people in rural and remote regions, 'without having the normal increase in costs' (NOIE 2002a).

- The New England Area Health Service in New South Wales also expected substantial benefits — cost savings of \$530 000 and \$130 000 for fuel and vehicle repairs respectively, as well as significant reductions in unproductive staff time by providing some community health, home nursing and emergency services over the broadband network (staff sometimes spend more time travelling than providing care). Use of cheaper phone telephony is estimated to offer savings of between \$800 000 and \$1 million. (Dearne 2004a)
- A reportedly successful 18-month e-procurement pilot at the Royal Brisbane Hospital resulted in gains from automating workflow, and cost savings of 10–20 per cent. It did, however, take some time to 'get the data synchronisation completed' (Dearne 2004b, p. C01).

GPs, EDSS and electronic prescribing

A review of studies (cited in Beilby et al. 2005) found that 64 per cent documented improvements in practitioner performance, mainly in disease management systems, but also in prescribing, and reminder systems. Relatively few (4 per cent) reported improvements in diagnosis. Of those that examined patient outcomes, however, only 13 per cent showed improvement.

In general, although there are various potential benefits of ICT uptake by GPs, for the most part, it appears that ICT is not being applied in the most cost effective way in Australian general practice. For example, GPs tend to use ICT mainly for storage and retrieval of information, and are not integrating systems within their own practices, let alone using them for external information transfers (GAP 2005). External factors, such as costs, a lack of a unified system to link to (because hospitals are not online), and an inability to automatically electronically invoice Medicare (efficiently) (Audet et al. 2004; *The Economist* 2005; HealthConnect Program Office 2003a, 2005a), have influenced the nature of ICT use by GPs and, therefore, the benefits derived in practice. Internal factors are also important. For example, practice managers, the main decision-makers for technology issues within practices, were identified during the HealthConnect and MediConnect trials as key influences on GP participation (DBI 2004; HealthConnect Program Office 2005a).

Most discussion in the literature has related to the impact of electronic prescribing. On the one hand, when accompanied by appropriate decision support, e-prescribing is seen as a 'key initiative to prevent patient harm', as it decreases the chance of prescribing error and

increases patient safety (Coombes et al. 2004, p. 141). GPs in one Australian study reported that using the software increased awareness of patient allergies, was sometimes useful to educate patients, assisted with compliance and facilitated doctor–patient interaction (Ahearn and Kerr 2003).

On the other hand, many problems with e-prescribing software have also been noted. This includes the extra time need to generate prescriptions, while some GPs have expressed concerns about inadequate prescriber support offered by current packages, including:

- irrelevant, repetitious and time-consuming prompts, and excessive information on drug interactions — all being listed regardless of frequency or severity — which can desensitise GPs to them, creating the risk that important alerts or information are missed (ACT Health, sub. 11; Ahearn and Kerr 2003);
- that not all important interactions mentioned in printed textbooks are in the interactive checking facilities of some programs (Ahearn and Kerr 2003); and
- lack of ready access to information on newly approved drug uses (ACT Health, sub. 11).

Coombes et al. (2004) also noted that e-prescribing without decision support has been associated with *increased* errors and inappropriate medication use. It has also been suggested that the prescription software program used by most GPs has contributed to inappropriate prescribing and increased Pharmaceutical Benefits Scheme (PBS) expenditure (Stafford 2005a).

- One Australian study (Newby et al. 2003) found that doctors using e-prescribing software were more likely to issue repeat prescriptions for antibiotics to treat upper respiratory tract infections than were those issuing handwritten scripts (69 and 40 per cent issued with repeats respectively). The authors attributed this to the default settings on the software, and suggested it could result in an extra 500 000 prescriptions of the medications in question being dispensed annually.
 - Default settings were the target of one attempt to contain PBS costs in the 2005-06 Australian Government budget. It included measures to install new prescribing software with the default set to select the cheaper generic medicine (Frenkel et al. 2005).
- Others have pointed to the influence of an apparent lack of independent comparative information and the advertisements that appear when doctors enter information on the system (see, for example, Dearne 2005g; Harvey et al. 2005; Pollard 2005b). Harvey et al. (2005, p. 78) suggested that, as well as leading to unrealistic consumer expectations, ‘pharmaceutical promotion in prescribing software, occurring at the time of physician–patient decisionmaking, may be more powerful than promotion in medical journals, gimmicks and giveaways’.

Electronic health records

Many see EHR as the ultimate aim of ICT investment (BCG 2004). Indeed, many Australian health ICT initiatives, at State and Territory and national level, incorporate, support or lay the foundation for EHR (section K.3).

EHR, by providing improved access to patient information, are seen to be a means of facilitating the better cooperation and coordination of healthcare workers, offering various potential cost savings and benefits to consumers, health service providers and the health system in general (box K.8). Sixty-five per cent of respondents to an Australian health informatics survey conducted in 2004 described a ‘single patient record’ as ‘vital’ to the healthcare industry, with perceived benefits including better health outcomes (79 per cent of respondents), better customer service (62 per cent), increased productivity/efficiency (60 per cent) and greater ease working with partner organisations (56 per cent) (InterSystems 2004).

The benefits are seen to be especially significant in relation to patients with chronic conditions, who have a long-term medical history and/or need to see many different providers. In addition, implementation of EHR is seen as critical to facilitate the development of other health ICT applications, such as telehealth and telemedicine (Alvarez 2005), and neural networking (Bates and Gawande 2003).

Some of the expected benefits that have driven the desire to implement EHR appear to have been realised in Australian trials so far. For example, many users of *HealthConnect* perceived the information collected to be of clinical use, with improved communication between hospitals and GPs, while the South Australian Oacis system has seen a ‘noticeable reduction’ in the number of pathology and radiology tests ordered (*HealthConnect* Program Office 2003a). It has also been found that providers seek information more often when using EHR, potentially improving their ability to manage chronic disease.

The report of the National Electronic Health Records Taskforce (table K.2; cited in *HealthConnect* Program Office 2003a) provided some indicative — apparently conservative — figures of \$300 million in annual cost savings due to EHR. These comprised reductions in hospitalisations and deaths arising from adverse events, reductions in unnecessary duplication of tests, increased productivity through reduced absenteeism, and reduced expenditure on disability support. In the United States, annual net savings resulting from widespread adoption of EHR have been estimated to be between 7.5 and 30 per cent of annual healthcare expenditure (Lewin Group 2005).

Box K.8 **Current problems potentially reduced by EHR**

Adverse events. There is no accurate figure of the number of adverse events that occur in Australian healthcare. A 1995 study found that 16.6 per cent of people admitted to hospitals in the sample experienced an adverse event, 51 per cent of which were estimated to be preventable (although this figure varies across studies). Of the reported events, 13.7 per cent resulted in permanent disability, 4.9 per cent in death. More recent research has suggested that 10 per cent of all hospital admissions are due to avoidable adverse events (medication and non-medication).

In terms of overall numbers, it has been estimated that about 3000 adverse events occur across Australia each year:

- associated with 3.3 million patient bed days (\$800 million per year), and an average length of stay of 7 days each; and
- a high proportion of which may occur in older patients, so may increase in line with the ageing of the Australian population.

Medication errors. Around 140 000 (2–3 per cent of total) hospital admissions each year are associated with medication errors (misuse, underuse, overuse and reactions), with the number growing each year. About 32 to 70 per cent of these are estimated to be preventable. It has been estimated that:

- preventable drug errors cause about 4000 patient deaths annually, and cost the health budget about \$1.5 billion in direct and indirect costs; and
- inappropriate medicine use costs the public hospital system approximately \$380 million per year.

Recent research even suggests that about 10 per cent of hospital admissions are due to some medication ‘mishap’.

Transcription errors resulting in redundant pathology tests — can account for up to 40 per cent of tests in some cases (total test expenditure is \$1.4 billion, or around 4 per cent of total health service expenditure nationally).

Communication problems between hospitals and general practitioners — one study finding that nearly 80 per cent of GPs had not been told their patients had been hospitalised, and more than 70 per cent did not receive discharge information.

Sources: AHA, sub. 25; Australian Council for Safety and Quality in Health Care (2005); Dearne (2005c); DMR Consulting (2004); Richards (2005); VDHS, sub. 24.

DMR Consulting (2004) suggested that a significant proportion of adverse events could be eliminated by *HealthConnect*. (This would have subsequent benefits in terms of reduced morbidity and mortality, and improved patient care, but would not necessarily produce ‘obvious’ financial savings because hospitals are more likely to use any freed up resources to decrease waiting lists rather than close hospital beds.) Assuming 100 per cent uptake, it estimated that 47 per cent of avoidable adverse drug events could be avoided by *HealthConnect*, resulting in potential benefits worth \$231 million per year.

Other quantitative estimates of the *expected* cost savings and quality of care improvements resulting from EHR (and related ICT initiatives) have been made. The VDHS (sub. 24), noted for example, that its HealthSMART initiative is expected to produce benefits to hospitals such as:

- a 3.2 per cent decrease in length of stay;
- a 43 and 25 per cent reduction in turnaround time for radiology and pathology results respectively;
- faster filling of admission medication orders (over one hour faster), a 34 times faster filling of daily drug orders, and 81 per cent decrease in medication errors with electronic prescribing; and
- up to 15 per cent more time available for clinical staff to spend with patients.

K.5 Costs and cost effectiveness of ICT initiatives

Costs involved in implementing EHR relate to explicit government expenditure (incorporating infrastructure and recurrent costs involved in trials, planning, implementation and review), and staff time and training.

The cost of many ICT solutions, especially in early implementation stages, can be substantial. It has been commented, for example, that ‘developing a nationwide e-health records system for 20 million people may cost several billions of dollars’ (Dearne 2005c, p. C01). The HealthConnect Program Office (2003a) estimated total expenditure necessary for HealthConnect would comprise:

- *establishment costs* of about \$30 million per year, over ten years (with an initial loading in the first five years);
- *annual recurrent costs*, of around \$160 million; and
- *indirect costs*, of about \$2–3 billion dollars, to provide the underpinning infrastructure. Only part of the ‘indirect’ expenditure can be attributed to HealthConnect, however, as some of this is, or will be, incurred independently of the project.

International experience also points to potentially substantial expenditure requirements; the Federal Government in Canada committing Can\$500 million for EHR development work, with a further Can\$2–3 billion expected from the provinces. Twelve billion pounds over five years have been allocated for the UK’s information technology infrastructure and operations, including EHR implementation.

Actual budget allocations for health ICT projects in Australia appear substantial. For example, the governments of Queensland, New South Wales and Victoria are spending more than \$850 million over several years on clinical and patient management software for hospital ICT (Woodhead 2005f), while South Australia's Oacis hospital clinical data repository received \$90 million from June 2000 to June 2005.

Even this level of expenditure is no guarantee of success. The systems installed ultimately may not provide the benefits sought. A New South Wales report, for example, found that \$5 million was allocated to a Statewide clinical risk management system that failed its technical evaluation, while a community health information technology program costing more than \$50 million required a further \$20 million to refit, with only 1200 users involved (Pollard 2005a). An unofficial review apparently also claimed that \$300 million had been 'wasted' on flawed information systems in New South Wales since the early 1990s (Woodhead 2005a).

Several million dollars have also already been allocated to the *HealthConnect* trials. The NT and Tasmanian trials were initially allocated \$2.5 million (\$1.5 million for Tasmania) (Patterson 2002). The 12-month extension of these trials announced in July 2003 saw a further \$2.1 million in Australian Government funding, supplemented by the Tasmanian Government, allocated to the Tasmanian trial, and a further one million dollars (\$900 000 Australian Government, \$100 000 NT Government) allocated to the NT trial (Patterson 2003a, 2003b). A further \$908 000 was allocated to the NT trial in August 2004, allowing it to expand to full pilot implementation, covering the whole Katherine region (Abbott 2004a). Additional expenditure was incurred in planning (estimated to be \$151 000 for the Tasmanian trial, for example (HealthConnect Program Office (2003b)), and research and consultants reports. Funding of \$2.9 million was allocated to the Brisbane and North Queensland trial projects in April 2004 (Abbott 2004c).

In addition, \$128 million over four years has been allocated for the implementation of *HealthConnect* in Tasmania, Northern Territory and South Australia. NEHTA has suggested that set-up costs for those jurisdictions and New South Wales and Queensland will reach \$150 million (Dearne 2005c). Significant expenditure is also expected for State and Territory feeder systems.

Overall expenditure requirements depend on how EHR are implemented. It was found in Canada, for example, that a failure to align EHR nationally would increase costs significantly (HealthConnect Program Office 2003a). National standardisation would halve the expenditure required.

The registration method chosen — 'opt-in' or 'opt-out' — is also a crucial factor. An opt-out system has now been legislated in Canada as the more efficient option, after it was

found that only 1 per cent of people did not want to participate in the system. In contrast, an opt-in system is planned for *HealthConnect*, being seen as more feasible in the Australian context (GAP 2005). In June 2005, the NSW Government proposed changing the consent model for its Health e-link project to an opt-out system, mainly due to the cost of the alternative (estimated to be \$350 million) and the fact that consumer groups accepted it (Pollard 2005c). Issues surrounding the consent model remain unresolved.

Cost effectiveness of EHR

The potential benefits of EHR have been estimated to be several times the implementation costs (DoHA, sub. 34; *HealthConnect* Program Office 2003a; Lewin Group 2005).

- In the United States, one study found a net benefit of US\$84 600 per provider from using electronic medical records for a five-year period (due to savings in drug expenditures, improved use of radiology tests, better capture of charges, and decreased billing errors). The US Healthcare Information and Management System Society estimated net savings in excess of US\$87 billion per year from standardised electronic health data (*HealthConnect* Program Office 2003a).
- In the United Kingdom, one project has resulted in estimated time savings of 4 to 8 per cent, with implied annual expenditure savings equivalent to project costs over the next five years (*HealthConnect* Program Office 2003a). Another project has also reported time savings that are expected to outweigh development and implementation costs as rollout expands.

At a general level, the overall cost effectiveness of systemwide EHR will be affected by how they are implemented, participation rates, and the time taken to implement — longer timeframes tend to reduce cost effectiveness. The impact of delays has been evident in State and Territory Government hospital ICT initiatives. These have faced concerns about tendering; sometimes significant cost blowouts, with reviews and overhauls often required (Bryan 2004b; Parnell 2004); and delays in implementation. The clinical system project in Queensland, for example, has been scaled back, with more autonomy given to local area health services, which had been frustrated by delays occurring under the more centralised approach (Woodhead 2005d).

The initial *HealthConnect* timeframe has not been met: the research and development phase initially proposed to run from July 2001 until June 2003, was subsequently expanded until June 2005. The duration of the *MediConnect* field trials (section K.3), also considerably exceeded the scheduled timeframes (*HealthConnect* Program Office 2005a). The revised implementation strategy published in 2005 did not provide a timeframe for completion.

To date, the trials have produced mixed results. Although demonstrating technical feasibility and some, if limited, benefits, many difficulties have also emerged.

- Forty per cent of respondents to a questionnaire in the early stages of the Tasmanian trial found *HealthConnect* difficult or very difficult to use.
- It was felt that much of the information recorded was not of use, printed summaries were still used (so the electronic component became an administrative ‘add on’), and connection time, cited as the main barrier to use, was sometimes excessive (though a broadband connection made things easier) (*HealthConnect* Program Office 2003b).
- The number of patients involved in the trials comprised only a small proportion of the total workload of the relevant hospital staff (*HealthConnect* Program Office 2003b).
- Low participation rates and problems with ICT infrastructure in hospitals, with the *HealthConnect* Program Office (2005a) noting, among other things:
 - the trials ‘highlighted the need to better use clinical information systems within hospitals as a pre-cursor to implementing *HealthConnect*’ (p. 54);
 - a low level of readiness of GPs to participate, attributed to the fact that ‘many GPs do not utilise some of the facilities within the GP desktop that would be required for successful interoperability with *HealthConnect*’ (p. 57); and
 - that electronic prescriptions were only used in 1 per cent of cases in the Tasmanian trial, due to delays of up to 20 minutes between the time a prescription left the GP system and arrived at *HealthConnect* (p. 93).

Indeed, the size of some of the trials has been too small to provide insights for broader implementation (BCG 2004), with BCG (2004, p. 46) suggesting that ‘standardising these [PAS and CIS] initiatives is likely to contribute more to long-term EHR achievement than dedicated health records pilots or evaluatory research’.

The overall scope of the *HealthConnect* project has also changed, becoming far less ambitious. In contrast to the approaches adopted in the United States and United Kingdom, it does not involve building an entire electronic health environment (Dearne 2005c). Instead, it has become a ‘watered down’ version of what was originally planned, aiming to link existing and planned systems (that is, building on other initiatives). Dearne (2005c) commented:

The original plans for a grand, cradle-to-grave system have been dropped in favour of what it [the Government] hopes will be a more achievable goal — a stripped-down national network built around patient information ‘summaries’, rather than full clinical records. (p. C01)

After seven years of research and development, and 30 independent evaluation reports

(some unpublished), many unresolved issues remain — including database design and quality; whether *HealthConnect* will be a ‘passive’ or ‘active’ database; privacy, security and access control measures; and stakeholder liability (*HealthConnect* Program Office 2005b). That this is the case suggests that there have been gaps in the planning and evaluation of the project and/or how these have been acted upon — for example, why some issues that are fundamental to implementation, such as standards and database design — were not addressed earlier (see, for example, Dearne 2005j).

K.6 Telehealth and telemedicine

Although the terms are sometimes used interchangeably, telehealth and telemedicine can be seen as two different, though closely related, applications of ICT in medicine. In this appendix:

- *telehealth* refers to the electronic transmission of images, voice and/or data between two or more sites to provide health services such as clinical advice, consultation, education and training services, and administrative data processing;
- *telemedicine* relates to the provision of medical services by off-site practitioners, using telecommunication technologies (*HealthConnect* Program Office 2003a; VDHS, sub. 24).

The convergence of information and communications technologies (section K.1) has been a particularly important enabling factor in the development of telehealth and telemedicine. Telehealth applications in Australia have included the provision of information to consumers and healthcare providers (box K.9), with telemedicine applications including teleradiology and wound management (box K.10), and telepsychiatry.

The pace and diffusion of telehealth and telemedicine have varied across applications, influenced not only by their perceived benefits but also by the characteristics of the technology they require. At a general level, telehealth and telemedicine are seen as particularly important in improving access to medical services and information in Australia, given the vast distances and sparsely populated areas that characterise the nation. On the other hand, the technology required for many of these services can be extremely costly, if available at all, and is sometimes still inadequate for the desired application/s.

Box K.9 **Examples of Australian telehealth applications**

Providing consumer information. Various State and Territory Governments operate health information websites for consumers. Launched in 1999, the Victorian Government's Better Health Channel is an online consumer health information website that seeks to provide comprehensive, quality-assured, accessible, online health and health service information. The Australian Government also operates a consumer information website called *Health/Insite*. It acts as a single gateway to 'quality' consumer health information (about general health issues, medical conditions, and health support services) and provides links to 'authoritative' health organisations.

Providing education and information to health professionals. In April 2004, the BCG identified 12 initiatives to provide online knowledge management, clinical guidelines, and training and library services to providers. The Victorian Government's Clinicians Health Channel aims to provide access to clinical knowledge bases for public healthcare practitioners, facilitate electronic dissemination of information, and support integration of evidence-based practice into healthcare. Since March 2000, it has also provided access to citation databases, detailed drug and prescribing information, clinical practice guidelines, over 40 core textbooks and a range of other information resources.

More formal education, undertaken by various providers, is also being performed electronically, such as the provision of Royal Australian and New Zealand College of Psychiatrists (RANZCP) accredited supervision for psychiatric trainees, when locally based supervisors are not readily available.

More than 80 per cent of doctors in one survey reported that the ability to participate by broadband video link in continuing medical education from their home or surgery would be 'very' or 'somewhat' valuable.

Sources: BCG (2004); DBI (2004); Litster (2005); RANZCP (2002); VDHS, sub. 24.

Precisely quantifying the costs and benefits of these applications in practice is especially difficult for several reasons. Few formal cost-effectiveness studies are available. Even where the information is available, the extent of benefits and costs in practice is highly context-specific. Nonetheless, some suggestive findings are possible, as shown by the examples in boxes K.9 and K.10.

Telehealth — consumer information

Traditionally, doctors and other health professionals have been the primary information sources for health-related issues, with consumers almost entirely reliant on the knowledge and advice of specially- and highly-trained medical staff. Although these traditional information sources remain important, the development of the internet and proliferation of health information websites have provided consumers with an additional source of information, which they appear to be using.

Box K.10 Examples of Australian telemedicine applications

Telepaediatrics. Over 2000 video consultations, covering most medical specialties have been conducted in Queensland from Brisbane's Royal Children's Hospital, in partnership with hospitals in Mackay, Hervey Bay and other smaller hospitals. It has provided benefits for parents (faster access to specialists and less travel); remote-area doctors who can email referrals to a centralised call centre and receive a guaranteed response; and Queensland Health, which saves an estimated \$250 000 a year.

Teleophthalmology. A pilot in remote Queensland indicated the suitability of teleophthalmology for diagnosis and management of acute conditions and postoperative assessment of patients in remote areas. No adverse outcomes were identified, and there were several benefits, including fewer patients transferred for urgent assessment, and improved service. The technology apparently 'paid for itself' in the first year by avoiding unnecessary travel costs, and helped address the shortage of specialists.

Wound management — the Alfred/Medseed Wound Imaging System. Enables wound images and assessment data to be securely transmitted via the internet for review or consultation wherever the system is installed. A 2003 study of remote wound consultation for diabetic Indigenous people with chronic leg ulcers in the Kimberley (Western Australia) found significantly improved clinical outcomes and reduced costs.

Teleradiology. Teleradiology involves the electronic transmission of images in digital form from one location to another allowing, for example, interpretation of images by off-site radiologists. One US company provides 'off-hour' radiology services to hospitals and medical centres, allowing images to be transferred over the internet to radiologists in other time zones (such as Australia) for almost immediate reporting. A new microwave network developed in Victoria allows diagnostic images such as X-rays and scans to be sent across the State, making specialists more readily available to patients in otherwise underserved regions. BreastScreen Victoria has proposed an integrated mobile teleradiology mammography service that has the potential to dramatically improve turnaround times and convenience for women, and reduce costs. The cost effectiveness of teleradiology, compared with retrieving remote patients, can be 'dramatic', given the distances between remote and metropolitan hospitals. The Women's and Children's Hospital in Adelaide, which has used teleradiology since 1998, has also experienced cost savings when patients are not unnecessarily transferred, although other benefits have been difficult to quantify.

Sources: AHA, sub. 25; Access Economics (2003b); BreastScreen Victoria, sub. 22; Edmiston (2004); Gillespie (2005); Litster (2005); NOIE (2002b); Rose (2004); VDHS, sub. 24.

A recent poll found that 89 per cent of Australian patients sought medical information via the internet, with one in five using it to decide whether or not to seek medical advice (Muller 2005). The Victorian Government site, the Better Health Channel (box K.9), receives about 900 000 sessions per month, for a total 2.5 million page views (VDHS, sub. 24, p. 28), although health professionals use the site three times more often than general consumers. This additional source of information provides several potential benefits to consumers, including the potential to develop an increased awareness of health-

related issues and treatment options and to take a more active role in the management of their health, with subsequent benefits for health outcomes (Brotherton et al. 2002; Muller 2005). It has been suggested that the internet can be especially useful for patients who have been diagnosed, as a way keep up-to-date about their condition (Muller 2005).

Increased access to more information is not without problems.

- Patients may discover information about treatments that either are not available or are not subsidised in Australia (Cassrels 2005).
- The quality (accuracy) of web-based information is highly variable and there are concerns about the (in)ability of people to distinguish between the ‘good’ and the ‘bad’. Even where the information is ‘good’, patients may have difficulty interpreting it.
- Some doctors have expressed concerns about a tendency to self-diagnose using information on the internet and so-called ‘cyberchondria’ (Muller 2005).

Better access to information may also have an impact on demand for medical technology (GlaxoSmithKline Australia, sub. 21, att. 1; Medicines Australia, sub. 30). The VDHS (sub. 24, p. 28) noted, for example, that ‘improved availability of information to consumers on health through the internet is an important driver of the rate of uptake of new technology’.

Telemedicine

Medical consultations traditionally have required face-to-face encounters between patients and doctors. Increasingly, however, ICT is allowing the interaction of patients and doctors who are in different locations. This offers numerous potential benefits to consumers (especially in rural and remote areas, and for those with mobility problems; to providers (including reduced travel and associated costs); and broader benefits such as reduced inequities in access to diagnostic and treatment services.

Telemedicine in Australia has been used over a number of years for various services, including diabetes, chronic pain management, oncology, radiology, rehabilitation, ophthalmology, cardiology, dental services, palliative care and psychiatry (box K.11) (Access Economics 2003b). The number of telemedicine facilities in Australia is increasing rapidly, funded largely by State Governments. In New South Wales, for example, the number of sites with telemedicine facilities increased from 16 in 1996 to over 200 by 2003 (Access Economics 2003b).

Box K.11 **Telepsychiatry in Australia**

Telepsychiatry involves the provision over a distance of psychiatric consultations, advice or services in digital form via electronic transmission. Various modes of telepsychiatry are possible, including outpatient therapy, case conferencing, and inpatient support for rural patients being treated in city hospitals, which allows them to communicate with family and/or rural providers before discharge. It is generally seen as an enhancement to, rather than a replacement for, traditional services.

Telepsychiatry has been widely used in Australia for many years, mainly in State health systems, and on 1 November 2002, the Australian Government introduced Medicare Benefits Scheme (MBS) rebates for telepsychiatry consultations for people living in rural and remote areas. It involved the introduction of five new Medicare items, allowing up to 12 consultations for people in rural and remote areas conducted by a psychiatrist in a regional or metropolitan location. Every fifth consultation must be face-to-face. To perform telepsychiatry consultations, the practitioner must complete the online telepsychiatry certification module available on the website of the RANZCP.

Although the use of telepsychiatry is increasing, it comprises a small proportion of total psychiatric consultations in Australia (in 2004-05, there were 228 telepsychiatry, compared with 1.9 million in-room, MBS-subsidised consultations). The number of MBS-subsidised telepsychiatry consultations is also significantly lower than the number occurring through State hospital systems (Adelaide's Glenside Hospital alone conducts about 1000–2000 telepsychiatry consultations each year, for example, but only six MBS-subsidised services were recorded in South Australia in 2004-05). The number of telepsychiatric consultations is also significantly lower than the number of psychiatric consultations undertaken by metropolitan practitioners as part of rural visiting services.

Benefits of telepsychiatry have included improved access to care; the provision of two opinions (of both primary care provider and specialist) rather than one; reduced transfers for emergencies; reduced appointment waiting times; reduced time off work; earlier assessment and treatment; and reduced metropolitan hospital admissions. In many cases, it has improved recovery because patients can be treated close to home and in familiar surroundings.

Continued barriers to adoption include cultural and clinical factors — such as practitioner resistance (seen as a more significant problem than consumer resistance) and referral patterns; organisational and structural factors — particularly a lack of training; and technical barriers, such as inadequate support and technical problems. It has been estimated that greater broadband availability could see the total number of private consultations performed by telepsychiatry in Australia rise to about 44 000 (about 2 per cent of total psychiatric consultations). Government funding (rebates for services) has also been cited as a factor influencing uptake.

Sources: Access Economics (2003b); Buist and Silvas (1998); DoHA (2004i); HIC (2005a); Hilty et al. (2004); NOIE (2002d); RANZCP (2002); VDHS, sub. 24; Wilde (2004).

Nonetheless, costs and technological requirements can constrain the use of telemedicine for some services and locations. It requires appropriate facilities, such as

videoconferencing equipment, as well as network connections that provide sufficient transmission quality for the intended purpose. Telemedicine will not be suitable for all applications. The most developed uses of telemedicine in Australia are telepsychiatry, and the electronic transmission of medical images (teleradiology and foetal teleultrasound) (Access Economics 2003b).

K.7 ICT — concluding comments

The discussion of this section has highlighted some of the broad and specific areas in which advances in ICT have had applications in the healthcare sector. These are by no means, and are not intended to be, exhaustive. Various other medical advances, not all of which relate directly to the provision of care to patients, have been enabled or at least facilitated by advances in ICT (chapter 11).

ICT has allowed medical advances that would not even have been considered possible ten to twenty years ago. However, the variety of applications, early stage of development of many of them, and a general difficulty in quantifying costs and benefits in these areas, make it difficult to make overall conclusions about the impact of ICT advances in Australia. ICT appears in many cases to have promoted improvements in the quality, effectiveness and efficiency of healthcare delivery, enhanced access to treatment, and contributed to improvements in health. But often potential benefits are not being realised despite considerable expenditure, reflecting in large part a lack of systematic planning and evaluation processes.

Given the rapidity of ICT advances, it is unwise to make definitive predictions about where ICT may take medicine in the future, even the relatively near future of the next decade. Overall, however, it appears to offer significant opportunities to improve the way healthcare is delivered (including its efficiency and effectiveness), the range and nature of treatment options, and the wellbeing of the community. None of this is guaranteed, however. Capturing many of these potential benefits will require a concerted effort (and possibly significant expenditure) to overcome the challenges and obstacles presented by advances in ICT.

One estimate suggested that ICT expenditure may need to increase to about 5 per cent of total health expenditure in Australia (implying a possible twofold increase from current levels) (GAP 2005). Noting the significantly higher UK and US expenditure directed towards rectifying legacy issues and investing in new ICT infrastructure, AEEMA also pointed to estimates ‘that Australia needs to double its ICT investment to 4 per cent or more of health costs over 5 years to gain parity with comparable spending levels in the USA and the UK’ (sub. PR49, p. 5).

It is not within the scope of this report to comment in detail on the return Australia has received, or could receive, from its ICT involvement in healthcare. However, from the reports of others noted in this appendix, there are many worrying indications that the investments made to date may not deliver on their potential or on expectations. These signs include:

- inadequate cost–benefit analysis before the projects started;
- project scopes which have been adjusted and compromised over time to try to counter cost blowouts;
- project completion delays;
- insufficient investment into developing and monitoring national standards to ensure compatibility across systems; and
- important ethical, privacy and other issues remaining to be resolved despite significant expenditure prior to this occurring.

With ICT spending currently accounting for 1–3 per cent of total healthcare costs and, based on international experience, likely to climb to 4–5 per cent, it is vital that this money be well spent. This will require greater national coordination and discipline than appears to have been in place over the past decade in ICT spending on healthcare.

L Genetic testing of women for breast cancer

L.1 Introduction

Inherited gene mutations account for between 1 and 5 per cent of all breast and ovarian cancers, and probably a higher proportion of early onset cases (NHMRC NBCC 2000). In Australia, 130 to 660 new cases of breast and ovarian cancer identified in 2001 may have been related to a mutated gene.

Some of the gene mutations associated with breast and ovarian cancer were isolated in the 1990s, but most inherited genetic mutations associated with breast and ovarian cancer have not yet been discovered (Griffith, Edwards and Gray 2004). Several genes are known to play a role in breast cancer: BRCA1 and BRCA2, the Tp53 gene, the ATM gene and the HRAS gene (South Eastern Sydney Area Health Service 2001).

The chance of an Australian woman developing breast cancer before the age of 75 in 2001 was about 1 in 11 (AIHW and AACR 2004). However, for those with a faulty gene, the risk rises to 1 in 4 or higher.

- Mutations in BRCA genes (BRCA1 and BRCA2) are carried by about 1 in 1000 women but may be more common in particular groups (for example, 1 in 50 among Ashkenazi Jews) (South Eastern Sydney Area Health Service 2001). BRCA gene mutations are associated with a 40–80 per cent risk of breast cancer, and a 10–60 per cent risk of ovarian cancer (NHMRC NBCC 2000).¹ BRCA gene mutations are also associated with up to 10 per cent lifetime risk of pancreatic cancer in both sexes, and other cancers in males.
- The Tp53 gene (Li-Fraumeni syndrome) is carried by about 1 in 10 000 women and is associated with a 50 per cent risk of breast cancer, and a risk of bone or soft tissue cancer of 50 per cent or less (NHMRC NBCC 2000).² The Tp53 gene is also associated with up to 10 per cent lifetime risk of brain, lung and adrenal gland cancer.

¹ Risk to age 75.

² Risk to age 75.

Eligibility for genetic testing in Australia

Familial cancer services offering genetic counselling and testing were established by most State governments in the late 1990s. Patients may self refer to testing clinics, or be referred by their general practitioner (GP), or specialist. Testing is generally offered to those with moderate or high risk of carrying the gene — that is, those with the strongest family history of breast or ovarian cancer. For example, the Victorian Family Cancer Genetics Service suggests contacting a GP or a Family Cancer Centre if:

- There are three or more close blood relatives on the same side of the family with breast or ovarian cancer;
- There are two or more close blood relatives on one side of the family (mother's or father's) with breast or ovarian cancer who have one or more of the following features on the same side of the family:
 - cancer in both breasts
 - onset of breast cancer before the age of 40
 - onset of ovarian cancer before the age of 50
 - breast and ovarian cancer in the same relative
 - breast cancer in a male relative
 - Jewish ancestry
- A relative was diagnosed with breast cancer at or before 45 years of age plus a relative on the same side of the family diagnosed with bone or soft tissue cancer at or before 45 years of age
- Three or more close relatives on the same side of the family had/have cancer of the bowel or uterus
- A family member has had a genetic test that has shown that they have an inherited change in a gene associated with breast or ovarian cancer. (2005)

For an eligible patient, the testing process involves two stages. First, a sample is taken from a living family member previously diagnosed with cancer to search for a causative gene. Subsequently, if a gene mutation is found, other family members may undergo predictive testing for the same mutation.

A negative test result does not exclude the possibility of an inherited risk because mutations occur in as yet unknown genes, so the information provided by testing is incomplete. However, if a known gene has already been found in the family, a negative test means that the individual does not carry the high cancer risk associated with that particular gene mutation. The risk of a false negative for presymptomatic BRCA1/2 is very small — less than 0.01 per cent (Griffith, Edwards and Gray 2004). The risk of a false positive after two positive tests is 0.04 per cent (Grann et al. 1999).

The decision about whether to undergo testing is a difficult one and some women are reluctant because of perceptions about the potential social or economic impact of being an identified gene mutation carrier, for example the impact on their ability to obtain insurance or employment. (However, Keogh et al. (2004) questioned whether this is a major consideration at present in Australia.) Some women may be sensitive about informing relatives. Other women choose against testing because of the potentially high costs (in personal terms) of their choices if they test positive, and the uncertain benefits (see below).

The benefit of BRCA1/2 testing for all women with a family history of breast or ovarian cancer is controversial ... many of the available breast cancer risk-reduction interventions involve significant trade-offs ... (Armstrong et al. 2005, p. 1734)

A study to assess the utilisation of genetic testing services was undertaken on a population of Melbourne and Sydney women who were diagnosed with invasive breast cancer when they were aged less than 40, and who were found to have a BRCA mutation. Their relatives (siblings, parents, grandparents and aunts) were also asked to participate in the study. Of those who gave a blood sample and who were subsequently offered genetic counselling, 44 per cent chose to learn their mutation status (Keogh et al. 2004).

Choices available to those with a gene mutation

Women carrying a gene mutation have a number of choices (other than to do nothing).

- They may seek counselling and ongoing psychological support.
- They may undergo more intensive cancer surveillance than otherwise. The most suitable approach will differ for each individual according to a number of factors such as personal preference, and that mammograms are generally not effective for women under 40 because of the density of breast tissue. The Australian National Breast Cancer Centre recommends that women who are at increased risk of developing breast cancer develop an individualised surveillance program in consultation with their GP and/or specialist. This might include regular self examination, clinical breast examination and breast imaging with mammography and/or ultrasound (NBCC 2004).
- They may choose to have prophylactic surgery, including removal of the breasts (bilateral mastectomy) and or removal of the ovaries (oophorectomy). However, currently available prophylactic surgery can be associated with substantial physical and psychological distress and is not 100 per cent effective. A woman's likelihood of developing breast cancer may be reduced by:
 - 90 per cent with a bilateral mastectomy;

-
- 40 per cent with an oophorectomy; and
 - 91 per cent by both (Griffith, Edwards and Gray (2004) quoting the findings of other studies).

In addition, some genes are not only associated with an increased risk of breast or ovarian cancer, but heightened risk of other types of cancers against which these types of prophylaxis have no effect.

- Chemoprevention is available in some countries and was available to Australian women who entered the International Breast Cancer Prevention Study.³ It involves women with a family history of breast cancer taking an estrogen antagonist such as Tamoxifen. The length of time on treatment with Tamoxifen has yet to be determined, but women currently receive it for chemoprevention purposes for around five years. Chemoprevention with Tamoxifen was licensed by the United States' Food and Drug Administration (FDA) in 1998 for reducing the incidence of breast cancer in women at high risk. The licence was based on a US study in women who were judged to be at increased risk of breast cancer and showed that Tamoxifen reduced the chance of getting breast cancer by 44 percent (FDA 1998). However, side effects can include a risk of endometrial cancer, and blood clots which can lead to strokes (FDA 1998). The current trials involving Australian women will examine the benefits for mutation carriers in particular.

L.2 Need and use

The prevalence of gene mutations across demographic groups (such as geographic region and socioeconomic status) is unknown. Patterns of incidence and prevalence of breast cancer are outlined in the appendix on Herceptin (appendix I), although as mentioned earlier, only a small proportion of these cancers relate to mutated genes.

The potential demand for genetic testing for breast cancer in Australia could range from 650 to 3300 women per year. This estimate assumes that:

- all new cases of breast and ovarian cancer in 2001 that may have been related to a mutated gene, present to a family cancer service (1 to 5 per cent of all new breast or ovarian cancers in 2001); and
- each affected woman had five close female relatives (based on the approach of the Genetics Advisory Committee, Anti-Cancer Council of Victoria, 1999).

³ The International Breast Cancer Prevention Study is examining whether Tamoxifen is effective in preventing breast cancer. Australian clinicians and patients are participating in the trial.

The actual usage might be 75 per cent of this estimate (Genetics Advisory Committee, Anti-Cancer Council of Victoria, 1999), or even less (Keogh et al. 2004).

There is international evidence that individuals from lower socioeconomic backgrounds are under-represented as patients of genetics clinics (Steel et al. 1999). Education (Steel et al. 1999 and Armstrong et al. 2005) and annual income levels (Armstrong et al. 2005) are also associated with use of BRCA1/2 counselling overseas. In addition, large disparities in the use of BRCA1/2 counselling have been found in the US between African American and white women with a family history of breast or ovarian cancer (Armstrong et al. 2005). White women had almost five times the odds of undergoing BRCA1/2 counselling as African American women. The disparity was not explained by differences in the probability of carrying a BRCA1/2 gene mutation, socioeconomic status, cancer risk perception and worry, attitudes about the risks and benefits of BRCA1/2 testing or primary care physician discussions of BRCA1/2 testing. The authors suggested several explanations including health care related distrust and concern about racial discrimination on the basis of genetic testing, and differences in the characteristics of primary care physicians (Armstrong et al. 2005).

The Commission obtained data from family cancer clinics in New South Wales, Victoria and South Australia on the age and residential post code of their clients between 1997 and 2004. Clients were grouped according to the nature of their contact with the clinic:

- intake, or first contact with the clinic (either women who were referred, self referred, or telephoned for information);
- consultations, or women who received counselling about testing;
- women who underwent a test to search for the presence of a gene mutation; and
- women who had a predictive test once a gene mutation had been found in an affected blood relative.

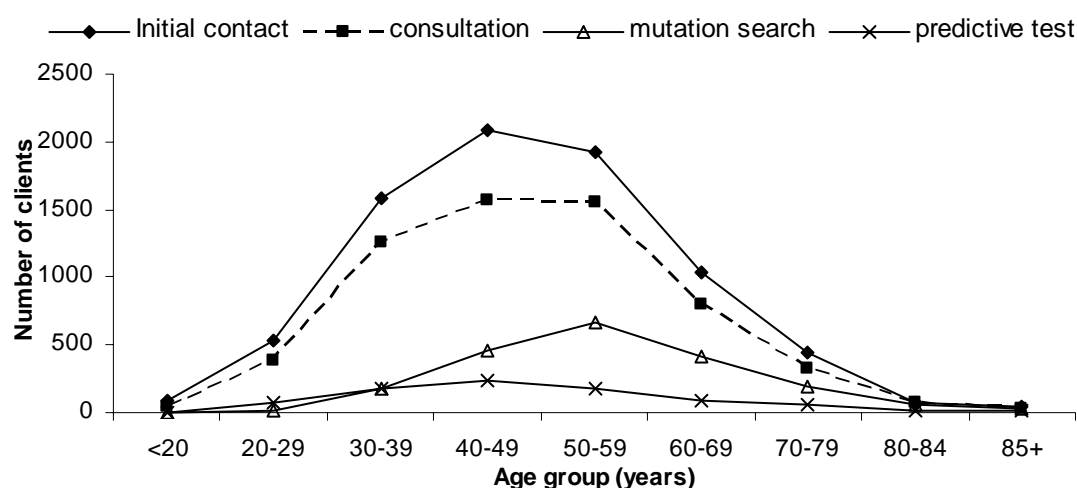
The South Australian data are census data for the State and therefore most representative at a State level. The data for the other States are from a sample of clinics and so are not necessarily representative at the State level. In addition, the New South Wales' and Victorian data are for clinics in capital cities only as data from regional clinics were not available in time. The extent of missing data on client characteristics varied across clinics and over time.

Counselling forms the major focus of familial cancer service activities. A small proportion of those who are counselled actually undergo testing in Australia. Based on the sample of family cancer clinics in New South Wales, Victoria and South Australia, between 1997 and

2004, the number of searches for a causative gene comprised 25–45 per cent of consultations and the number of predictive tests comprised 13–33 per cent of consultations. In Pennsylvania in the US, between 2000–2003, around 75 per cent of women who underwent counselling completed BRCA1/2 testing after counselling (Armstrong et al. 2005).

The age profiles of clients in the breast and ovarian cancer stream of the sample of family clinics in question for the period 1997 to 2004 are presented in figure L.1. Over 70 per cent of women initially contacting the service, undergoing counselling or having a predictive test were aged between 30 and 59 years. Ten per cent of women having a predictive test were aged 70 or over.

Figure L.1 **Age profiles of clients, 1997–2004^{a,b}**



^a Initial contact refers to the first contact made by clients with the clinic. Mutation search refers to the test for the existence of a causative cancer gene in the family. Predictive test refers to the subsequent test for the existence of the same causative gene in other family members. ^b The proportion of missing data from clinics varied across clinics and over time.

Data source: Unpublished data from family cancer clinics in New South Wales, Victoria and South Australia.

Those in the most disadvantaged groups were less likely to present to family cancer clinics. With the exception of predictive tests carried out in South Australia, those in the most disadvantaged groups were also underrepresented in testing (table L.1).

Table L.1 **Genetic testing by socioeconomic status, 1997–2004^{a,b}**

	2/1	3/1	4/1	5/1	6/1
Rate ratio (rates based on population of women in each socioeconomic group in each State)					
Intake (initial contact)					
NSW	0.9	1.1	1.8	2.3	3.3
Vic	1.3	1.4	1.6	1.9	2.4
SA	1.2	1.1	1.1	1.3	1.6
Consultation					
NSW	0.9	1.1	1.9	2.5	3.9
Vic	1.1	1.6	1.8	2.1	3.0
SA	1.2	1.1	1.1	1.4	1.7
Search for a causative gene (mutation search)					
NSW	1.2	1.2	1.9	2.6	4.1
Vic	1.5	2.1	2.0	2.4	3.6
SA	1.4	1.1	1.2	1.2	1.9
Predictive test					
NSW	1.3	1.4	2.1	2.2	4.6
Vic	0.9	1.5	1.4	1.7	2.9
SA	0.9	1.3	0.5	1.3	1.0

^a A high index score (6) means the area has few families of low income and few people with little training and in unskilled occupations. A high score reflects lack of disadvantage (ABS 2001). Rate ratios reflect differences between each level of disadvantage, for example, the least disadvantaged over the most disadvantaged (age specific procedure rate for group six divided by age specific procedure rate for group one). ^b The proportion of missing data from clinics varied across clinics and over time.

Source: Unpublished data from family cancer clinics in New South Wales, Victoria and South Australia; Unpublished data from the ABS 2001 Census.

The rates of client contacts, counselling and testing by remoteness area are presented in table L.2. The South Australian census data suggest that those in regional areas were slightly less likely to present to a clinic and therefore less likely to have a consultation, but were more likely to have a test. The New South Wales' and Victorian data probably reflect the location in capital cities of clinics providing the data.

Table L.2 **Genetic testing by remoteness area, 1997–2004^{a,b}**

	<i>Major cities</i>	<i>Regional</i>	<i>Remote</i>
Rate per 100 000 women in each region in each State			
Intake (initial contact)			
NSW	128.2	55.0	44.7 ^c
Vic	114.9	92.8	356.7 ^c
SA	192.1	173.1	191.3
Consultation			
NSW	82.2	30.7	22.4 ^c
Vic	100.2	77.5	237.8 ^c
SA	180.0	164.8	168.8
Search for a causative gene (mutation search)			
NSW	27.0	11.8	22.4 ^c
Vic	22.7	24.8	118.9 ^c
SA	79.3	77.9	67.5
Predictive test			
NSW	9.2	6.2	0.0
Vic	15.9	12.9	277.4 ^c
SA	19.9	30.6	41.3

^a Remoteness categories based on the Australian Standard Geographical Classification System. Regional includes inner and outer regional. Remote includes remote and very remote. ^b The proportion of missing data from clinics varied across clinics and over time. ^c Based on very small numbers.

Source: Unpublished data from family cancer clinics in New South Wales, Victoria and South Australia; Unpublished data from the ABS 2001 Census.

L.3 Expenditure

Gene tests for breast cancer are not listed on the Medicare Benefits Schedule (MBS), but offered through family cancer clinics funded by State Governments. In at least three States (New South Wales, Victoria, and South Australia) testing is free to eligible patients. Patients may also pay for testing by a private company, Genetic Technologies Limited (GTG). GTG is licensed to perform testing in Australia and New Zealand for BRCA1 and BRCA2 gene mutations by the US patent owner, Myriad. Most medical genetic testing, however is provided through the public sector (The Cancer Council Australia/Clinical Oncological Society of Australia, sub. 32).

It is difficult to isolate government budget allocations for genetic testing for breast cancer, but direct spending by each State government on family cancer clinics lies between half to one million dollars a year. Up to 70 per cent of this might be spent on familial cancer services for breast cancer. Family cancer clinics are often co-located with hospitals and the latter may also contribute funding. The National Institute for Health and Clinical Excellence (England and Wales) (NICE) faced similar difficulties identifying funding for

genetic screening in costing its guidelines for familial breast cancer (NICE and Secta 2004).

No Australian estimates for the cost of counselling are available, but Grann et al. (1999) assumed a cost of genetic counselling in the US in 1995 of US\$300 (around A\$450).⁴ Griffith et al. (2004) noted estimates of counselling in 2002-03 ranged from around £90 to £550 (A\$195 to \$1200).

The cost of searching for gene mutation can depend on whether a full or partial sequence analysis is undertaken. The cost of searching for a BRCA gene is around A\$2000–\$2500 in Australia. In the UK, NICE and Secta (2004) estimated the cost of screening for a BRCA gene mutation at around £900 (A\$1860). Myriad's price under patent in the US for screening for BRCA genes is US\$2970 (A\$3830) (NICE and Secta 2004). Predictive tests in other family members once the initial mutation is found are substantially less expensive:

The laboratory workload in identifying whether family members carry a mutation is approximately 25 per cent of that required in the identification of the mutation in [the first place]. (Genetics Advisory Committee, Anti-Cancer Council of Victoria 1999, p. 13)

Other costs include:

- The costs of ongoing counselling and psychological support.
- The costs of additional surveillance in those with a gene mutation (over and above the current population mammographic screening program funded by Australian and State Governments). Under the MBS, the fee for a breast examination by a GP is \$30.85, the fee for a mammography of one breast is \$53.95, and for an ultrasound is \$98.25 for one breast and \$109.10 for two. The Australian Government contributes 85 per cent of these costs, or 75 per cent if the services are provided in hospital.
- The costs of prophylactic surgery. In 2002-03, the average cost of a major procedure for a non-malignant breast condition was around \$4000–\$5000, and for oophorectomy was around \$5000–\$8000 (DoHA 2005b). In many cases, this can be balanced against the costs of cancer treatments prevented. However, in some cases, women who might not have developed cancer undergo prophylactic surgery, in which case such surgery unequivocally increases health expenditure. In addition, given prophylactic surgery is not 100 per cent effective in preventing cancer it will add to health expenditure where cancer treatment is still required.

⁴ Overseas currencies are inflated to 2002 prices using an implicit GDP deflator for the relevant country, and then converted into Australian dollars using purchasing power parity.

Wainberg and Husted (2004) outlined studies undertaken in the US and the Netherlands of the uptake of prophylactic surgery. The results of the various studies suggested that the proportion of BRCA mutation carriers who chose prophylactic bilateral mastectomy over screening in the 12 months following disclosure of BRCA mutation status varied from 0 per cent in the US to 54 per cent in the Netherlands. The large range was attributed in part to differences across the two countries in guidelines recommending prophylactic mastectomy for mutation carriers (prophylactic mastectomy is recommended in the Netherlands) and coverage of prophylactic surgery by public sector insurance (it is not covered by public health insurance in the US). Between 13 and 53 per cent of women chose prophylactic oophorectomy in the 12 months following disclosure of the BRCA test results, with the range attributed to various factors including age and socioeconomic status.

NICE and Secta (2004) estimated the additional cost of the NICE clinical guidelines on familial breast cancer to the National Health Service (United Kingdom) (NHS). On an annual basis, implementation of the guidelines (including the introduction of annual mammographic screening for moderate and high risk women aged 40–49, provision of genetic testing to high risk women, and psychological support) would add £2.5 million (A\$5.2 million) to NHS expenditure (or less than one pound per woman in the UK⁵ — equivalent to less than one dollar per woman in Australia). The costs (and cost savings) associated with prophylactic surgery were excluded from the calculations.

Cost savings

Genetic services may also reduce health expenditure in the following ways.

- For those women who had prophylactic surgery, and who would otherwise have developed breast cancer, the cost of cancer treatment is avoided.
- The costs of more intensive cancer surveillance are avoided for women who were at risk of familial cancer but who tested negative for the presence of a mutated gene.

L.4 Benefits

The benefits of familial cancer services might be summarised as follows.

⁵ Based on UK 2003 female population data from <http://www.statistics.gov.uk/STATBASE/Expodata/Spreadsheets/D9042.xls>, accessed 9 August 2005.

-
- Depending on the choices of those women found to be carriers, some cancers may be prevented, and therefore survival extended.
 - Gene mutations are often associated with the early onset of disease — that is, women developing cancer at a younger age. More intensive surveillance of women carrying a gene mutation may result in diagnosis at an earlier stage in the cancer's progress and thus a better prognosis. Further, since these women tend to be younger, the benefits in terms of life years saved are relatively greater than for cancers diagnosed at the same stage in women in older age groups.
 - The anxiety levels of women at high risk of carrying a mutated gene who test negative for the presence of the mutation, may fall. Relief may in part be linked to knowledge that relatives are also at less risk of cancer. On the other hand, patients of family cancer clinics and their families may experience increased anxiety and distress during the process of testing and those who test positive may also experience a high degree of anxiety.

International mathematical modelling analyses have estimated the incremental survival benefits of genetic testing services and various forms of prophylactic surgery over either no genetic services, or surveillance alone. The studies are difficult to compare because the results are sensitive to assumptions about:

- the risk of those in the populations being tested carrying a mutation (for example, BRCA carriers, or those with a family history of breast cancer, or broader groups who are not necessarily at increased risk of carrying a mutation);
- the risk of cancer among gene carriers;
- mortality and the impact of cancer screening (such as mammography) or preventive surgery on survival;
- age at testing;
- the length of the observation period; and
- discount rates.

In addition, not all of the studies adjusted the potential impact on life expectancy for quality of life, despite the importance of the potential impact of genetic screening on psychological distress (Cohen, Barton, Gray and Brain 2004). Where quality-adjusted life-years (QALYs) were used, assumptions about QALY weightings may also differ (Griffith, Edwards and Gray 2004). In general, the studies show that cancer genetic services, increase survival and:

As long as genetic services do not induce adverse psychological effects they also provide greater quality of life. (Griffith, Edwards and Gray 2004, p. 1918).

The range of estimated benefits and differing assumptions are illustrated by the three studies outlined below.

- Grann et al. (1999) examined the cost effectiveness of genetic screening compared with no genetic screening amongst Ashkenazi Jewish women. The study assumed that women were screened at age 30, and used mathematical modelling to estimate likely costs and benefits over a 50 year period. The authors noted the importance of the psychological, social and economic distress potentially associated with screening, but justified their use of unadjusted estimates of survival by reference to studies suggesting that genetic screening may alleviate rather than cause stress. Their estimates of undiscounted, unadjusted incremental survival associated with screening were relatively low: six days for surveillance, 11 days for oophorectomy, 33 days for mastectomy and 38 days for combined mastectomy and oophorectomy. As Griffith et al. (2004) pointed out, the low estimates of gains relative to other studies were due to the ‘untargeted’ nature of testing — that is, the testing population encompassed all Ashkenazi Jewish women and not only those with a family history of breast or ovarian cancer.
- In another study, Grann et al. (2002) estimated the survival benefits in a population of 30 year old women who tested positive for a BRCA1/2 gene mutation and elected to undergo various treatment options compared with surveillance alone. While the study population was not limited to Ashkenazi Jewish women, the modelling was based on a cancer risk equivalent to those of Ashkenazi Jewish women (which is relatively high), so the estimated benefits of preventive treatments may be relatively high as a result. Survival outcomes were modelled over a 70 year period. For a woman aged 30, having prophylactic mastectomy with oophorectomy extended survival by 4.9 life years or 2.6 QALYs over surveillance alone. Mastectomy was associated with an additional 3.5 life years or 2.6 QALYs, oophorectomy with an additional 2.6 life years and 4.4 QALYs, and treatment with Tamoxifen with an additional 1.8 life years and 2.8 QALYs over surveillance alone.
- Griffith, Edwards and Gray (2004) calculated survival estimates for all women at increased risk of developing cancer (rather than restricting the analysis to BRCA carriers or Ashkenazi Jewish women). The model studied women at 35 years of age for up to 24 years.
 - The study found a positive impact on unadjusted life expectancy of all types of prophylactic surgery. Genetic assessment with regular presymptomatic surveillance also had a positive impact on survival, but the benefits were lower than for prophylactic treatment. Survival benefits were greatest for women with identified mutations (such as BRCA).

-
- Adjusting for quality of life changed the results, however. Cancer genetic services were forecast to generally increase quality of life for women, except for those who chose to undergo combined prophylactic bilateral mastectomy and oophorectomy, and women who experienced psychological distress because of cancer genetic services. Both of these last two groups were found to be worse off (Griffith, Edwards and Gray 2004a).

L.5 Cost effectiveness

Genetic testing for breast cancer has not been considered by the Medical Services Advisory Committee as MBS listing has not yet been pursued, so no Australian cost effectiveness analyses are available. However, some work is underway on this in South Australia. A number of international cost effectiveness studies have been undertaken, some of which are summarised below. However, the results are sensitive to assumptions about the variables listed above, as well other factors such as the cost of testing.

- Discounted incremental cost effectiveness ratios calculated by Grann et al. (1999) ranged from around US\$20 700 (A\$31 300) per life year for mastectomy and oophorectomy combined, US\$30 000 (A\$45 300) for mastectomy alone, US\$72 800 (A\$110 000) for oophorectomy alone to US\$134 300 (A\$203 000) for surveillance alone. The study concluded that genetic screening plus prophylactic surgery is more cost effective than surveillance alone for Ashkenazi Jewish women.
- Tengs and Berry (2000) concluded that testing for mutations in BRCA genes was cost effective for women at a higher than average risk of carrying a mutation. Cost effectiveness of testing was US\$1.6 million (A\$2.3 million) per QALY for women with average population risk, US\$34 000 (A\$47 400) per QALY for women with a slightly elevated risk of carrying a BRCA mutation, US\$15 000 (A\$20 900) for women at moderate risk and US\$3500–\$4900 (A\$4900–\$6800) per QALY for women at high risk.
- Griffith et al. (2004) mentioned a Scottish study estimating the cost per life year saved by presymptomatic surveillance and/or prophylactic surgery in 1998 of £2100 (A\$4900) for members of high risk families.

L.6 Future

The ethical debate, the impact on individuals and the insurance industry are debates that will need considerable discussion (Australian Institute of Medical Scientists, sub. 3, p. 4).

A number of factors will determine the impact on health expenditure of genetic testing for gene mutations associated with breast cancer: patents and the further identification of genes; public and private sector responses to insurance of those carrying genes associated with heightened risk of disease; developments in the accuracy and cost effectiveness of testing and surveillance; and the cost effectiveness of prophylactic and curative treatments. Some of these are discussed below.

The allocation of patents to commercial organisations and their subsequent enforcement have implications for estimates of the costs of genetic testing services. GTG has indicated that it does not intend to enforce the BRCA patents in Australia or New Zealand and has allowed the existing public hospital cancer genetics laboratories to continue to perform tests (ALRC 2004). However, it is difficult to predict what might happen in future. Several European countries are currently in the process of challenging Myriad's patent on the BRCA1 gene (NICE and Secta 2004). The Cancer Council Australia/Clinical Oncological Society of Australia suggests that private providers are facing an 'increasingly receptive market' for testing services (the Cancer Council Australia/Clinical Oncological Society of Australia sub. 32, p. 19) which may increase incentives for patent enforcement.

The Cancer Council Australia/Clinical Oncological Society of Australia suggests that further identification of genes for breast cancer in future are likely, although the timing of these advances is uncertain.

While the list of genes and mutations will continue to expand, the current focus on individual genes is likely to be augmented by genome-wide genetic profiling in the next few years. This global approach, where many genes are scanned simultaneously, has the power to predict the risk of developing common diseases whose aetiology (cause) is genetically complex. (The Cancer Council Australia/Clinical Oncological Society of Australia, sub. 32, p. 18)

In addition, the accuracy and affordability of testing are also likely to improve.

The development of automated "DNA chip" technology may yet enable testing for numerous genetic mutations that is both reliable and financially affordable. (The Cancer Council Australia/Clinical Oncological Society of Australia, sub. 32, p. 20)

The ability, with the development of large scale computational bioinformatics, to analyse increasingly complex DNA microarrays to produce expression profiles has the potential to dramatically improve knowledge of cancer genomics leading to early diagnosis and predisposition profiling, especially in such diseases as ovarian and breast cancer. (Australian Association of Pathology Practices Inc., sub. 4, p. 7)

Developments in surveillance are likely in the next five to ten years with various implications for cost effectiveness estimates of genetic testing.

-
- NICE and Secta (2004) refer to two studies of mammographic screening currently underway in the UK: a study evaluating the cost effectiveness of annual mammographic surveillance of women under 50 with a family history of breast cancer, with results expected around 2010; and a study of annual screening for breast cancer for all women aged 40–49 (regardless of family history) due to report in two to three years. If introduced in Australia, annual population screening of women aged 40–49 might reduce the incremental benefits of genetic testing services.
 - The Cancer Council Australia/Clinical Oncological Society of Australia recommended inclusion of stereotactic MRI screening for young women at very high risk of breast cancer as part of a ‘full surveillance program’, citing ‘conclusive’ evidence from several large international studies that stereotactic magnetic resonance imaging (MRI) is a far more sensitive method than mammography to screen women at very high risk of developing breast cancer (sub. 32, p. 19). A study of MRI screening for high risk women, due for completion in five years, is underway in the United Kingdom (NICE and Secta 2004). MRI is at least three times more expensive than mammography or ultrasound — over A\$300 on the MBS.

The availability of chemoprevention in Australia will depend on whether the clinical trials currently underway show a benefit for mutation carriers. If approved, the expenditure implications depend on the cost of Tamoxifen and how many women would be eligible, as well as the cost savings associated with the potential for fewer cases of disease. One month’s supply of Tamoxifen costs about US\$200 (A\$260). However, the price is likely to drop now that generic Tamoxifen is available in the United States (Breastcancer.org 2005b).

According to the Cancer Council Australia/Clinical Oncological Society of Australia:

... even the most conservative scientists and clinicians would agree that genetics will have a significant impact on medical services within the next 10 years. (sub. 32, p. 18)

L.7 Conclusion

Like all genetic testing, testing for gene mutations associated with a higher than average risk of breast cancer is associated with contentious policy issues such as the allocation of patents, and the use of information about identified gene carriers.

As far as the Commission is aware, there are no Australian estimates of the benefits of genetic testing for breast cancer, or its cost effectiveness. International modelling of the impact of genetic testing services on length of life suggests there are positive benefits,

although the projected addition to length of life is highly sensitive to assumptions such as the estimated risk of those tested carrying a mutated gene, and the risk of cancer developing among gene carriers. It is preferable to measure the potential benefits in terms of quality of life because genetic testing and the associated prophylactic treatments can have an adverse effect on patients' psychological well being. One international study found that the impact of genetic testing on quality of life was negative for women carrying a mutation who chose to undergo combined prophylactic bilateral mastectomy and oophorectomy, and women who experienced psychological distress because of cancer genetic services. International cost effectiveness studies suggest that testing is more cost effective for those at high risk of carrying a gene mutation.

Based on data from a sample of family cancer clinics in New South Wales, Victoria and South Australia, between 1997 and 2004, those in the most disadvantaged groups were less likely to present to family cancer clinics and were therefore underrepresented in testing.

At present, the information provided by testing is incomplete as most gene mutations associated with an increased risk of cancer remain unknown. In addition, prophylactic treatments currently available do not necessarily always prevent cancer. However, genetic testing has the potential to improve life expectancy in future as more gene mutations are identified, as the accuracy of testing and surveillance improves, and with advances in the effectiveness of prophylactic and curative treatments. The timing of most of these advances is unpredictable with the exception of developments in surveillance which are likely to have an impact on both expenditure and benefits in the next five to ten years.

M Cataract surgery

M.1 Introduction

Cataracts are the leading cause of blindness worldwide (Solomon and Donnenfeld 2003) and surgery to remove cataracts is common amongst older people in Australia (Keeffe and Taylor 1996). A cataract involves a clouding of the (usually clear) lens of the eye, which prevents light from passing through the lens to the retina. Cataracts can affect one or both eyes causing problems such as cloudy or blurry vision, double vision or decreased night vision. Cataracts become denser over time, thus vision continues to deteriorate. There are various types of cataract but most are age related. Smoking, diabetes and exposure to ultraviolet (UV) light are also risk factors for cataract (Access Economics 2004). In other cases, cataracts can be congenital, caused by certain medical conditions such as diabetes, or occur as a result of eye injury (Access Economics 2004).

According to Solomon and Donnenfeld (2003), there are no proven ways to prevent age-related cataracts and no drug or spectacle treatments that can be used, thus the only ‘cure’ is surgery. During surgery, the cataract/lens is removed and replaced, usually with an intraocular lens (IOL) — a permanent artificial lens that is implanted in the eye.

In the 1990s, cataract surgery was transformed in Australia and other developed countries with wide adoption of the phacoemulsification technique to remove the cataract-affected lens, combined with implantation of a foldable intraocular lens. Phacoemulsification, first introduced by Kelman in 1967, involves emulsifying the lens (which allows it to be vacuumed out of the eye) through the vibration of the tip of an ultrasonic probe inserted in the eye (Solomon and Donnenfeld 2003). The first IOL was used in 1949 and has since evolved into the small foldable lens (Solomon and Donnenfeld 2003). Making the lens foldable was a key advance as this allowed surgeons to take advantage of the smaller (2–3mm) unsutured incision in the eye that was made possible by phacoemulsification (Linebarger et al. 1999).

Before availability of foldable IOLs, a procedure known as extracapsular cataract extraction (ECCE) was used to remove the lens and either a rigid IOL was inserted

(which therefore required a larger surgical incision — 10 to 11mm) or patients had to wear a special type of thick spectacles (aphakic spectacles) after surgery.

Partly as a result of population ageing, there has been strong growth in cataract surgery over the past decade. But improved surgical techniques and therefore results also have likely played a role:

- by lowering the threshold of loss of visual acuity required before surgery is recommended (previously patients effectively had to be legally blind to qualify because post-surgery vision outcomes were so poor) (Tan et al. 2004); and
- by reducing the length of hospital stay for the procedure (Keeffe and Taylor 1996) (see below).

M.2 Cataract surgery — use and expenditure

The total number of separations for cataract surgery (for both public and private patients) increased from about 71 000 in 1993-94 to almost 136 000 in 2002-03, an increase of almost 91 per cent (AIHW 2005d). An increasing trend in cataract extractions in Australia was also observed over the 10 years to 1994 (Keeffe and Taylor 1996).

Age

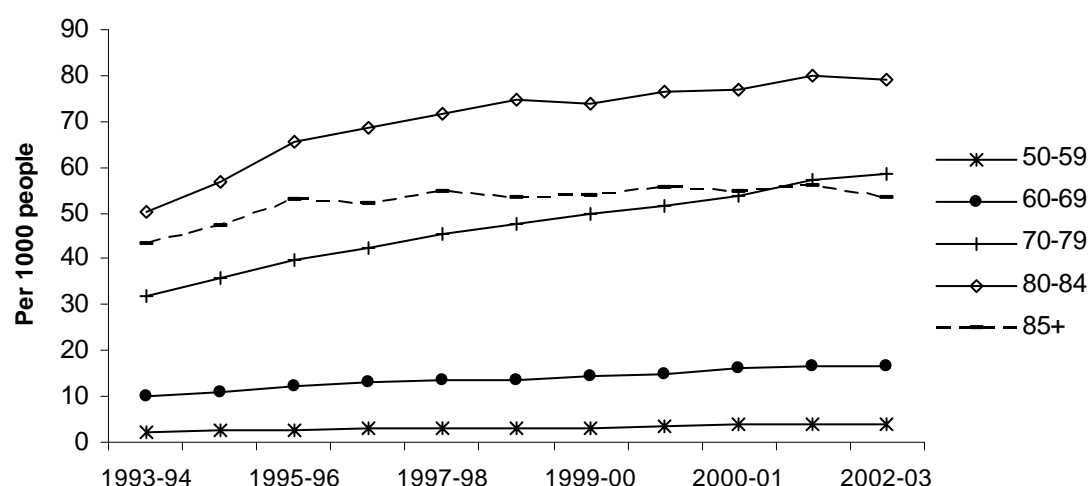
As the prevalence of cataract increases with age, lens insertion and/or removal rates are higher for those in older age groups (figure M.1). In fact, age is the most important risk factor for cataract (Taylor 2000). Australian data (Brian and Taylor 2001, p. 249) show that ‘prevalence doubles with each decade of age after 40 years, so that everyone in their nineties is affected’. Data from other developed countries show similar results.

In 2001, the estimated prevalence of age-related cataract amongst Australians aged 50 years or older was around 35 per cent of women and 27 per cent of men (Rochtchina et al. 2003). According to the Blue Mountains Eye Study, by the age of 80 years, 80 per cent of participants either had significant cataract present in one or both eyes or had undergone cataract surgery (Panchapakesan et al. 2003).

There are three major types of age-related cataract — nuclear, cortical, and posterior subcapsular. Risk factors for these include: UV exposure for cortical cataract (Taylor et al. 1988); smoking for nuclear cataract (McCarty et al. 1999); and diabetes for both cortical and nuclear cataract (McCarty et al. 1999). Women aged over 50 years also appear to have

a higher overall prevalence of cortical cataract than men (age adjusted) (Mitchell et al. 1997 and Rochtchina et al. 2003).

Figure M.1 Age-specific separation rates for lens insertion and/or removal

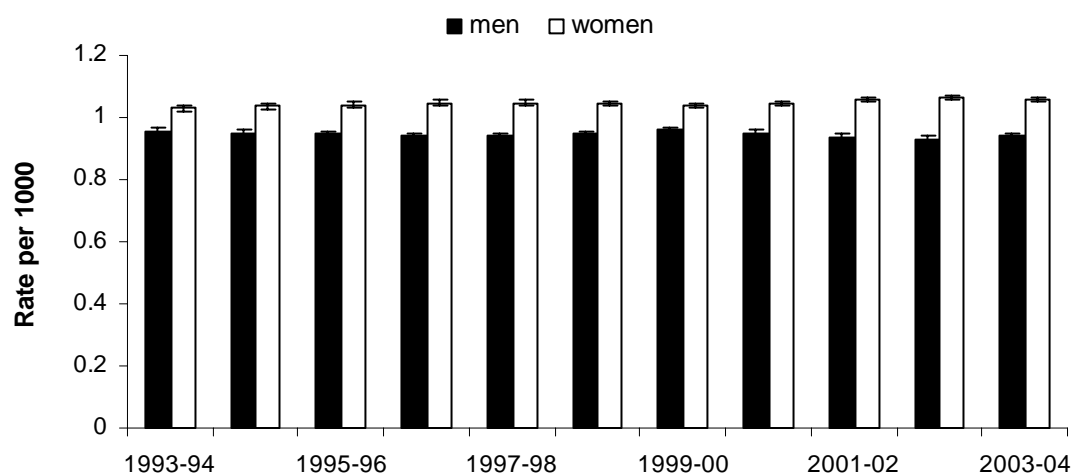


Data source: AIHW (unpublished data) and ABS (2004 unpublished) estimated resident population data. Data available in technical paper 4.

Gender

Age-adjusted rates of lens insertion and/or removal were significantly higher for women, consistent with their higher susceptibility to cortical cataract than men (figure M.2). McCarty et al. (1999) also found, controlling for age, that women were significantly more likely to have cataracts than men.

Figure M.2 **Age-standardised separation rates for lens insertion and/or removal^a**



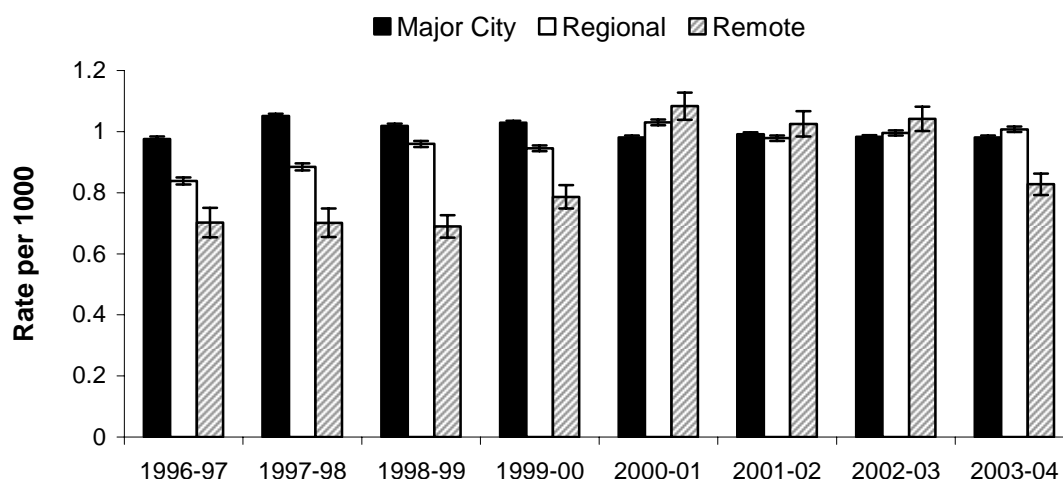
^a Separation rates are shown with 95 per cent confidence intervals.

Data source: AIHW (unpublished data). Data available in technical paper 4.

Remoteness area

Prior to 2000-01, those living in major cities were significantly more likely to undergo lens insertion and/or removal (figure M.3). However, in 2000-01, the differences in lens insertion and removal rates across regions fell markedly — a change also observed for some other medical procedures examined in this study (chapter 6).

Figure M.3 Age-standardised separation rates for lens insertion and/or removal by remoteness area^a



^a Separation rates are shown with 95 per cent confidence intervals.

Data source: AIHW (unpublished data). Data available in technical paper 4.

Socioeconomic status

There is no evidence in Australia that socioeconomic status, occupation or education levels are predictors of cataract (Panchapakesan et al. 2003; Younan et al. 2002). However, in theory, since cataract rates are linked to UV exposure and smoking, those in disadvantaged socioeconomic groups or in more remote areas may be more susceptible (because they may be more likely to have occupations that lead to UV exposure, for example). For similar reasons, and because of their high rates of diabetes, Indigenous people are also likely to be at relatively high risk of cataract (see below).

Ratios of procedure rates for those in the most disadvantaged group to those in other socioeconomic groups are presented in table M.1 for the period 1998-99 to 2003-04. Ratios of less than one indicate that those in more disadvantaged regions have higher procedure rates than those in less disadvantaged areas, reflecting partly the possibility that those in more disadvantaged regions are more susceptible to cataract because of links between cataract and smoking and UV exposure.

Table M.1 Lens insertion and/or removal by socioeconomic status, 1998-99 to 2003-04

	20–29 years	30–39 years	40–49 years	50–59 years	60–69 years	70+
Rate ratio						
2/1	1.1	1.0	1.1	1.1	1.2	1.3
3/1	0.9	0.9	0.9	0.9	1.0	1.2
4/1	1.1	1.0	1.0	1.1	1.2	1.4
5/1	0.7	0.6	0.7	0.8	0.9	1.1

^a A high index score (5) means the area has few families of low income and few people with little training and in unskilled occupations. A high score reflects lack of disadvantage (ABS 2001). Rate ratios reflect differences between each level of disadvantage, for example, the least disadvantaged over the most disadvantaged (age specific procedure rate for group five divided by age specific procedure rate for group one). ^b Procedure rates are per 1000 people in each age group and each IRSD category.

Source: Productivity Commission calculations based on AIHW (unpublished data) and ABS (2004 unpublished) estimated resident population data. Data available in technical paper 4.

Patterns of lens insertion and/or removal across socioeconomic groups show that:

- those in the second most disadvantaged group (socioeconomic group '2' in the table) were more likely to undergo surgery than those in the least disadvantaged and most disadvantaged groups;
- ratios were more likely to be less than one for younger than older people; and
- those aged 70 years or more in the most disadvantaged areas were the least likely in their age group to receive a procedure.

Indigenous status

In a study undertaken in the 1970s, Indigenous people were found to have twice the prevalence of lens abnormalities compared with non-Indigenous people (Taylor 1997). Despite their relatively higher risk of cataract, and documented higher prevalence of lens abnormalities, Indigenous Australians were significantly less likely (on an age-adjusted basis), to undergo lens insertion and/or removal than non-Indigenous Australians between 2001-02 and 2003-04 (table M.2).

Table M.2 Age-standardised rates of lens insertion and/or removal by Indigenous status

<i>Year</i>	<i>Indigenous status</i>	<i>LCL^a</i>	<i>Age standardised separation rate</i>	<i>UCL^a</i>
2001-02	Indigenous	0.53	0.57	0.61
	Non-Indigenous	1.00	1.00	1.01
2002-03	Indigenous	0.59	0.63	0.67
	Non-Indigenous	1.00	1.00	1.01
2003-04	Indigenous	0.65	0.69	0.74
	Non-Indigenous	1.00	1.00	1.01

^a LCL and UCL denote lower and upper confidence limits at 95 per cent.

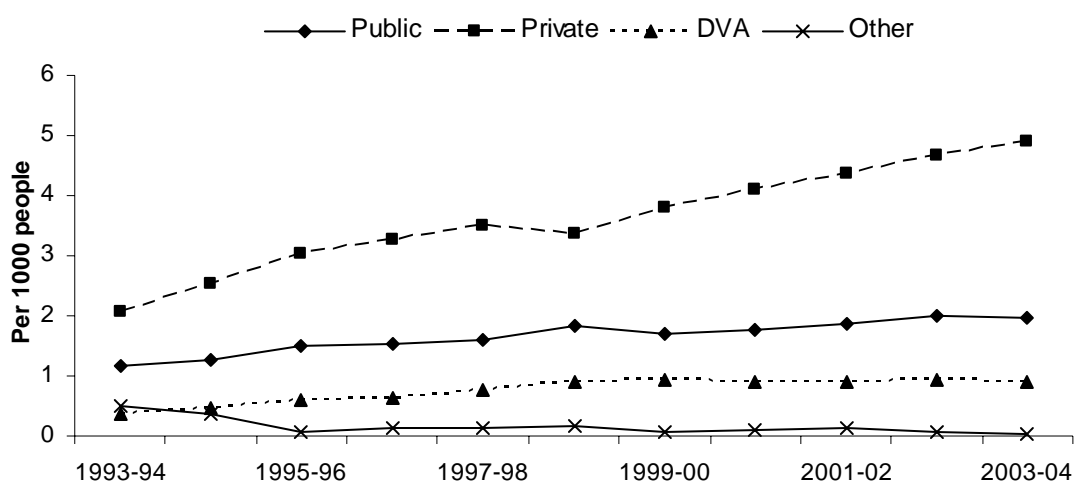
Source: AIHW (unpublished data).

Patient funding status

In Australia, patients can undergo cataract surgery in a public hospital, as either a public or private patient, or in a private day surgery or hospital, as a private patient.

Between 1993-94 and 2003-04, on average, private patients were more than twice as likely to undergo lens insertion and/or removal than public patients (figure M.4). In 1986, almost 80 per cent of cataract operations were private procedures (Keeffe and Taylor 1996). However, the rate of growth in procedure rates per year during the period was highest for veterans (10 per cent per year for patients funded by the Department of Veterans' Affairs, 9 per cent per year for privately-funded patients and 6 per cent per year for publicly-funded patients). (Separation rates have not been adjusted for differences in age profiles over time or across sectors.)

Figure M.4 Rates of lens insertion and/or removal by patient funding status

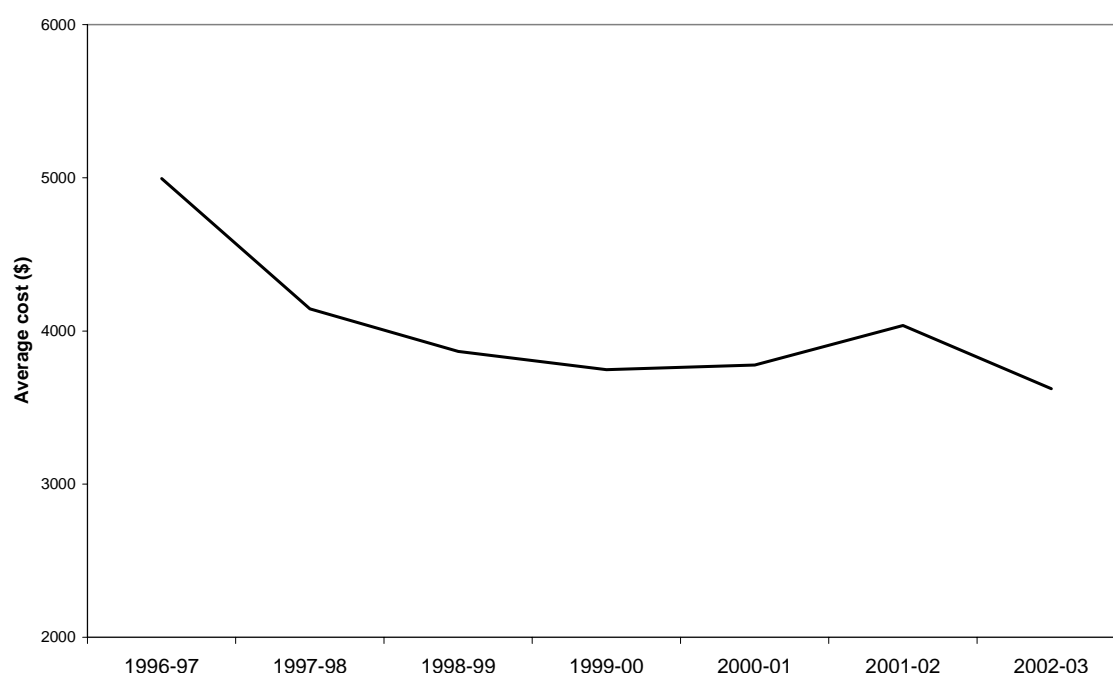


Data source: AIHW (unpublished data). Data available in technical paper 4.

Total expenditure

In 2002-03, actual expenditure on cataract surgery was \$492.5 million, up from \$430.3 million in 1996-97 (DoHA 2005b). In real terms, expenditure stayed approximately constant. Separations for cataract surgery over the last decade or so have almost doubled. Separations increased from 99 013 in 1996-97 to 135 939 in 2002-03 (AIHW 2005d) and average cost per cataract procedure fell (figure M.5).

Figure M.5 **Average cost per IOL procedure**



Data source: DoHA (2005b).

Asimakis et al. (1996) consider that developments in phacoemulsification techniques and adoption of foldable IOLs have contributed to the fall in the costs of cataract surgery by:

- reducing surgeons' labour input for each operation, therefore increasing their productivity;
- shortening patients' length of stay in hospital (figure M.6); and
- minimising post-surgery complications and costs.

As shown in figure M.6, the average length of stay in hospital fell from almost two days in 1993-94 to about one day in 2002-03. Taylor (2000) observed that, in the past, the number of hospital beds available limited the volume of cataract surgery

performed, but that this is no longer an important constraint because theatre availability now plays a greater role in determining access to surgery.

Figure M.6 Average length of hospital stay



Data source: AIHW (2005d).

M.3 Benefits

In general terms, the key benefit of cataract surgery is improved vision which results in significant improvements in quality of life for patients and their carers, increased workforce participation of patients and carers, reduced reliance on health and community services such as nursing homes, and reduced calls on medical and hospital services for conditions related to vision impairment, such as falls and fractures.

With respect to the adoption of phacoemulsification combined with foldable IOLs, the benefits relative to previously-used techniques also include:

- better results from surgery in terms of vision improvement — for example, some previous approaches required the use of aphakic spectacles after surgery which resulted in distorted vision for patients (Olson et al 2003);
- surgery has changed from an in-patient procedure requiring a hospital stay of four to five days (Keefe and Taylor 1996) to a day-patient procedure using local or regional

anaesthetic (rather than general anaesthetic, unless patient comorbidities require it (Sugar 2000));

- fewer intra-operative risks and complications, such as haemorrhage;
- fewer post-operative complications and shorter recovery times; and
- it is feasible, easier, and arguably safer, to perform cataract surgery when the cataract is at an early stage and thus the loss of visual acuity is less pronounced. The previous dominant approach, ECCE, is easier to perform on mature cataracts so surgery was usually delayed until vision loss was significant in both eyes.

M.4 Cost effectiveness

In a study on cost effectiveness of cataract surgery in the United States, Busbee et al. (2002) found that initial cataract surgery (the patient's first procedure) resulted in US\$2020 (A\$2707) spent per QALY gained. Sensitivity analysis (involving variations to costs, utility values or the discount rate used) produced cost per QALY results ranging between US\$1432 (A\$1919) and \$US4398 (A\$5893).

Busbee et al. commented that:

... cataract surgery with IOL implantation is a very cost-effective intervention using conventional standards. Although the standards for cost-effectiveness in health care vary from one society to another, depending on the resources that society has to expend, it has been suggested that interventions costing less than US\$20 000/QALY [A\$26 800/QALY] gained are highly cost-effective, whereas those costing more than US\$100 000/QALY [A\$134 000/QALY] are not cost-effective. With a cost-effectiveness of US\$2020/QALY [A\$2707/QALY] gained, cataract surgery falls well within the very cost-effective range. (2002, p. 609)

M.5 Future developments

In the foreseeable future, it is expected that surgical removal will continue to be the standard treatment for cataract, although improvements in safety and in terms of vision outcomes are also expected (Olson et al. 2003).

Surgical improvements could increase the number of patients eligible or recommended for surgery if visual acuity thresholds for surgery continue to fall. Nonetheless, regardless of whether surgical improvements occur, cataract surgery will increase in future as a result of population ageing. For example, McCarty (2002, p. 91) expects that 'the relative number of cataracts will double over the next 50 years due to the ageing of the population'.

Advances in phacoemulsification machinery and alternative phacoemulsification techniques — laser and sonic — may lead to improvements in current phacoemulsification techniques, which can cause burns and eye damage through the heat they generate (Solomon and Donnenfeld 2003; Sugar and Scherzer 1999). These advances would also allow for even smaller eye incisions, although IOLs are not yet small enough to fit through these openings (Solomon and Donnenfeld 2003). Further, while laser and sonic lens removal may prove to be safer, they are currently less successful than the dominant ultrasound technique for removing very hard cataracts (Olson et al. 2003).

Apart from refinements to existing techniques, the most significant advance in cataract surgery in the next 5 to 10 years is expected to be further development and adoption of ‘accommodating’ IOLs. ‘Accommodating’ IOLs attempt to maintain the eye’s ability to focus on objects at any distance. Currently, cataract surgery removes this ability which means that the patient has to use bifocal spectacles after surgery. Due to the risks involved, surgery to remove a clear lens to allow insertion of an IOL for refractive purposes is considered controversial, particularly in cases other than for older patients who already have early cataract change and who are nonetheless seeking refractive surgery (Olson et al. 2003). However, the surgery is becoming increasingly accepted in the United States (Olson et al. 2003).

Widespread use of ‘accommodating’ IOLs would be expected to increase expenditure on cataract surgery substantially if it were to reduce vision acuity thresholds to such an extent that cataract surgery methods become the preferred treatment for refractive error. Cataract surgery methods, usually involving the insertion of monofocal single-power IOLs, already have been used recently to correct refractive error in eyes that have little or no cataract (Sugar 2000).

In contrast, if techniques for preventing or slowing the progression of cataracts, even to a minor extent, could be identified in future, expenditure on cataracts could be significantly deferred or reduced (Olson et al. 2003). While some authors consider that successful preventative strategies for cataract are currently unknown or untested (McCarty 2002), Brian and Taylor (2001, p. 250) have stated that, in industrialised countries, ‘cataract could be halved’ by eliminating smoking and reducing UVB radiation. In any case, cost-effectiveness assessments of preventative strategies would be required to compare these strategies to the cost effectiveness of cataract surgery (McCarty 2002).

M.6 Conclusion

Advances in cataract surgery, especially widespread adoption of phacoemulsification techniques combined with foldable IOLs, have contributed to the rise in cataract surgery in Australia over the past decade. These technological advances have improved outcomes from cataract surgery and generated significant benefits for patients and the community.

Expenditure on cataract surgery was virtually unchanged in real terms between 1996-97 and 2002-03 yet the number of separations for cataract surgery over the same period increased substantially, indicating a significant reduction in the average cost per surgery. In comparison with other medical interventions, cataract surgery is considered one of the most cost-effective treatments offered to patients.

Population ageing, particularly ageing of the ‘oldest old’, is expected to be the key factor driving demand for cataract surgery in the future. However, other factors will also play a role, such as continued improvements in surgeon productivity and increased incomes and living standards which could translate into reduced tolerance for any given level of visual impairment, and thus greater demand for cataract surgery.

References

- Abbott, T. (Minister for Health and Ageing) 2005a, *Australia–United States Free Trade Agreement and the Pharmaceutical Benefits Scheme*, Media release no. ABB008/05, 4 February.
- 2005b, *Private Health Premiums*, Media release no. ABB019/05, 2 March.
- 2005c, *Pricing of Lipitor (atorvastatin) on the Pharmaceutical Benefits Scheme*, Media release no. ABB019/05, 15 July.
- 2004a, *Katherine HealthConnect Trial to Pioneer Electronic Health Records in the Northern Territory*, Media release no. ABB128/04, 4 August.
- 2004b, *New PBS Medicines Available Faster: Report Plan*, Media release no. ABB122/04, 27 July.
- 2004c, *Two HealthConnect Trials for Queensland*, Media release no. ABB047/04, 29 April.
- Abelson, P. 2003, 'The value of life and health for public policy', *The Economic Record*, vol. 79, Special issue, Selected papers from the 31st National Conference of Economists, Adelaide, 30 September–4 October, pp. s2–s13.
- ABS (Australian Bureau of Statistics) 2004a, *Australian Historical Population Statistics.*, Cat. no. 3105.0.65.001, ABS, Canberra.
- 2004b, *Population by Age and Sex*, Australian States and Territories, Cat. no. 3201.0, ABS, Canberra, June.
- 2004c, *National Income, Expenditure and Product, Australian National Accounts*, Cat. no. 5206.0, ABS, Canberra, March.
- 2004d, *Deaths Australia 2003*, Cat. no. 3302.0, ABS, Canberra.
- 2004e, *Suicides: Recent Trends, Australia*, Cat. no. 3309.0.55.001, ABS, Canberra, December.
- 2003a, *Information Paper: Suicides, Australia*, Cat. no. 3309.0.55.001, ABS, Canberra, February.
- 2003b, *Causes of Death*, Cat. no. 3303.0, ABS, Canberra.
- 2002a, *National Health Survey 2001: Summary of Results*, Cat. no. 4364.0, ABS, Canberra, 25 October.
- 2002b, *Population Projections 2002 to 2101*, Cat. no. 3222.0, ABS, Canberra.

-
- 2002c, *Year Book Australia 2002*, Cat. no. 1301.0, ABS, Canberra.
- 2001, *Census of Population and Housing — Socioeconomic Indexes for Areas*, Australia, Cat. no. 2039.0, ABS, Canberra.
- 2000, *Australian Social Trends 2000*, Cat. no. 4102.0, ABS, Canberra, July.
- 1998, *Mental Health and Wellbeing: Profile of Adults, Australia*, Cat. no. 4326.0, ABS, Canberra.
- and AIHW (Australian Institute of Health and Welfare) 2003, *The Health and Welfare of Australia's Aboriginal and Torres Strait Islander Peoples*, ABS Cat. no. 4704.0, ABS, Canberra.
- ACAM (Australian Centre for Asthma Monitoring) 2005a, *Asthma in Australia 2005*, AIHW Asthma Series 2, AIHW Cat. no. ACM 6, AIHW, Canberra.
- 2005b, *Health Care Expenditure and the Burden of Disease due to Asthma in Australia*, Cat. no. ACM 5, AIHW, Canberra.
- 2003, *Asthma in Australia 2003*, AIHW Asthma Series 1, AIHW Cat. no. ACM 1, AIHW, Canberra.
- Access Economics 2005, *Arthritis — the Bottom Line: the Economic Impact of Arthritis in Australia*, Report prepared for Arthritis Australia, Canberra.
- 2004, *Clear Insight, The Economic Impact and Cost of Vision Loss in Australia*, Report prepared for the Centre for Eye Research Australia and the Eye Research Australia Foundation, Canberra, August.
- 2003a, *The Dementia Epidemic: Economic Impact and Positive Solutions for Australia*, Report for Alzheimer's Australia, Canberra, March.
- 2003b, *The Economic Impact of an Accelerated Rollout of Broadband in Hospitals*, Report prepared for the National Office for the Information Economy, Canberra, December.
- 2003c, *Exceptional Returns: The Value of Investing in Health R&D in Australia*, Report prepared for the Australian Society for Medical Research, Canberra, September.
- ACPMH (Australian Centre for Post-traumatic Mental Health) 2003a, *About the Australian WHOQoL-100*, http://www.acpmh.unimelb.edu.au/whoqol/whoqol-100_1.html (accessed 2 March 2005).
- 2003b, *About the World Health Organisation Quality of Life (WHOQoL) Project*, <http://www.acpmh.unimelb.edu.au/whoqol/aboutProject.html> (accessed 2 March 2005).
- Agency for Healthcare Research and Quality 2002, *Rating the Strength of Scientific Research Findings*, AHRQ Publication no. 02-P022, AHRQ, Rockville, Maryland.

-
- Ahearn, M.D. and Kerr, S.J. 2003, 'General practitioners' perceptions of the pharmaceutical decision-support tools in their prescribing software', *Medical Journal of Australia*, vol. 179, no. 1, pp. 34–7.
- AHIA (Australian Health Insurance Association) 2005, *Submission to Senate Community Affairs Legislation Committee on National Health Amendment (Prostheses) Bill 2004*, Canberra.
- AHTAC (Australian Health Technology Advisory Committee) 1996, *Prostate cancer screening: Summary of the review prepared by the Australian Health Technology Advisory Committee*, <http://www7.health.gov.au/pubs/ahtac/prostate.htm> (accessed 14 June 2005).
- AHWAC, AMWAC and AHWOC (Australian Health Workforce Advisory Committee, Australian Medical Workforce Advisory Committee, and Australian Health Workforce Officials' Committee) 2004, *Technology and Health Workforce Planning*, Health Workforce Issues Paper 2, Draft, December.
- AIHW (Australian Institute of Health and Welfare) 2005a, *Interactive Cancer Data*, online statistics, <http://www.aihw.gov.au/cancer/datacubes/index.cfm> (accessed 2 August 2005).
- 2005b, *Australian Hospital Statistics 2003-04*, Health Services Series no. 23, Cat. no. HSE 37, AIHW, Canberra.
- 2005c, *Mortality FAQs*, <http://www.aihw.gov.au/mortality/faqs.cfm> (accessed 22 March 2005).
- 2005d, *National Hospital Morbidity Database*, online statistics, http://www.aihw.gov.au/hospitals/NHM_database.cfm (accessed 17 March 2005).
- 2004a, *Australian Hospital Statistics 2002-03*, Health Services Series no. 22, Cat. no. HSE 32, AIHW, Canberra.
- 2004b, *Australia's Health 2004*, Cat. no. AUS 44, AIHW, Canberra.
- 2004c, *Health System Expenditure on Disease and Injury in Australia, 2000-01*, Health and Welfare Expenditure Series no. 19, Cat. no. HWE 26, AIHW, Canberra.
- 2004d, *Health Expenditure Australia 2002-03*, Health and Welfare Expenditure Series no. 20, Cat. no. HWE 27, AIHW, Canberra.
- 2004e, *Coronary Heart Disease*, <http://www.aihw.gov.au/cvd/majordiseases/coronary.html> (accessed 27 January 2005).
- 2004f, *Cardiovascular Disease*, Data Briefing no. 1, Canberra, September.

-
- 2003a, *Rural, Regional and Remote Health, A Study on Mortality*, Rural Health Series no. 2, Cat. no. PHE 45, AIHW, Canberra.
- 2003b, *Health Expenditure Australia 2001-02*, Health and Welfare Expenditure Series no. 17, Cat. no. HWE 24, AIHW, Canberra.
- 2000, *Waiting Times for Elective Surgery 1999-00*, Health Services Series no. 18, Cat. no. HSE 18, AIHW, Canberra.
- and AACR (Australasian Association of Cancer Registries) 2004, *Cancer in Australia 2001*, Cancer Series no. 28, AIHW Cat. no. CAN 23, AIHW, Canberra.
- 2001, *Cancer Survival in Australia, 2001, Part 1: National summary statistics*, AIHW Cancer Series no. 18, AIHW Cat. no. CAN 13, AIHW, Canberra.
- , NHMRC and NBCC (National Health and Medical Research Council and National Breast Cancer Centre) 1999, *Breast Cancer in Australian Women, 1982–1996*, AIHW Cancer Series, Cat. no. CAN 6, AIHW, Canberra.
- AIHW and NHF (National Heart Foundation of Australia) 2004, *Heart, Stroke and Vascular Diseases — Australian Facts 2004*, Cardiovascular Disease Series no. 22, AIHW, Cat. no. CVD 27, Canberra.
- Allen, L. 2005, 'Attention deficit drugs in spotlight', *Australian Financial Review*, 1 July, p. 27.
- ALRC (Australian Law Reform Commission) 2004, *Genes and Ingenuity, Gene Patenting and Human Health*, ALRC publication no. 99, ALRC, Sydney.
- and AHEC (Australian Health Ethics Committee) 2003, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC no. 96, ALRC, Sydney.
- Altenstetter, C. 2002, 'EU and Member State Medical Devices Regulation', *International Journal of Technology Assessment in Health Care*, vol. 19, no. 1, pp. 228–48.
- Alter, D., Naylor, D., Austin, P., Chan, B. and Tu, J. 2003, 'Geography and service supply do not explain socioeconomic gradients in angiography use after acute myocardial infarction', *Canadian Medical Association Journal*, vol. 168, no. 3, February, pp. 261–4.
- Alter, D., Naylor, D., Austin, P. and Tu, J. 1999, 'Effects of socioeconomic status on access to invasive cardiac procedures and on mortality after acute myocardial infarction', *The New England Journal of Medicine*, vol. 341, no. 18, pp. 1359–67.
- Alvarez, J. 2004, 'Cardiac surgery in octogenarians and beyond', *Medical Journal of Australia*, vol. 181, no. 4, pp. 181–2.

-
- Alvarez, R. 2003, 'Health care has to move into the hi-tech age', *Bulletin of the World Health Organization*, vol. 83, no. 5, p. 323.
- AMA (Australian Medical Association) 2005, *Super BUPA blooper on private medical care*, Media release, 20 January.
- Amensen, T. and Nord, E. 1999, 'The value of DALY life: problems with ethics and validity of disability adjusted life years', *British Medical Journal*, vol. 319, 27 November, pp. 1423–5.
- Ament, A., Baltussen, R., Duru, G., Rigaud-Bully, C., de Graeve D., Ortqvist, A., Jonsson, B., Verhaegen, J., Gaillat, J., Christie, P., Cifre, A.S., Vivas, D., Loiseau, C. and Fedson, D.S. 2000, 'Cost-effectiveness of pneumococcal vaccination of older people: a study in 5 western European countries', *Clinical Infectious Diseases*, vol. 31, no. 2, pp. 445–50.
- American Urological Association 2000, 'Prostate-specific antigen (PSA) best practice policy', *Oncology*, vol. 14, no. 2, pp. 267–86.
- Andersen, R. 1995, 'Revisiting the behavioural model and access to medical care: does it matter?', *Journal of Health and Social Behaviour*, vol. 36, no. 1, pp. 1–10.
- Anderson, A.N., Moodley, I. and Kropman, K. 2000, 'South African pharmaco-economic analysis of the acute infarction ramipril efficacy (AIRE) study', *Cardiovascular Journal of South Africa*, vol. 11, no. 2, pp. 89–94.
- Anderson, J.N., Fennessy, P.A., Fenessey, G.A., Schattner, R.L. and Burrows, E.A. 1999, 'Picking Winners: Assessing New Health Technology', *Medical Journal of Australia*, vol. 171, no. 10, pp. 557–9.
- Andrology Australia 2003, *Treatment of Prostate Cancer*, <http://www.andrologyaustralia.org/prostate/treatment/localised.htm> (accessed 23 June 2005).
- Angioplasty 2005, Drug-eluting stents, US, <http://www.angioplasty.org/articles/des1.html> (accessed 13 January 2005).
- AOA NJRR (Australian Orthopaedic Association National Joint Replacement Registry) 2004a, *Annual Report*, AOA, Adelaide.
- 2004b, Background to the AOA NJRR, Adelaide, <http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp> (accessed 10 February 2005).
- Armstrong, K., Micco, E., Carney, A., Stopfer, J. and Putt, M. 2005, 'Racial differences in the use of BRCA1/2 testing among women with a family history of breast or ovarian cancer', *Journal of the American Medical Association*, vol. 293, no. 14, April, pp. 1729–36.
- Asada, Y. and Ohkusa, Y. 2002, *Analysis of Health and Activity Limitation Index (HALex), its Distribution, and its Distribution by Income in Japan, 1989 and*

-
- 1998, Discussion paper no. 569, Institute of Social and Economic Research, Osaka University, November, <http://www.iser.osaka-u.ac.jp/library/dp/2002/DP0569.PDF> (accessed 2 March 2005).
- ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures - Surgical) 2004, *Da Vinci Surgical Robotic System: Technology Overview*, Executive Summary, <http://www.surgeons.org/asernip-s/publications.htm> (accessed 22 March 2005).
- Asimakis, P., Coster, D.J. and Lewis, D.J. 1996, 'Cost effectiveness of cataract surgery: a comparison of conventional extracapsular surgery and phacoemulsification at Flinders Medical Centre', *Australian and New Zealand Journal of Ophthalmology*, vol. 24, pp. 319–25.
- ATC (American Thoracic Society) 2004, *Instruments: the Nottingham Health Profile (NHP)*, <http://www.atsqol.org/nott.asp> (accessed 2 March 2005).
- Atkins, D., Siegel, J. and Slutsky, J. 2005, 'Making policy when the evidence is in dispute', *Health Affairs*, vol. 24, no. 1, pp. 102–13.
- Atkins, J.H. and Gershell, L.J. 2002, 'From the analyst's couch, selective anticancer drugs', *Nature Reviews*, vol. 1, pp. 491–2.
- Audet, A-M., Doty, M., Peugh, J., Shamasdin, J., Zapert, K. and Schoenbaum, S. 2004, 'Information technologies: when will they make it into physicians' black bags?', *Medscape General Medicine*, 7 December, http://www.cmwf.org/publications/publications_show.htm?doc_id=251984 (accessed 21 December 2004).
- Australian Council for Safety and Quality in Health Care 2005, *Adverse Event Rates*, Fact sheet, <http://www.safetyandquality.org/articles/Action/advrsefact.pdf> (accessed 18 July 2005).
- Australian Financial Review* 2005, 'Renewed deal talk about Regenera', 27 January, p. 16.
- Australian Health Care Agreement between the Commonwealth of Australia and the State of NSW 2003–2008*, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-ahca-agreement.htm> (accessed 9 April 2005).
- Babapulle, M., Joseph, L., Belisle, P., Brophy, J. and Eisenberg, M. 2004, 'A hierarchical Bayesian meta-analysis of randomised clinical trials of drug-eluting stents', *The Lancet*, vol. 364, pp. 583–91.
- Baim, D. 2004, 'New devices for percutaneous coronary intervention are rapidly making bypass surgery obsolete', *Current Opinion Cardiology*, vol. 19, no. 6, pp. 593–7.

-
- Baker, A.H. 2002, 'Vascular gene therapy: implications for future treatment of cardiovascular disease', in *Biotechnology and Healthy Ageing, Policy Implications of New Research*, OECD, Paris, pp. 85–90.
- Baker, L., Birnbaum, H., Geppert, J., Mishol, D. and Moyner, E. 2003, 'The relationship between technology availability and health care spending', *Health Affairs*, 5 November, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.537v1> (accessed 4 April 2005).
- Barrett, B., Byford, S. and Knapp, M. 2005, 'Evidence of cost-effective treatments for depression: a systematic review', *Journal of Affective Disorders*, vol. 84, pp. 1–13.
- Baselga, J., Carbonell, X., Castaneda-Soto, N., Clemens, M., Green, M., Harvey, V., Morales, S., Barton, C. and Ghahramani, P. 2005, 'Phase II study of efficacy, safety and pharmacokinetics of trastuzumab monotherapy administered on a 3-weekly schedule', *Journal of Clinical Oncology*, vol. 23, no. 10, pp. 2162–71.
- Bates, D.W. and Gawande, A.A. 2003, 'Improving patient safety with information technology', *New England Journal of Medicine*, vol. 348, no. 25, pp. 2526–34.
- BBi 2003, *Medical Device Innovation, Vol. IV, What's New at Selected Development-Stage Companies*, Thomson Bioworld, Atlanta.
- BCG (Boston Consulting Group) 2004, *National Health Information Management and Information & Communications Technology Strategy*, E-Health Strategy, Final report for the National Health Information Group and Australian Health Information Group, April.
- Becker, J.R. 2005, A list of future treatments for depression, anxiety, sleep disorders and psychosis, www.neurotransmitter.net/newdrugs.html (accessed 16 March 2005).
- Beilby, J.J., Duszynski, A.J. and Wilson, A. 2005, 'Electronic decision support systems at point of care: trusting the *deus ex machina*', *Medical Journal of Australia*, vol. 183, no. 2, pp. 99–100.
- Bell, G. 2005, 'Joy in a jar', *Sydney Morning Herald*, 25 June, p. 41.
- Bell, R. 2002, 'What can we learn from Herceptin trials in metastatic breast cancer?', *Oncology*, vol. 63, supp. no. 1, pp. 39–46.
- Benoit, R.M., Gronberg, H. and Naslund, M.J. 2001, 'A quantitative analysis of the costs and benefits of prostate cancer screening', *Prostate Cancer and Prostatic Diseases*, vol. 4, no. 3, pp. 138–45.

-
- Benoit, R.M. and Naslund, M.J. 1997, 'The socioeconomic implications of prostate-specific antigen screening', *Urologic Clinics of North America*, vol. 24, no. 2, May, pp. 451–8.
- Bensoussan, A. and Lewith, G.L. 2004, 'Complementary medicine research in Australia: a strategy for the future', *Medical Journal of Australia*, vol. 181, no. 6, pp. 331–3.
- Berg, A.O. 2003, 'Screening for prostate cancer', *Annals of Internal Medicine*, vol. 139, no. 6, p. 532.
- Berg, M., van der Grinten, T. and Klazinga, N. 2004, 'Technology assessment, priority setting, and appropriate care in Dutch health care', *International Journal of Technology Assessment in Health Care*, vol. 20, no. 1, pp. 35–43.
- Berndt, E.R., Cutler, D.M., Frank, R.G., Griliches, Z., Newhouse, J.P. and Triplett, J.E. 2000, 'Medical care prices and output', in Arrow, K. and Intriligator, M.D. (eds), *Handbook of Health Economics*, volume 1A, Elsevier, Amsterdam, pp. 119–80.
- Berry, D.J., Berger, R.A., Callaghan, J.J. and Dorr, L.D. 2003, 'Symposium: Minimally invasive total hip arthroplasty', *Journal of Bone and Joint Surgery (American Volume)*, vol. 85, no. 11, pp. 2235–6.
- Bickerdyke, I., Dolamore, R., Monday, I. and Preston, R. 2002, *Supplier-Induced Demand for Medical Services*, Staff working paper, Productivity Commission, Canberra, November.
- Bilous, M. (on behalf of the HER2 testing advisory board) 2001, 'HER2 testing recommendations in Australia', *Pathology*, vol. 33, pp. 425–7.
- Binder, J., Brautigam, R., Jonas, D. and Bentas, W. 2004, 'Robotic surgery in urology: fact or fantasy?', *British Journal of Urology International*, vol. 94, pp. 1183–7.
- Birkett, D.J., Mitchell, A.S. and McManus, P.A. 2001, 'A cost-effectiveness approach to drug subsidy and pricing in Australia', *Health Affairs*, vol. 20, no. 3, pp. 104–14.
- Birrell, F., Johnell, O. and Silman, A. 1999, 'Projecting the need for hip replacement over the next three decades: influence of changing demography and threshold for surgery', *Annals of the Rheumatic Diseases*, vol. 58, pp. 569–72.
- Bishop, J. (Minister for Ageing) 2005, *Independent Committee to Review Human Cloning and Embryo Research Legislation*, Media release no. JB079/05, 17 July.
- Blendon, R.J., Schoen, C., DesRoches, C.M., Osborn, R., Zapert, K. and Raleigh, E. 2004, 'Confronting competing demands to improve quality: a five-country hospital survey', *Health Affairs*, vol. 23, no. 3, pp. 119–35.

-
- Blomqvist, A.G and Carter, R.A.L. 1997, 'Is health care really a luxury?', *Journal of Health Economics*, vol. 16, pp. 207–229.
- Bloom, D., Canning, D. and Jamison, D. 2004, 'Health, wealth and welfare', *Finance and Development*, vol. 41, no. 1, pp. 10–15.
- Blum, D. 2003, *Agency for Healthcare Research and Quality*, E-text on Health Technology Assessment (HTA) Information Resources, www.nlm.nih.gov/nichsr/eha/chapter7.html (accessed 30 March 2004).
- Bosch, J.L., Tetteroo, E., Mali, W.P. and Hunink, M.G. 1998, 'Iliac arterial occlusive disease: cost-effectiveness analysis of stent placement versus percutaneous transluminal angioplasty. Dutch Iliac Stent Trial Study Group', *Radiology*, vol. 208, no. 3, pp. 664–8.
- Bozzette, S.A., Joyce, G., McCaffrey, D.F., Leibowitz, A.A., Morton, S.C., Berry, S.H., Rastegar, A., Timberlake, D., Shapiro, M.F. and Goldman, D.P. 2001, 'Expenditures for the care of HIV-infected patients in the era of highly active antiretroviral therapy', *The New England Journal of Medicine*, vol. 344, no. 11, pp. 817–23.
- Braidotti, G. 2005, 'Super glue for plastic people. Polymers may ease the pain of broken bones', *CSIRO Solve, A CSIRO Review of Scientific Innovations for Australian Industry*, Issue 2, February, p. 3.
- Brazier, J., Deverill, M., Green, C., Harper, R. and Booth, A. 1999, 'A review of the use of health status measures in economic evaluation', *Health Technology Assessment*, vol. 3, no. 9.
- Breastcancer.org, 2005a, Combination of Herceptin and Navelbine effective, http://www.breastcancer.org/research_herceptin_050002c.html (accessed 14 June 2005).
- 2005b, Purchasing and costs, http://www.breastcancer.org/tre_sys_tamox_Final.html (accessed 4 July).
- Brettler, D. 2005, 'Gene therapy for haemophilia', *Journal of Thrombosis and Haemostasis*, vol. 3, pp. 1317–9.
- Brian G. and Taylor H. 2001, 'Cataract blindness — challenges for the 21st century', *Bulletin of the World Health Organization*, vol. 79, no. 3, pp. 249–56.
- Bright, A. 2003, 'Confidentiality guidelines for consumer representatives on MSAC supporting committees', *Australian Health Consumer*, no. 3 (2002-03), pp. 25–7.
- Britt, H., Valenti, L. and Miller, G. 2002, 'Time for care: length of general practice consultations in Australia', *Australian Family Physician*, vol. 31, p. 9.

-
- Britton, A., Shipley, M., Marmot, M. and Hemingway, H. 2004, 'Does access to cardiac investigation and treatment contribute to social and ethnic differences in coronary heart disease? Whitehall II prospective cohort study', *British Medical Journal*, doi:10.1136/bmj.38156.690150.AE (published 5 July).
- Brooks, P.M., Hooper, M.J. and Smallwood, R.A. 2004, 'Bone and joint diseases: prevention and control', *Medical Journal of Australia*, vol. 180, no. 9, suppl., pp. s4–s5.
- Brotherton, J.M.L., Clarke, S.J. and Quine, S. 2002, 'Use of the internet by oncology patients: its effect on the doctor–patient relationship', Letters, *Medical Journal of Australia*, vol. 177, no. 7, p. 395.
- Brouwer, W.B.F. and Koopmanschap, M.A. 1998, 'How to calculate indirect costs in economic evaluations', *Pharmacoeconomics*, vol. 13, no. 5, pp. 563–6.
- Brown, I., Wilson, C., Doughty, J., Weiler-Mithoff, E. and George, W. 2003, 'Re: inequalities in breast cancer reconstructive surgery according to social and locational status in Western Australia', Correspondence, *European Journal of Surgical Oncology*, vol. 29, pp. 931–2.
- Bryan, M. 2004a, 'Help for healthy ideas', *Australian Financial Review*, 1 July, p. 19.
- 2004b, 'NSW to revamp clinical system', *Australian Financial Review*, 13 July, p. 29.
- Bryant, B., Knights, K. and Salerno, E. 2003, *Pharmacology for Health Professionals*, Elsevier (Australia) Pty Limited, New South Wales.
- Bryce, C.L. and Cline, K.E. 1998, 'The supply and use of selected medical technologies', *Health Affairs*, vol. 17, no. 1, January/February, pp. 213–24.
- Bucher, H.C., Guyatt, G.H., Cook, D.J., Holbrook, A. and McAlister, F.A. 1999, 'Users' guides to the medical literature, XIX: applying clinical trial results, A: how to use an article measuring the effect of an intervention on surrogate end points', Prepared for the Evidence-Based Medicine Working Group, *Journal of the American Medical Association*, vol. 282, pp. 771–8.
- Buist, A. and Silvas, A. 1998, *Evaluation of the Victorian Telepsychiatry Program*, Report prepared for the Mental Health Branch, Department of Human Services, Victoria.
- Burgess, M. 2004, 'Vaccines: The New Australian Best-Practice Schedule', *Medical Journal of Australia*, vol. 180, no. 10, pp. 494–6.
- Burstin, F. 2004, 'Old implant is still hip', *The Herald Sun*, 11 November, p. 26.

-
- Burton, W., Morrison, A. and Wertheimer, A. 2003, 'Pharmaceuticals and workers productivity loss: a critical review of the literature', *Journal of Occupational and Environmental Medicine*, vol. 45, no. 6, June, pp. 610–21.
- Busbee, B.G., Brown, M., Brown, G. and Sharma, S. 2002, 'Incremental cost-effectiveness of initial cataract surgery', *Ophthalmology*, vol. 109, no. 3, pp. 606–12.
- Cadden, D. 2005, 'Taking pain out of care', *Sydney Morning Herald*, 13 January, p. 7.
- Cai, L. and Kalb, G. 2005, *Health Status and Labour Force Status of Older Working-Age Australian Men*, Melbourne Institute Working Paper Series, no. 9/05, July.
- Cairns, J. 1996, 'Measuring health outcomes', *British Medical Journal*, vol. 313, p. 6.
- Callahan, D. 2003, 'Living and dying with medical technology', *Critical Care Medicine*, vol. 31, no. 5, suppl., pp. s344–s346.
- Cameron, A. 2005, 'A spoonful of medicine', *Sun-Herald*, 15 May, p. 28.
- Cameron, R. (Parliamentary Secretary to the Treasurer) 2004, *Productivity Commission Study of the Impact of Advances in Medical Technology on Healthcare Expenditure in Australia*, Media release no. 27, 31 August.
- Cancer Research UK 2005, A European study into high intensity focused ultrasound (HIFU) for men with early stage prostate cancer, <http://www.cancerhelp.org.uk/trials/trials/selectsearch.asp> (accessed 7 July 2005).
- Capdeville, R., Buchdunger, E., Zimmermann, J. and Matter, A. 2002, 'Glivec (STI571, Imatinib), a rationally developed, targeted anticancer drug', *Nature Reviews*, vol. 1, pp. 493–502.
- Carlsson, P. 2004, 'Health technology assessment and priority setting for health policy in Sweden', *International Journal of Technology Assessment in Health Care*, vol. 20, no. 1, pp. 44–54.
- Cass, A., Cunningham, J., Snelling, P., Wang, Z. and Hoy, W. 2003, 'Renal transplantation for Indigenous Australians: identifying the barriers to equitable access', *Ethnicity and Health*, vol. 8, no. 2, pp. 111–9.
- Cass, A., Cunningham, J., Wang, Z. and Hoy, W. 2001, 'Regional variation in the incidence of end stage renal disease in Indigenous Australians', *Medical Journal of Australia*, vol. 175, no. 1, pp. 24–7.
- Cassrels, D. 2005, 'The holes in the net', *Sydney Morning Herald*, 11 August, p. 4.

-
- CCOHTA (Canadian Coordinating Office for Health Technology Assessment) 2005, *Common Drug Review*, www.ccohta.ca/CDR/cdr_intro_e.cfm (accessed 10 May 2005).
- 2004, 'Bioabsorbable stents for coronary artery disease', CCOHTA publication no. 23, December.
- 2003, *Annual Report 2002-03*, Ottawa.
- Centre for Devices and Radiological Health 2004, *CDRH FY 2004 Annual Report*, US Department of Health and Human Services, Food and Drug Administration.
- Centre for Genetics Education 2004a, *Genetic Counselling*, Genetics Fact Sheet no. 5, <http://www.genetics.com.au/pdf/factSheets/FS5.pdf> (accessed 11 July 2005)
- 2004b, *Gene Therapy*, Genetics Fact Sheet no. 25, <http://www.genetics.com.au/pdf/factSheets/FS25.pdf> (accessed 11 July 2005)
- 2004c, *Pharmacogenetics*, Genetics Fact Sheet no. 25, <http://www.genetics.com.au/pdf/factSheets/FS23.pdf> (accessed 11 July 2005)
- Centre for Health Informatics 2002, 'Electronic decision support activities in different healthcare settings in Australia', in National Electronic Decision Support Taskforce 2003, *Electronic Decision Support for Australia's Health Sector*, DoHA, Canberra.
- Chandra, R., Knickrehm, M. and Miller, A. 1995, 'Healthcare's IT mistake', *The McKinsey Quarterly*, no. 3, pp. 90–100.
- Chang, R.W., Pellissier, J.M. and Hazen, G.B. 1996, 'A cost-effectiveness analysis of total hip arthroplasty for osteoarthritis of the hip', *Journal of the American Medical Association*, vol. 275, no. 11, pp. 858–66.
- Chen, T.H., Yen, M.F. and Tung, T.H. 2001 'A computer simulation model for cost-effectiveness analysis of mass screening for Type 2 diabetes mellitus', *Diabetes Research Clinical Practice*, vol. 54, pp. s37–s42.
- Chernew, M., Fendrick, A.M. and Hirth, R.A. 1997, 'Managed care and medical technology implications for cost growth', *Health Affairs*, vol. 16, no. 2, pp. 196–206.
- Chew, D. 2005, 'Cost effectiveness of drug-eluting stents: if only all things were equal', *Medical Journal of Australia*, vol. 182, no. 8, pp. 376–7.
- Choice* 2004, 'A spoonful of sugar ...', June, pp. 8–13.
- Cipriani, A., Barbui, C. and Geddes, J.R. 2005, 'Suicide, depression, and antidepressants', *British Medical Journal*, vol. 330, pp. 373–4.

-
- Cleland, J.G. and Walker, A. 1998, 'Therapeutic options and cost considerations in the treatment of ischemic heart disease', *Cardiovascular Drugs and Therapy*, vol. 12, pp. 225–32.
- Clinical Trials Working Group 2003, *Advancing Clinical Trial Research in Victoria*, Report for the Victorian Department of Human Services, Melbourne.
- CMA (Canadian Medical Association) 2005, *CMA Infobase Clinical Practice Guidelines*, <http://mdm.ca/cpgsnew/cpgs/index.asp> (accessed 29 June 2005).
- CoA (Commonwealth of Australia) 2005, *Budget Measures 2005-06*, Budget Paper no. 2, Canberra.
- 2002, *Intergenerational Report 2002-03*, Budget Paper no. 5, Canberra.
- COAG (Council of Australian Governments) 1996, *Communiqué 14 June 1996*, Attachment B - Reform of Health and Related Community Services.
- Cochrane, N. 2005, 'Wireless devices are just what the doctor ordered', *The Age*, 18 January, p. 12.
- Coghlan, A. 2004, 'Do you believe in miracles?', *New Scientist*, 9 October, pp. 36–40.
- Cohen, D., Barton, G., Gray, J. and Brain, K. 2004, 'Health economics and genetic service development: a familial cancer genetic example', *Familial Cancer*, vol. 3, pp. 61–7.
- Cohen, D.J., Bakhai, A., Shi, C., Githiora L., Lavelle, T., Berezin, R.H., Leon, M.B., Moses, J.W., Carrozza, J.P., Zidar, J.P. and Kuntz, R.E. 2004, 'Cost-effectiveness of sirolimus-eluting stents for treatment of complex coronary stenoses results from the sirolimus-eluting balloon expandable stent in the treatment of patients with de novo native coronary artery lesions (SIRIUS) Trial', *Circulation*, vol. 110, August, pp. 508–24.
- Cohn, W. 2004, 'Surgical coronary revascularisation remains relevant in the era of stents', *Current Opinion Cardiology*, vol. 19, no. 6, November, pp. 589–92.
- Coleman, D.J. 2003, 'What's new in ophthalmic surgery?', *Journal of American College of Surgeons*, vol. 197, no. 5, pp. 802–5.
- Coleman, K., Norris, S., Weston, A., Grimmer, K., Hillier, S., Merlin, T., Middleton, P. and Salisbury, J. 2005, *NHMRC Additional Levels of Evidence and Grades for Recommendations for Developers of Guidelines*, Pilot Program 2005, NHMRC document, Canberra.
- Condon, J.R., Armstrong, B.K., Barnes, A. and Zhao, Y. 2005, 'Cancer incidence and survival in Indigenous Australians in the Northern Territory', *Australian and New Zealand Journal of Public Health* (in press).

-
- Connelly, L.B. and Doessel, D.P. 2004, 'Medical expenditure and health status in Australia: a story of increasing or decreasing returns?', *Australian Economic Review*, vol. 37, no. 1, pp. 12–30.
- Cook, J., Richardson, J. and Street, A. 1994, 'A cost utility analysis of treatment options for gallstone disease: methodological issues and results', *Health Economics*, vol. 3, no. 3, pp. 157–68.
- Cooke, R., Gawthorpe, S., Langton, D., Tinnion, R. and Yap, W. 2000, 'Explaining the inverse care law in cardiac surgery, 2000, rapid response to Pell et al. 2000,' *British Medical Journal*, vol. 320, pp. 15–19.
- Coombes, I.D., Stowasser, A., Mitchell, C.A. and Varghese, P. 2004, 'Effect of computerised prescribing on the use of antibiotics', Letters, *Medical Journal of Australia*, vol. 180, no. 3, pp. 140–1.
- Cooper, C. and Hagan, P. 1999; *The Ageing Australian Population and Future Health Costs: 1996–2051*, Occasional Papers: New Series no. 7, Department of Health and Aged Care, Canberra.
- Cooper, G.M. 2004, *The Cell: A Molecular Approach*, 2nd edn, Sinauer Associates Inc., Massachusetts.
- Coory, M.D. and Baade, P.D. 2005, 'Urban-rural differences in prostate cancer mortality, radical prostatectomy and prostate-specific antigen testing in Australia', *Medical Journal of Australia*, vol. 182, no. 3, pp. 112–15.
- Coory, M., Fagan, P., Muller, J. and Dunn, N. 2002, 'Participation in cervical cancer screening by women in rural and remote Aboriginal and Torres Strait Islander communities in Queensland', *Medical Journal of Australia*, vol. 177, no. 10, pp. 544–7.
- Coory, M., Scott, I. and Baade, P. 2002, 'Differential effect of socioeconomic status on rates of invasive coronary procedures across the public and private sectors in Queensland, Australia', *Journal of Epidemiology and Community Health*, vol. 56, pp. 233–4.
- Coory, M. and Walsh, W. 2005, 'Rates of percutaneous coronary interventions and bypass surgery after acute myocardial infarction in Indigenous patients', *Medical Journal of Australia*, vol. 182, no. 10, pp. 507–12.
- Correll, P.K., Law, M.G., McDonald, A.M., Cooper, D.A. and Kaldor, J.M. 1998, 'HIV disease progression in Australia in the time of combination antiretroviral therapies', *Medical Journal of Australia*, vol. 169, pp. 469–72.
- Cox, J., Chen, E. and Naylor, D. 1994, 'Revascularisation after acute myocardial infarction, impact of hospital teaching status and on-site invasive facilities', *Journal of General Internal Medicine*, vol. 9, no. 12, pp. 674–8.

-
- Coyle, D. and Drummond, M. 1993, 'Does expenditure on pharmaceuticals give good value for money?: current evidence and policy implications', *Health Policy*, vol. 26, pp. 55–75.
- Crawford, M. 2005, 'Stalled electronic records frustrate IT health sector vendors', *Computer World*, <http://www.computerworld.com.au/index.php?id=507056649> (accessed 14 June 2005).
- Crémieux, P-Y., Meilleur, M-C., Ouellette, P., Petit, P., Zelder, M. and Potvin, K. 2005, 'Public and private pharmaceutical spending as determinants of health outcomes in Canada', *Health Economics*, vol. 14, pp. 107–16.
- Cresswell, A. 2005a, 'Generic drugs to save PBS \$280m', *The Australian*, 6 January.
- 2005b, 'Doctor's pocket PC 'could be a life saver'', *The Australian*, 1 August, p. 4.
- Cronin, D. 2005, 'Outrage at 'work harder' memo', *The Canberra Times*, 17 February, p. 1.
- Cropper, C.M. 2005, 'The robot is in — and ready to operate', *Business Week*, no. 12, 15 March.
- Crystal, S., Sambamoorthi, U. and Merzel, C. 1995, 'The diffusion of innovation in AIDS treatment: Zidovudine use in two New Jersey cohorts', *Health Services Research*, vol. 30, no. 4, pp. 593–614.
- Cummings, L. 2005, 'Bitter little pill? Ritalin's risky chemistry lesson', *Daily Telegraph*, 6 August, p. 31.
- Cunningham, J. 2002, 'Diagnostic and therapeutic procedures among Australian hospital patients identified as Indigenous', *Medical Journal of Australia*, vol. 176, no. 2, pp. 58–62.
- Cutler, D.M. 2004, *Are the Benefits of Medicine Worth What We Pay for It?*, 15th Annual Herbert Lourie Memorial Lecture on Health Policy, Policy Brief no. 27/2004, Syracuse University, NY.
- and Kadiyala, S. 2003, 'The return to biomedical research: treatment and behavioural effects', in Murphy, K. and Topel, R.H (eds), *Measuring the Gains from Medical Research*, University of Chicago Press, Chicago, pp. 110–62.
- 1999, *The Economics of Better Health: the Case of Cardiovascular Disease*, Research paper presented at a conference sponsored by Lasker/Funding First, about the economic value of medical research and returns to the nation's economy, 17 November, http://www.laskerfoundation.org/reports/pdf/better_health.pdf (accessed 16 February 2005).

-
- 1995, 'Technology, health costs and the NIH', *National Institutes of Health Economics Roundtable on Biomedical Research*, Harvard University and National Bureau of Economic Research.
- Cutler, D.M. and McClellan, M. 2001, 'Is technological change worth it?', *Health Affairs*, vol. 20, no. 5, pp. 11–29.
- Cykert, S., Phifer, N. and Hansen, C. 2004, 'Tamoxifen for breast cancer prevention: a framework for clinical decisions', *Obstetrics and Gynaecology*, September, vol. 104, no. 3, pp. 433–42.
- DACEHTA (Danish Centre for Evaluation and Health Technology Assessment) 2005, *Danish Centre for Evaluation and Health Technology Assessment*, http://www.sst.dk/Planlaegning_og_behandling/Medicinsk_teknologivurdering.aspx?lang=en (accessed 8 August 2005).
- Darby, A. 2005, 'Caesarians could soon outstrip normal births, despite the cost and risks', *The Age*, 12 April, p. 3.
- Davies, P. 2004, Community pharmacy — the custodians of the PBS, Australian Pharmacy Professional Conference: Capturing the health agenda: pharmacy's cost saving solution, 21 March.
- Davis, K. 2004, 'Coming soon: the first cancer vaccine', *New Scientist*, 20 November, p. 17.
- DBI (Digital Business Insights) 2004, *GP Access to Broadband Technology, The Current State of Play*, A report on the GP Access to Broadband Technology Survey prepared for the Australian Government Department of Health and Ageing, January.
- Dearne, K. 2005a, 'Consensus is the key to good e-health', *The Australian*, 8 February, p. C07.
- 2005b, 'E-health project privacy concerns', *The Australian*, 1 March, p. C04.
- 2005c, 'High price of e-health', *The Australian*, 25 January, pp. C01, C04.
- 2005d, 'Precise dose of e-medicine', *The Australian*, 25 January, p. C04.
- 2005e, '\$4m e-health software trashed', *The Australian*, 11 January, p. 26.
- 2005f, 'Bush man in health's tower of Babel', *The Australian*, 3 May, p. C06.
- 2005g, 'Doctors get relief from ads on screen', *The Australian*, 5 July, p. 30.
- 2005h, 'Doctors spurn Abbott's plan', *The Australian*, 9 August, p. 30.
- 2005i, 'E-health project vendors uneasy', *The Australian*, 26 July, p. 30.

-
- 2005j, 'HealthConnect hazy on details', *The Australian*, 2 June, <http://australianit.news.com.au/articles/0,7204,15485811^15336^nbv^15306-15316,00.html> (accessed 6 June 2005).
- 2005k, 'Health standards stoush on draft', *The Australian*, 19 July, p. 31.
- 2005l, 'Opening up clinical code', *The Australian*, 17 May, p. 31.
- 2005m, 'E-health updates work plan', *The Australian*, 23 August, p. 30.
- 2005n, 'Tasmania plays guinea pig to HealthConnect', *The Australian*, 2 August, p. 31.
- 2004a, 'Breaking the broadband drought', *The Australian*, 20 July, p. C01.
- 2004b, 'Supply chain bypass', *The Australian*, 5 October, pp. C01–2.
- Dendreon 2005, *Provenge current trials*, http://www.dendreon.com/dndn/provenge_trials (accessed 21 June 2005).
- Denniss, R. 2005a, *Who benefits from private health insurance in Australia?*, The Australia Institute, <http://www.tai.org.au/>, accessed March 2005.
- 2005b, *Demographic trends in private health insurance membership*, The Australia Institute, <http://www.tai.org.au/>, accessed February 2005.
- Derbyshire, D. 2004, 'New technique gently 'melts' prostate cancer', *The Age*, 7 November, <http://www.theage.com.au/articles/2004/11/06/1099547435312.html?from=storylhs> (accessed 22 April 2005).
- Deschamps, J-Y., Franciose, A.R., Gouin, E. and Sai, P. 2005, 'Reluctance of French patients with type 1 diabetes to undergo pig pancreatic islet xenotransplantation', *Xenotransplantation*, vol. 12, pp. 175–80.
- DFID (Department for International Development Health Systems Resource Centre) (UK) 2000, *DALYs and Essential Packages*, Briefing paper, DFID Health Systems Resource Centre, <http://www.ihsd.org/docs/HSRC/DALYs.pdf> (accessed 23 February 2005).
- Dickson, M., Hurst, J. and Jacobzone, S. 2003, *Survey of Pharmacoeconomic Assessment Activity in Eleven Countries*, OECD Health Working Paper No. 4, OECD, Paris.
- Dieppe, P.A., Ebrahim, S., Martin, R.M. and Jüni, P. 2004, 'Lessons from the withdrawal of rofecoxib', *British Medical Journal*, vol. 329, 16 October, pp. 867–8.
- Di Matteo, L. 2005, 'The macro determinants of health expenditure in the United States and Canada: assessing the impact of income, age distribution and time', *Health Policy*, vol. 71, no. 1, pp. 23–42.

-
- Dixon, T., Shaw, M., Ebrahim, S. and Dieppe, P. 2004, 'Trends in hip and knee joint replacement: socioeconomic inequalities and projection of need', *Annals of the Rheumatic Diseases*, vol. 63, no. 7, pp. 825–30.
- DMA (Danish Medicines Agency) 2004, *Danish Medicines Agency*, Copenhagen.
- DMR Consulting 2004, *Indicative Benefits Report*, Final Version, Report For HealthConnect, February, Canberra.
- DoHA (Department of Health and Ageing) 2005a, *Broadband for health: pharmacy initiative*, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-ehealth-broadband-initiativep> (accessed 4 April 2005).
- 2005b, *National Hospital Cost Data Collection*, <http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-casemix-costing-costmain1.htm> (accessed 24 January 2005).
- 2005c, *Pharmaceutical Benefits Scheme (PBS): Payments for wholesale distribution of PBS medicines, Request for comment*, 9 August, [http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pharmacy-paywd/\\$file/4cpawdp.pdf](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pharmacy-paywd/$file/4cpawdp.pdf) (accessed 17 August 2005).
- 2005d, *Portfolio Budget Statements 2005-06: Health and Ageing Portfolio*, Budget Related Paper No. 1.11, Canberra.
- 2005e, *Reference Site*, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-ehealth-broadband-reference.htm> (accessed 6 April 2005).
- 2005f, *Submission to Senate Community Affairs Legislation Committee Inquiry into the National Health Amendment (Prostheses) Bill 2004*, Canberra.
- 2004a, *Expenditure and prescriptions twelve months to 30 June 2004: Tables of prescription volume and Government costs (expenditures) under the Pharmaceutical Benefits Scheme*, www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pubs-pbbexp-jun04.htm (accessed 9 February 2005).
- 2004b, *Schedule of Pharmaceutical Benefits effective from 1 December 2004*, www1.health.gov.au/pbs/scripts/search.cfm (accessed 20 December 2004).
- 2004c, *Commonwealth Telepsychiatry Initiative Overview New Medicare Rebates for Telepsychiatry*, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/mentalhealth-mhinfo-hsector-teleinit-index.htm> (accessed 3 February 2005).
- 2004d, *The Initiative*, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-ehealth-broadband-initiative.htm> (accessed 9 February 2005).
- 2004e, *Medicare Benefits Schedule Book*, November 2004, Canberra.

-
- 2004f, *The Proposed Reform of Prostheses Management*, Version 3.1, July 2004, Canberra.
- 2004g, *Annual Report 2003-04*, Canberra.
- 2004h, *PBS Processing Report*, Canberra.
- 2004i, *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners*, August, Canberra.
- 2004j, *Frequently asked questions*, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-ehealth-broadband-faq.htm> (accessed 9 February 2005).
- 2003a, *Australian Statistics on Medicines 1999-2000*, Canberra.
- 2003b, *Annual Report 2002-03*, Canberra.
- 2003c, *Glossary to Accompany the Guidelines for the Pharmaceutical Industries or Preparation of Submissions to the PBAC*, Canberra.
- 2002a, *Annual Report 2001-02*, Canberra.
- 2002b, *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceuticals Benefits Advisory Committee*, Canberra.
- 2001a, *Annual Report 2000-01*, Canberra.
- 2001b, *An outline of the Practice Incentives Program July 2001*, http://www.hic.gov.au/providers/resources/incentives_allowances/pip/outline_pip_whole.pdf (accessed 29 March 2005).
- 2000, *Better Health Outcomes Newsletter*, vol. 6, no. 3, Canberra, Spring.
- 1999, *National Medicines Policy*, www.nmp.health.gov.au (accessed 12 January 2005).
- and Medicines Australia 2004, *Working Together to Improve the Pharmaceutical Benefits Scheme: Review of Post PBAC Processes Report*, DoHA, Canberra.
- Dollman, W.B., LeBlanc, V.T., Stevens, L., O'Connor, P.J. and Turnidge, J.D. 2005, 'A community-based intervention to reduce antibiotic use for upper respiratory tract infections in regional South Australia', *Medical Journal of Australia*, vol. 182, no. 12, pp. 617–20.
- Dolan, P. 2000, 'The measurement of health-related quality of life for use in resource allocation decisions' in Culyer, A.J. and Newhouse, J.P. (eds), *Handbook of Health Economics*, vol. 1, Elsevier Science B.V., Amsterdam, pp. 1723–60.

-
- Donald, A. 2003, *What is Quality of Life?*, Aventis 'What is...?' Bulletins series, vol. 1, no. 9, May, <http://www.evidence-based-medicine.co.uk/ebmfiles/WhatisQoL.pdf> (accessed 18 July 2005).
- Donoghue, J. and Hylan, T.R. 2001, 'Antidepressant use in clinical practice: efficacy v. effectiveness', *British Journal of Psychiatry*, vol. 179, supp. 42, pp. s9–s17.
- Douw, K., Vondeling, H., Eskildsen, D. and Simpson, S. 2003, 'Use of the internet in scanning the horizon for new and emerging health technologies: a survey of agencies involved in horizon scanning', *Journal of Medical Internet Research*, vol. 5, no. 1, <http://www.jmir.org/2003/1/e6/> (accessed 11 April 2005).
- Dracup, K., McKinley, S. and Moser, D. 1997, 'Australian patients' delay in response to heart attack symptoms', *Medical Journal of Australia*, vol. 166, no. 5, pp. 233–6.
- Draper, G., Turrell, G. and Oldenburg, B. 2004, *Health Inequalities in Australia: Mortality*, Health Inequalities Monitoring Series no. 1, AIHW Cat no. PHE 55, Queensland University of Technology and the AIHW, Canberra.
- Dreger, C. and Reimers, H.E. 2005, *Health Care Expenditures in OECD Countries: A Panel Unit Root and Cointegration Analysis*, The Institute for the Study of Labor Discussion Paper no. 1469, The Institute for the Study of Labor, Bonn.
- Dunn, A. 2005, 'Baby, you have a lot of living to do', *The Sunday Age*, 12 June, <http://www.theage.com.au/text/articles/2005/06/11/1118347632699.html?oneclick=true> (accessed 24 August 2005).
- Dunlevy, S. 2005, 'Hyperactivity drug discount — Ritalin prescriptions to soar', *Daily Telegraph*, 2 August, p. 2.
- Eadie, M.J. 2002, 'The secrecy of drug regulatory information', *Australian Prescriber*, vol. 25, pp. 78–9.
- Ebeling, P.R., Phillips, S.P., Sambrook, P.N. and Seeman, E. 2002, 'Preventing osteoporosis: outcomes of the Australian Fracture Prevention Summit', *Medical Journal of Australia*, vol. 176, no. 8, pp. s1–s16.
- Ebrahim, S., Davey Smith, G., McCabe, C., Payne, N., Pickin, M., Sheldon, T.A., Lampe, F., Sampson, F., Ward, S. and Wannamethee, G. 1999, 'What role for statins? A review and economic model', *Health Technology Assessment*, NHS R&D HTA Programme, vol. 3, no. 19.
- ECCMHS (Expert Committee on Complementary Medicines in the Health System) 2003, *Complementary Medicines in the Australian Health System*, Report to the Parliamentary Secretary to the Minister for Health and Ageing, Canberra.

-
- Edmestone, L. 2004, 'Telepaediatrics puts medicine in the picture', *The Courier-Mail*, 9 December, p. 12.
- Eisenberg, J.M. and Zarin, D. 2002, 'Health technology assessment in the United States: past, present and future', *International Journal of Technology Assessment in Health Care*, vol. 18, no. 2, pp. 192–8.
- El-Hakim, A. and Tewari, A. 2004, 'Robotic prostatectomy: a review', *Medscape General Medicine*, vol. 6, no. 4, http://www.medscape.com/viewarticle/489212_print (accessed 5 May 2005).
- Elkin, E., Weinstein, M., Winer, E., Kuntz, K., Schnitt, S. and Weeks, J. 2004, 'HER2 testing and trastuzumab therapy for metastatic breast cancer: a cost-effectiveness analysis', *Journal of Clinical Oncology*, vol. 22, no. 5, pp. 854–63.
- Elliot, R., Escobar, L., Calafiore, R., Basta, G., Garkavenko, O., Vasconcellos, A. and Bambra, C. 2005, 'Transplantation of micro- and macroencapsulated piglet isles into mice and monkeys', *Transplantation Proceedings*, vol. 37, no. 1, pp. 466–9.
- Ellis, P.M., Hickie, I.B. and Smith, D.A.R. 2003, 'Summary of guidelines for the treatment of depression', *Australasian Psychiatry*, vol. 11, no. 11, pp. 34–8.
- Essink-Bot, M.L. 2003, 'Including the quality-of-life effects in the evaluation of prostate cancer screening: expert opinions revisited?', *British Journal of Urology International*, vol. 92, suppl. 2, pp. 101–5.
- Ethgen, O., Bruyere, O., Richy, F., Dardennes, C. and Reginster, J-Y. 2004, 'Health-related quality of life outcomes in total hip and knee replacements: a qualitative and systematic review of the literature', *Journal of Bone and Joint Surgery (American volume)*, Boston, vol. 86, no. 5, pp. 963–75.
- Eucomed 2001, *Health Technology Assessment for Medical Devices in Europe — What has to be Considered*, Position Paper, June, <http://www.eucomed.be/?x=13&y=29&z=58&id=280> (accessed 8 April 2005).
- European Commission 2000, *Pharmaceuticals in the European Union*, Office for Official Publications of the European Communities, Luxembourg.
- EuroScan 2005, *About EuroScan*, <http://www.publichealth.bham.ac.uk/euroscan/about.htm> (accessed 28 July 2005).
- Exter, A., Hermans, H., Dosljak, M. and Busse, R. 2004, *Health Care Systems in Transition: Netherlands*, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, Copenhagen.
- Faulkner, A., Kennedy, L.G., Baxter, K., Donovan, J., Wilkinson, M. and Bevan, G. 1998, 'Effectiveness of hip prostheses in primary total hip replacement: a critical

-
- review of evidence and an economic model', *Health Technology Assessment*, NHS R&D HTA Programme, vol. 2, no. 6.
- FDA (Food and Drug Administration) 2003, *FDA Patient Representative Program*, www.fda.gov/oashi/patrep/patientrep.html (accessed 16 June 2005).
- 2002a, *Better Health Care with Quality Medical Devices: FDA on the Cutting Edge of Device Technology*, Publication no. FS 01-5, Revised February 2002.
- 2002b, *FDA and the Drug Development Process: How the Agency Ensures that Drugs are Safe and Effective*, Publication no. FS 02-5, February 2002.
- 2002c, *FDA's Center on the Front Line of the Biomedical Frontier*, Publication no. FS 01-4, Revised February 2002.
- 1998a, Product Approval Information, Reference number 98-0369, <http://www.fda.gov/cder/foi/appletter/1998/trasgen092598L.htm> (accessed 2 June 2005).
- 1998b, *Tamoxifen approved for reducing breast cancer incidence*, October 29, <http://www.fda.gov/bbs/topics/NEWS/NEW00662.html> (accessed 30 June 2005).
- Feldstein, M. 1971, *The Rising Costs of Hospital Care*, Information Resources Press, Washington, D.C.
- Fett, M. 2000, *Technology, Health and Health Care*, Occasional Papers: Health Financing Series, vol. 5, AusInfo, Canberra.
- Fiscella, K. and Franks, P. 1996, 'Cost effectiveness of the transdermal nicotine patch as an adjunct to physicians' smoking cessation counselling', *Journal of the American Medical Association*, vol. 275, no. 16, pp. 1247–51.
- Fisher, D. and Weeramanthri, T. 2002, 'Hospital care for Aboriginals and Torres Strait Islanders: appropriateness and decision making', *Medical Journal of Australia*, vol. 176, no. 2, pp. 49–51.
- Foreshaw, J. 2005, 'Revamp for state health websites', *The Australian*, 17 May, p. 30.
- Forge, B. and Briganti, E. 2001, 'Lipid lowering and coronary heart disease risk: how appropriate are the national guidelines?', *Medical Journal of Australia*, vol. 175, no. 9, pp. 471–5.
- Frech, H. and Miller, R. 2004, 'The effects of pharmaceutical consumption and obesity on the quality of life in OECD countries', *Pharmacoeconomics*, vol. 22, supp. 2, pp. 25–36.
- Frenkel, J., Harvey, M. and McManus, G. '\$800 million boost for cheaper medicine', *Herald Sun*, 9 May, p. 5.

-
- Fuchs, V.R. 1998, *Health care for the Elderly: How Much? Who Will Pay for It?*, National Bureau of Economics Research Working Paper no. 6755.
- 1996, 'Economics, values and health care reform', *The American Economic Review*, vol. 86, no 1, pp. 1–24.
- (ed.) 1972, *Essays in the Economics of Health and Medical Care*, National Bureau of Economic Research, New York.
- and Garber, M. 2003, 'Medical innovation: promise pitfalls', *Brookings Review*, Winter, pp. 44–8.
- Fujitsu Consulting 2004a, *The HealthConnect Benefits Realisation Framework*, Final Version 1, Report prepared in collaboration with the Australian Government Department of Health and Ageing, 12 October.
- 2004b, *The HealthConnect Implementation Approach*, Version 1.0, 26 November.
- Furler, J., Harris, E., Chondros, P., Gawaine Powell Davies, P., Harris, M. and Young, D. 2002, 'The inverse care law revisited: impact of disadvantaged location on accessing longer GP consultation times', *Medical Journal of Australia*, vol. 177, no. 2, pp. 80–3.
- Fynes-Clinton, J. 2005, 'Make the choice, pay the price', *The Courier-Mail*, 28 April, p. 17.
- GAC (Guidelines Advisory Committee) 2005, *Guidelines Advisory Committee*, <http://gacguidelines.ca/> (accessed 29 June 2005).
- GAP (Global Access Partners) 2005, *Better Health Care through Electronic Information, Report*, GAP Forum 2004, 14–15 September, Sydney, http://www.globalaccesspartners.org/ehr_report.pdf (accessed 7 February 2005).
- 2004a, *Better health care through computers?*, Media release, 2 September.
- 2004b, *Gap Forum On Informatics In Biology & Medicine, Report*, 4–5 December 2003, Melbourne, http://www.globalaccesspartners.org/bio_report.pdf (accessed 7 February 2005).
- Garber, A.M., Weinstein, M.C., Torrance, G.W. and Kamlet, M.S. 1996, 'Theoretical foundations of cost-effectiveness analysis', in Gold, M.R., Russell, L.B., Siegel, J.E. and Weinstein, M.C. (eds), *Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 25–53.
- Gattellari, M. and Ward, J.E. 2005, 'Men's reactions to disclosed and undisclosed opportunistic PSA screening for prostate cancer', *Medical Journal of Australia*, vol. 182, no. 8, pp. 386–9.

-
- Gattellari, M., Young, J.M. and Ward, J.E. 2003, 'GP and patient predictors of PSA screening in Australian general practice', *Family Practice*, vol. 20, pp. 294–303.
- Geisler, E. 1999, 'Multiple-perspectives model of medical technology', *Health Care Management Review*, vol. 24, no. 3, pp. 55–63.
- Gelijns, A. and Rosenberg, N. 1996, 'Making choices about medical technology', Chapter 3 in Gunning-Schepers, L.J., Kronjee, G.J. and Spasoff, R.A. (eds), *Fundamental questions about the future of health care*, Conference report, Sdu Uitgevers, The Hague, pp. 45–68.
- 1994, 'The dynamics of technological change in medicine', *Health Affairs*, Summer, pp. 28–46.
- Genetics Advisory Committee, Anti-Cancer Council of Victoria, 1999, *Cancer Family Services in Victoria, A Statewide 5 year plan*, 24 March.
- George, B., Harris A. and Mitchell, A. 2001, 'Cost-effectiveness analysis and the consistency of decision making', *Pharmacoeconomics*, vol. 19, no. 11, pp. 1102–9.
- Gerdtham, U., Sogaard, J., Anderson, F. and Jonsson, B. 1992, 'An econometric analysis of healthcare expenditure: a cross-section study of OECD countries', *Journal of Health Economics*, vol. 11, no. 1, pp. 63–84.
- Gerdtham, U.G. 1992, 'Pooling international health expenditure data', *Health Economics*, vol. 1, pp. 217–31.
- and Löthgren, M. 2000, 'On stationarity and cointegration of international health expenditure and GDP', *Journal of Health Economics*, vol. 19, pp. 461–75.
- Getzen, T. 2000, 'Health care is an individual necessity and a national luxury: applying multilevel decision models to the analysis of health care expenditures', *Journal of Health Economics*, vol. 19, no. 2, pp. 259–70.
- 1992, 'Population ageing and growth of health expenditures', *Journal of Gerontology*, vol. 47, no. 3, pp. s98–s104.
- Gillespie, G. 2005, 'Down under image readers cover U.S. radiologists', *Health Data Management*, July, <http://www.healthdatamanagement.com/html/current/PastIssueStory.cfm?PostID=19810&PastMonth=July&PastYear=2005> (accessed 28 June 2005).
- Girgis, S., Ward, J.E. and Thomson, C.J.H. 1999, 'General practitioners' perceptions of medicolegal risk: Using case scenarios to assess the potential impact of prostate cancer screening guidelines', *Medical Journal of Australia*, vol. 171, no. 7, pp. 362–6.
- Glasson, B. 2004, The Pharmaceutical Benefits Scheme: Separating Fact from Fiction, Speech to Harvard Health Australia, Sydney, 16 September.

-
- Glasziou, P.P., Eckermann, S.D., Mulray, S.E., Simes, J.R., Martin, A.J., Kirby, A.C., Hall, J.P., Caleo, S., White, H.D. and Tomkin, A.M. 2002, 'Cholesterol-lowering therapy with pravastatin in patients with average cholesterol levels and established ischaemic heart disease: is it cost-effective?', *Medical Journal of Australia*, vol. 177, no. 8, pp. 420–6.
- Glied, S. and Lleras-Muney, A. 2003, *Health Inequality, Education and Medical Innovation*, November, http://www.princeton.edu/chw/papers/Adriana_healthinequality.pdf (accessed 21 March 2005).
- Global Forum for Health Research 2004, *Monitoring financial flows for health research*, http://www.globalforumhealth.org/site/000__home.php (accessed 28 March 2005).
- Glover, J.D., Harris, K. and Tennant, S. 1999, *A Social Health Atlas of Australia*, 2nd edn, Public Health Information Development Unit, University of Adelaide, South Australia, Open Book publishers.
- Glover, J.D., Hetzel, D. and Tennant, S. 2004, 'The socioeconomic gradient and chronic illness and associated risk factors in Australia', *Australia and New Zealand Health Policy*, vol. 1, no. 8, <http://www.anzhealthpolicy.com/content/pdf/1743-8462-1-8.pdf> (accessed 11 April 2005).
- Goddeeris, J.H. 1984, 'Insurance and incentives for innovation in medical care', *Southern Economic Journal*, vol. 51, no. 2, October, pp. 530–9.
- Goh, R.H., Somers, S., Jurriaans, E. and Yu, J. 1999, 'Magnetic resonance imaging. Application to family practice', *Canadian Family Physician*, vol. 45, pp. 2118–28, 2131–2.
- Gold, M.R., Patrick, G.W., Torrance, G.W., Fryback, D.G., Hadorn, D.C., Kamlet, M.S., Daniels, N. and Weinstein, M.C. 1996a, 'Identifying and valuing outcomes', in Gold, M.R., Russell, L.B., Siegel, J.E. and Weinstein, M.C. (eds), *Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 82–134.
- Gold, M.R., Siegel, J.E., Russell, L.B. and Weinstein, M.C. 1996b, *Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York.
- Gold, R.G., Stevenson, D. and Fryback, D.G. 2002, 'HALYs and QALYs and DALYs, oh my: similarities and differences in summary measures of population health', *Annual Review of Public Health*, vol. 23, pp. 115–34.
- Goldman, D. and Smith, J.P. 2005, 'Socioeconomic differences in the adoption of new medical technologies', *American Economic Association Annual Meeting Papers*, www.aeaweb.org/annual-mtg-papers/2005/0109-1015-0802.pdf (accessed 28 February 2005).

-
- Goldman, D.P., Shekelle, P.G., Bhattacharya, J., Hurd, M., Joyce, G.F., Lakdawalla, D.N., Matsui, D.H., Newberry, S. J., Panis, C.W.A. and Shang, B. 2004, *Health Status and Medical Treatment of the Future Elderly*, Final Report, TR-169-CMS, Prepared for the Centers for Medicare and Medicaid Services, RAND Corporation, Santa Monica.
- Goldstein, B.J. and Goodnick, P.J. 1998, 'Selective serotonin reuptake inhibitors in the treatment of affective disorders-III. Tolerability, safety and pharmacoeconomics', *Journal of Psychopharmacology*, vol. 12, no. 3, supp. B, pp. s55–s87.
- Gorman, C. 2002, 'Rethinking breast cancer', *Time*, 18 February, pp. 42–50.
- Gottlob, C.A., Pelissier, J.M., Chang, R.W., Wixon, R.L., Stern, S.H. and Stulberg, S.D. 1996, Long term cost effectiveness of total knee arthroplasty for the treatment of osteoarthritis, Paper presented at 63rd Annual Meeting of the American Academy of Orthopaedic Surgeons, Atlanta, February.
- Grabowski, H., Vernon, J. and DiMasi, J.A. 2002, 'Returns on research and development for 1990s new drug introductions', *Pharmacoeconomics*, vol. 20, supp. 3, pp. 11–29.
- Grann, V., Jacobson, J., Thomason, D., Hershman, D., Heitjan, D. and Neugut, A. 2002, 'Effect of prevention strategies on survival and quality-adjusted survival of women with BRAC1/2 mutations: an updated decision analysis', *Journal of Clinical Oncology*, vol. 20, no. 10, pp. 2520–9.
- Grann, V., Whang, W., Jacobson, J., Heitjan, D., Antman, K. and Neugut, A. 1999, 'Benefits and costs of screening Ashkenzi Jewish women for BRCA1 and BRCA2', *Journal of Clinical Oncology*, vol. 17, no. 2, pp. 494–500.
- Gravelle, H. and Smith, D. 2000, *Discounting for Health Effects in Cost Benefit and Cost Effectiveness Analysis*, University of York Centre for Health Economics, Technical Paper Series, no. 20, October.
- Graves, S.E., Davidson, D., Ingerson, L., Ryan, P., Griffith, E.C., McDermott, B.F.J., McElroy, H.J. and Pratt, N.L. 2004, 'The Australian Orthopaedic Association National Joint Replacement Registry', *Medical Journal of Australia*, vol. 180, no. 5, suppl., pp. s31–s34.
- Gray, J.A.M. 1997, *Evidence-based Healthcare*, Churchill Livingstone, Edinburgh.
- Greenberg, D., Bakhai, A. and Cohen, D.J. 2004, 'Can we afford to eliminate restenosis? Can we afford not to?', *Journal of the American College of Cardiology*, vol. 43, no. 4, pp. 513–8.
- Greer, A.L. 1988, 'The state of the art versus the state of the science: the diffusion of new medical technologies into practice', *International Journal of Technology Assessment in Health Care*, vol. 4, pp. 5–26.

-
- Griffith, G., Edwards, R. and Gray, J. 2004, 'Cancer genetics services: a systematic review of the economic evidence and issues', *British Journal of Cancer*, vol. 90, pp. 1697–1703.
- , Wilkinson, C., Turner, J., France, B. and Bennett, P. 2004, 'Estimating the survival benefits gained from providing national cancer genetic services to women with a family history of breast cancer', *British Journal of Cancer*, vol. 90, pp. 1912–19.
- Grose, S. 2005, 'Mixed reactions to nuclear issues', *The Canberra Times*, 30 May, p. 6.
- Gross, P. 2003, *The economic value of innovation: measuring the linkages of pharmaceutical research, use of innovative drugs and productivity gains*, Health Economics Monograph no. 80, Health Group Strategies, March.
- Gruen, R., Knox, S. and Britt, H. 2002, 'Where there is no surgeon: the effect of specialist proximity on general practitioners' referral rates', *Medical Journal of Australia*, vol. 177, no. 2, pp. 111–15.
- GTRAP (Gene and Related Therapies Research Advisory Council) 2005, *Gene therapy: frequently asked questions*, <http://www.nhmrc.gov.au/about/committees/expert/gtrap/index.htm> (accessed 6 July 2005).
- Hall, B., Jaffe, A. and Trajtenberg, M. 2001, *The NBER Patents Citations Data File: Lessons, Insights and Methodological Tools*, National Bureau of Economics Research Working Paper no. 8498, Cambridge, Massachusetts.
- Hall, R. and Jones, C.I. 2004, *The value of life and the rise in health spending*, National Bureau of Economic Research Working Paper no. 10737, Cambridge, Massachusetts.
- Hall, S., Bulsara, C., Bulsara, M., Leahy, T., Culbong, M., Hendrie, D. and Holman, C. 2004, 'Treatment patterns for cancer in Western Australia: does being Indigenous make a difference?', *Medical Journal of Australia*, vol. 181, no. 4, pp. 191–4.
- Hall, S. and Holman, C. 2003, 'Inequalities in breast cancer reconstructive surgery according to social and locational status in Western Australia', *European Journal of Surgical Oncology*, vol. 29, pp. 519–25.
- Hall, W.D., Mant, A., Mitchell, P.B., Rendle, V.A., Hickie, I.B. and McManus, P. 2003, 'Association between antidepressant prescribing and suicide in Australia, 1991–2000: trend analysis', *British Medical Journal*, vol. 326, pp. 1008–11.
- Hall, W.D., Ward, R., Liauw, W.S., Brien, J.E. and Lu, C.Y. 2005, 'Tailoring access to high cost, genetically targeted drugs', *Medical Journal of Australia*, vol. 182, no. 12, pp. 607–8.

-
- Hamvas, A., Wise, P., Yang, R., Wampler, N., Noguchi, A., Maurer, M., Walentik, C., Schramm, W. Coles, F. 1996, 'The influence of the wider use of surfactant therapy on neonatal mortality among blacks and whites', *New England Journal of Medicine*, vol. 334, no. 25, pp. 1635–40.
- Hancock, L. 1993, *Defensive Medicine and Informed Consent*, Research Paper, Commonwealth Department of Health, Housing, Local Government and Community Services, AGPS, Canberra.
- Hansen, P. and King, A. 1996, 'The determinants of healthcare expenditure: a cointegration approach', *Journal of Health Economics*, vol. 15, no. 1, pp. 127–37.
- Hardidge, A.J., Hooper, J. and McMahon, S. 2003, 'Current attitudes to total hip replacement in younger patients: a comparison of two nations', *The Australian and New Zealand Journal of Surgery*, vol. 73, no. 5, pp. 280–4.
- Harper, R.W., Sampson, K.D., See, P.L., Kealey, J. L. and Meredith, I.T. 2000, 'Costs, charges and revenues of elective coronary angioplasty and stenting: the public versus the private system', *Medical Journal of Australia*, vol. 173, no. 6, pp. 296–300.
- Harris, R. and Lohr, K.N. 2002, 'Screening for prostate cancer: an update of the evidence for the U.S. Preventative Services Task Force', *Annals of Internal Medicine*, vol. 137, no. 11, pp. 917–29.
- Hart, J.A.L. 2004, 'Joint replacement surgery', *Medical Journal of Australia*, vol. 180, no. 5, suppl., pp. s27–s30.
- Harvey, K.J. 2002, *Securing the Future of the Pharmaceutical Benefits Scheme?, Symposium: The 2002-03 Federal Budget*, Sydney, 3 June.
- , Vitry, A.I., Roughead, E., Aroni, E., Ballenden, N. and Faggotter, R. 2005, 'Pharmaceutical advertisements in prescribing software: an analysis', *Medical Journal of Australia*, vol. 183, no. 1, pp. 75–9.
- HAS (*Haute Autorite de sante*) 2005, *The Haute Autorite de sante: Founding Principles, Mandate and Structure*, Media release, 26 January, Paris.
- Hawkes, N. 2005, 'Testing for prostate cancer turns corner', *The Australian*, 11 August, p. 3.
- Hawthorne, G., Richardson, J. and Day, N. 2003, A comparison of five multi attribute utility instruments, Paper presented to the 22nd Australian Conference of Health Economists 2000, June, <http://www.buseco.monash.edu.au/centres/che/pubs/wp140.pdf> (accessed 2 March 2005).
- 2002, *Using the Assessment of Quality of Life(AQoL) Instrument Version 1.0*, Centre for Health Program Evaluation, Technical Report no. 12,

-
- <http://www.acpmh.unimelb.edu.au/aqol/AQoL%20User%20Manual.pdf>
(accessed 2 March 2005).
- Hay, J.W., Yu, W.M. and Ashraf, T. 1999, 'Pharmacoeconomics of lipid-lowering agents for primary and secondary prevention of coronary artery disease', *Pharmacoeconomics*, vol. 15, no. 1, pp. 47–54.
- HCF (Hospitals Contribution Fund of Australia) 2004a, *Annual Report 2002-03*, Sydney.
- 2004b, *Fit & Well*, Winter, Sydney.
- Health Canada 2003, *Therapeutic Products Directorate*, www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_e.html (accessed 24 June 2005).
- HealthConnect Program Office 2005a, *Lessons Learned from the MediConnect Field Test and HealthConnect Trials*, Canberra.
- 2005b, *Legal Issues Report, Summary of Key Findings and Recommendations*, Canberra.
- 2004a, *HealthConnect: An Overview*, December.
- 2004b, *HealthConnect Newsletter*, vol. 3, no. 3, October.
- 2003a, 'Overview and Findings', *HealthConnect Interim Research Report*, vol. 1, August.
- 2003b, 'Tasmanian HealthConnect trial interim evaluation report', in 'Background documents', Part three, *HealthConnect Interim Research Report*, vol. 3, August.
- 2003c, 'NT HealthConnect Trial', in 'Background documents', Part four, *HealthConnect Interim Research Report*, vol. 3, August.
- Heaney, C. 2005, 'Palms unlock more info', *Herald Sun*, 4 August, p. 69.
- Heartdisease 2005, Restenosis after angioplasty and stenting, <http://heartdisease.about.com/cs/angioplastystents/a/restenosis.htm> (accessed 13 January 2005).
- Hegarty, K., Ames, D., Anderson, J., Johnson, C., McKinnon, R. and Moulds, R. 2003, 'Use of antidepressant medications in the general practice setting', *Australian Family Physician*, vol. 32, no. 4, pp. 229–42.
- Heidenreich, P. and McClellan, M. 2003, 'Biomedical research and then some: the causes of technological change in heart attack treatment', in Murphy, K. and Topel, R.H (eds), *Measuring the Gains from Medical Research*, University of Chicago Press, Chicago, pp. 163–205.
- Hendley, G.W., Wolfson, A.B., Mower, W.R. and Hoffman, J.R. 2002, 'Spinal cord injury without radiographic abnormality: results of the National Emergency

-
- X-Radiography Utilization Study in blunt cervical trauma', *Journal of Trauma Injury, Infection, and Critical Care*, vol. 53, pp. 1–4.
- Henry, D.A. and Hill, S.R. 1999, 'Assessing new health technologies: lessons to be learned from drugs', *Medical Journal of Australia*, vol. 171, no. 10, pp. 554–6.
- Hernandez, J. and Thompson, I.M. 2004, 'Prostate specific antigen: A review of the validation of the most commonly used cancer biomarker', *Cancer*, vol. 101, no. 5, pp. 894–904.
- Hetemaa, T., Keskimaki, I., Manderbacka, K., Leyland, A. and Koskinen, S. 2003, 'How did the recent increase in the supply of coronary operations in Finland affect socioeconomic and gender equity in their use?', *Journal of Epidemiology and Community Health*, vol. 57, pp. 178–85.
- HIC (Health Insurance Commission) 2005a, Medicare benefits schedule item statistics reports, http://www.hic.gov.au/statistics/dyn_mbs/forms/mbs_tab4.shtml Canberra (accessed 22 August 2005).
- 2005b, Pharmaceutical benefits schedule item statistics, www.hic.gov.au/statistics/dyn_pbs/forms/pbs_tab1.shtml (accessed 21 February 2005).
- 2005c, About Herceptin, http://www.hic.gov.au/providers/programs_services/herceptin.htm (accessed 2 June 2005).
- 2005d, Herceptin program information sheet, http://www.hic.gov.au/providers/resources/forms/herceptin/herceptin_info_consent_form.pdf (accessed 14 June 2005).
- 2005e, PBS online brochure, http://www.hic.gov.au/providers/resources/online_initiatives/pbs_online/PBS_Online_brochure.pdf (accessed 22 August 2005).
- 2005f, PBS online: a better business solution, http://www.hic.gov.au/providers/online_initiatives/pbs_online.htm (accessed 22 August).
- 2005g, *General Practice Statistics Reports*, <http://www.hic.gov.au/statistics/imd/forms/gpStatisticsDiv.shtml> (accessed 22 August 2005).
- 2004, *Annual Report 2003-04*, Canberra.
- 2003, *Annual Report 2002-03*, Canberra.
- 2002, *Annual Report 2001-02*, Canberra.
- 2001a, Pathology notes, vol. 6, no. 1, July, www.hic.gov.au/providers/resources/publications_guidelines/medicare/pn_0701.pdf (accessed 17 May 2005).
- 2001b, *Annual Report 2000-01*, Canberra.
- 2000, *Annual Report 1999-2000*, Canberra.

-
- 1999, *Annual Report 1998-99*, Canberra.
- 1998, *Annual Report 1997-98*, Canberra.
- Hickie, I.B., Davenport, T.A., Naismith, S.L., Scott, E.M., Hadzi-Pavlovic, D. and Koschera, A. 2001, 'Treatment of common mental disorders in Australian general practice', *Medical Journal of Australia*, vol. 175, suppl., pp. s25–s30.
- Hill, R., Bagust, A., Dickson, R., Dundar, Y., Haycox, A., Mota, M.R., Reaney, A., Roberts, D., Williamson, P. and Walley, T. 2004, *Health Technology Assessment 2004*, NHS R&D HTA programme, vol. 8, no. 35, UK.
- Hillman, A., Joseph, C.A., Mabry, M.R., Sunshine, J.H., Kennedy, S.D. and Noether, M. 1990, 'Frequency and costs of diagnostic imaging in office practice — a comparison of self-referring and radiologist — referring physicians', *New England Journal of Medicine*, vol. 323, no. 23, pp. 1604–8.
- Hilty, D.M., Marks, S.L., Urness, D., Yellowlees, P.M. and Nesbitt, T.S. 2004, 'Clinical and educational telepsychiatry applications: a review', *Canadian Journal of Psychiatry*, vol. 49, pp. 12–23.
- Himalayan Cataract Project 2005, *Overview*, <http://www.cureblindness.org/cataracts/index.html> (accessed 8 April).
- Hitiris, T. and Posnett, J. 1992, 'The determinants of health expenditure in developed countries', *Journal of Health Economics*, vol. 11, no. 2, pp. 173–81.
- Ho, V. 2002, 'Learning and the evolution of medical technologies: the diffusion of coronary angioplasty', *Journal of Health Economics*, vol. 21, pp. 873–85.
- HOAP (University of California San Diego Health Outcomes Assessment Program) 2005a, *EQ-5D*, <http://medicine.ucsd.edu/fpm/hoap/eq5d.htm> (accessed 2 March 2005).
- 2005b, *HUI*, <http://medicine.ucsd.edu/fpm/hoap/hui.htm> (accessed 2 March 2005).
- 2005c, *Preference-based measures*, <http://medicine.ucsd.edu/fpm/hoap/preference.htm> (accessed 3 March 2005).
- 2005d, *Psychometrically-based measures*, <http://medicine.uscd.edu/fpm/hoap/psychometric.htm> (accessed 3 March 2005).
- 2005e, *Quality of Well Being Scale (QWB)*, <http://medicine.ucsd.edu/fpm/hoap/qwb.htm> (accessed 2 March 2005).
- Hobbs, M., Bertuola, B., Geelhoed, E. and Hockey, R. 2002, 'Changes in medical treatment and their consequences for patient health outcomes' in 'The impact of new technology on the treatment and outcomes of acute myocardial infarction in

-
- Australia' in McClellan, M.B. and Kessler, D.P. (eds), *Technological Change in Health Care, A Global Analysis of Heart Attack*, University of Michigan Press.
- Hock, C., Konietzko, U., Streffer, J., Tracy, J., Signorell, A., Muller-Tillmanns, B., Lemke, U., Henke, K., Moritz, E., Garcia, E., Wollmer, M., Umbricht, D., de Quevarin, D., Hoffmann, M., Papassotiropoulos, A. and Nitsch, R. 2003, 'Antibodies against β -amyloid slow cognitive decline in Alzheimer's disease', *Neuron*, vol. 38, pp. 547–54.
- Hodgson, J.M., Bottner, R.F., Klein, L.W., Walpole, H.T., Cohen, D.J., Cutlip, D.E., Fenninger, R.B., Firth, B.G., Greenberg, D., Kalisky, I., Meskan, T., Powell, W., Stone, G.W., Zito, J.P. and Clark, M.A. 2004, 'Drug-eluting stent task force: final report and recommendations of the working committees on cost-effectiveness/economics, access to care, and medicolegal issues', *Catheterisation and Cardiovascular Interventions*, vol. 62, pp. 1–17.
- Hoeper, M.M., Oudiz, R.J., Peacock, A., Tapson, V.F., Haworth, S.G., Frost, A.E. and Torbicki, A. 2004, 'End points and clinical trial designs in pulmonary arterial hypertension', *Journal of the American College of Cardiology*, vol. 43, no. 12, suppl. s, pp. s48–s55.
- Holmberg, L., Bill-Axelson, A., Helgesen, F., Salo, J.O., Folmerz, P., Haggman, M., Andersson, S.O., Spangberg, A., Busch, C., Nordling, S., Palmgren, J., Adami, H.O., Johansson, J.E. and Norlen, B.J. 2002, 'A randomized trial comparing radical prostatectomy with watchful waiting in early prostate cancer', *The New England Journal of Medicine*, vol. 347, no. 11, pp. 781–9.
- Holmes, J., Arispe, I. and Moy, E. 2005, 'Heart disease and prevention: Race and age differences in heart disease prevention, treatment and mortality', *Medical Care*, vol. 43, suppl. 3, pp. I33–I44.
- Holston, S.S. 1997, The Value of Patient's Perspective in FDA's Decision Processes, Presentation to the 10th IMS International Symposium, Brussels, 3 November.
- Holt, G. and Gregori, A.G. 2005, 'Computer assisted knee arthroplasty is here today', *British Medical Journal*, Letters, vol. 330, 22 January, p. 197.
- Homedes, N. 2000, *The Disability-Adjusted Life Year (DALY): Definition, Measurement and Potential Use*, Human Capital Development and Operations Policy HCO Working Papers, www.worldbank.org/html/extdr/hnp/hddflash/workp/wp_00068.html (accessed 23 February 2005).
- HoR (House of Representatives) 2004, *National Health Amendment (Prostheses) Bill 2004*, Explanatory Memorandum, Canberra.

-
- HSE (Health and Safety Executive) 2004, *Horizon Scanning — Nanotechnologies*, www.hse.gov.uk/horizons/nanotech/ (accessed 1 March 2005).
- HSV (Public Health and Development Division, Department of Human Services and Health) 1999, *The Victorian Burden of Disease Study: Mortality*, Victorian Government Department of Human Services, Melbourne.
- Hu, T.W. 2004, 'The economic burden of depression and reimbursement policy in the Asia Pacific region', *Australasian Psychiatry*, vol. 12, supp. 1, pp. s11–s15.
- Hynes, P. 2005, 'Lives lost for sake of privacy', *Sydney Morning Herald*, 20 June, p. 11.
- 2005b, 'Privacy laws holding back health reforms', *The Canberra Times*, 13 June, p. 9.
- Iemma, M. (NSW Minister for Health) 2004, *Minister launches health e-link for healthy patient records*, Media release, Sydney, 9 May.
- IFF (Institute for the Future) 2003, *Health and Healthcare 2010, The Forecast, The Challenge*, SR-794, 2nd edn, Jossey-Bass, San Francisco, www.iftf.org/features/library.html (accessed 7 March 2005).
- 2001, *The Future of Pharmaceuticals*, SR-756, Institute for the Future, www.iftf.org/features/library.html (accessed 7 March 2005).
- Illing, D. 2005, 'Telemedicine still a safe connection', *The Australian*, 26 January, p. 22.
- 2004, 'Q.U.i.P.S. to look at risks', *The Australian*, 18 August, p. 42.
- INAHTA (International Network of Agencies for Health Technology Assessment) 2005, *About INAHTA*, http://www.inahta.org/inahta_web/renderpage.aso?catID=94&pageID=401 (accessed 27 July 2005).
- InterSystems 2004, *InterSystems Australian healthcare informatics survey finds strong support for single patient records*, Media release, Sydney, 7 September, <http://www.intersystems.com.au/analysts/2004/SPR%20Survey%20Release.html> (accessed 8 June 2005).
- Isacsson, G. 2000, 'Suicide prevention — a medical breakthrough?', *Acta Psychiatrica Scandinavica*, vol. 102, pp. 113–17.
- Jackson, R. 2001, 'Are the new lipid management guidelines good for Australia's health', *Medical Journal of Australia*, vol. 175, no. 9, pp. 452–3.
- Jakubowski, L. 2005, 'Hospital gridlock', *The Australian*, 25 June, p. 32.
- Jay, C. 2004, 'Medicare payments take healthy turn', *Australian Financial Review*, 2 July, p. 76.

-
- Johannesson, M., Jonsson, B., Kjekshus, J., Olsson, A.G., Pedersen, T.R. and Wedel, H. 1997, 'Cost effectiveness of simvastatin treatment to lower cholesterol levels in patients with coronary heart disease', *New England Journal of Medicine*, vol. 336, no. 5, 30 January, pp. 332–6.
- Johns Hopkins Medicine 2005, *New Test for Early Detection of Prostate Cancer Shows Promise*, Media release, 12 May, http://www.hopkinsmedicine.org/Press_releases/2005/05_15_05.html (accessed 7 July 2005).
- Jong, K., Vale, P. and Armstrong, B. 2005, 'Rural inequalities in cancer care and outcome', *Medical Journal of Australia*, vol. 182, no. 1, pp. 13–14.
- Jonsson, B., Kanis, J., Dawson, A., Oden, A. and Johnell, O. 1999, 'Effect and offset of effect of treatments for hip fracture on health outcomes', *Osteoporosis International*, vol. 10, no. 3, pp. 193–9.
- Jonsson, E. 2002, 'Development of health technology assessment in Europe', *International Journal of Technology Assessment in Health Care*, vol. 18, no. 2, pp. 171–83.
- Jorm, A.F., Medway, J., Christensen, H., Korten, A.E., Jacomb, P.A. and Rodgers, B. 2000, 'Public beliefs about the helpfulness of interventions for depression: effects on actions taken when experiencing anxiety and depression symptoms', *Australian and New Zealand Journal of Psychiatry*, vol. 34, pp. 619–26.
- Kannel, W., D'Agostino, R., Sullivan, L. and Wilson, P. 2004, 'Concept and usefulness of cardiovascular risk profiles', *American Heart Journal*, vol. 148, no. 1, pp. 16–26.
- Kaplan, R.M. 1996, 'Utility assessment for estimating quality-adjusted life years', in Sloan, F.A. (ed.), *Valuing Health Care Costs, Benefits and Effectiveness of Pharmaceuticals and Other Medical Technologies*, Cambridge University Press, Cambridge, pp. 31–60.
- Kearney, B.J. 2004, *Evidence Based Health Financing in Australia: The Role of the Medical Services Advisory Committee*, MSAC, Canberra.
- Keeffe, J., Weih, L., McCarty, C. and Taylor, H. 2002, 'Utilisation of eye care services by urban and rural Australians', *British Journal of Ophthalmology*, vol. 86, pp. 24–7.
- Keeffe, J.E. and Taylor, H.R. 1996, 'Cataract surgery in Australia 1985–94', *Australia and New Zealand Journal of Ophthalmology*, vol. 24, no. 4, pp. 313–17.
- Kelly, A., Kerr, D., Patrick, I. and Walker, T. 2003, 'Call-to-needle times for thrombolysis in acute myocardial infarction in Victoria', *Medical Journal of Australia*, vol. 178, no. 8, pp. 381–5.

-
- Kelly, K.D., Voaklander, D.C., Johnston, D.W.C., Newman, S.C. and Suarez-Almazor, M.E. 2001, 'Change in pain and function while waiting for major joint arthroplasty', *The Journal of Arthroplasty*, vol. 16, no. 3, pp. 351–9.
- Kelman, C. 2002, The Value of Linked Data for Research into Health Services Use and Expenditure: An Australian Perspective, Symposium on Health Data Linkage, Sydney, 20–21 March.
- Keogh, L., Southey, M., Maskiell, J., Young, M.A., Gaff, C., Kirk, J., Tucker, K., Rosenthal, D., McCredie, M., Giles, G. and Hopper, J. 2004, 'Uptake of offer to receive genetic information about BRCA1 and BRCA2 mutations in an Australian population-based study', *Cancer Epidemiology Biomarkers and Prevention*, vol. 13, no. 12, pp. 2258–63.
- Kleinknecht, A., van Montfort, K. and Brouwer, E. 2002, 'The non-trivial choice between innovation indicators', *Economics of Innovation and New Technology*, vol. 11, no. 2, pp. 109–21.
- Kolata, G. 2004, 'Heart scanner stirs new hope and a debate', *The New York Times*, 17 November, p. 1.
- Koopmanschap, M., Burdof, A., Jacob, K., Meering, W.J., Brouwer, W. and Severens, H. 2005, 'Measuring productivity change in economic evaluation', *Pharmacoeconomics*, vol. 23, no. 1, pp. 47–54.
- KPMG Consulting 2001, *Impact of New Technology on Victorian Public Hospital Costs*, Report to the Victorian Department of Human Services, September, unpublished.
- Kricker, A., Haskill, J. and Armstrong, B.K. 2001, 'Breast conservation, mastectomy and axillary surgery in New South Wales women in 1992 and 1995', *British Journal of Cancer*, vol. 85, no. 5, pp. 668–73.
- Langreth, R. 2005 'Biotech behemoth', *Forbes Magazine*, www.forbes.com/free_forbes/2005/0110/128.html (accessed 23 March 2005).
- Lavernia, C.J., Guzman, J.F. and Gachupin-Garcia, A. 1997, 'Cost-effectiveness and quality of life in knee arthroplasty', *Clinical Orthopaedics*, vol. 345, December, pp. 134–9.
- Law, M.G., Yueming, L., McDonald, A.M., Cooper, D.A. and Kaldor, J.M. 2000, 'Estimating the population impact in Australia of improved antiretroviral treatment for HIV infection', *AIDS*, vol. 14, pp. 197–201.
- Lázaro, P. and Fitch, K. 1995, 'The distribution of "big ticket" medical technologies in OECD countries', *International Journal of Technology Assessment in Health Care*, vol. 11, no. 3, pp. 552–70.

-
- Lea, A.R. and Hailey, D.M. 1995, 'The cochlear implant. A technology for the profoundly deaf', *Medical Progress Through Technology*, vol. 21, no. 1, pp. 47–52.
- Leitch, J. 2003, 'Changing times in the treatment of myocardial infarction', *Medical Journal of Australia*, vol. 178, no. 8, pp. 367–8.
- Lewin Group, Inc. 2005, *Health Information Technology Leadership Panel*, Final Report, March.
- Lichtenberg, F.R. 2005, 'Availability of new drugs and Americans' ability to work', *Journal of Occupational and Environmental Medicine*, vol. 47, no. 4, pp. 373–80.
- 2004a, *The Effect of Drug Vintage on Survival: Micro Evidence from Puerto Rico's Medicaid Program*, National Bureau of Economic Research, Working Paper no. 10884, Cambridge USA, November.
- 2004b, *The Expanding Pharmaceutical Arsenal in the War against Cancer*, Working Paper, Columbia University and National Bureau of Economic Research, 26 January.
- 2003a, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-level Data from 52 Countries, 1982–2001*, Columbia University and National Bureau of Economic Research, 16 February.
- 2003b, 'Pharmaceutical innovation, mortality reduction, and economic growth', in Murphy, K. and Topel, R.H (eds), *Measuring the Gains from Medical Research*, University of Chicago Press, Chicago, pp. 74–109.
- 2002a, *The Effect of Changes in Drug Utilization on Labor Supply and Per Capita Output*, National Bureau of Economic Research, Working Paper no. 9139, Cambridge, Massachusetts, September.
- 2002b, *Benefits and Costs of Newer Drugs: An Update*, National Bureau of Economic Research, Working Paper no. 8996, Cambridge USA, June.
- 2001, 'Are the benefits of newer drugs worth their cost?', *Health Affairs*, vol. 20, no. 5, pp. 241–51.
- 1996, 'Do (more and better) drugs keep people out of hospitals?', *The American Economic Review*, vol. 86, no. 2, pp. 384–8.
- Lichtenberg, F.R. and Virabhak, S. 2002, *Pharmaceutical Embodied Technical Progress, Longevity, and Quality of Life: Drugs as "Equipment for Your Health"*, National Bureau Of Economic Research, Working Paper no. 9351, Cambridge USA, November.
- Liljas, B. 1998a, 'How to calculate indirect costs in economic evaluation', *Pharmacoeconomics*, vol. 13, no. 1, pp. 1–7.

-
- 1998b, 'How to calculate indirect costs in economic evaluations', (Author's reply), *Pharmacoeconomics*, vol. 13, no. 5, pp. 567–9.
- Lim, S.S., Vos, T., Peeters, A., Liew, D. and McNeil, J.J. 2001, 'Cost-effectiveness of prescribing statins according to Pharmaceutical Benefits Scheme criteria', *Medical Journal of Australia*, vol. 175, no. 9, pp. 459–64.
- Linebarger, E.J., Hardten, D.R., Shah, G.K. and Lindstrom, R.L. 1999, 'Phacoemulsification and modern cataract surgery', *Survey of Ophthalmology*, vol. 44, no. 2, pp. 123–47.
- Linton, K.D. and Hamdy, F.C. 2003, 'Early diagnosis and surgical management of prostate cancer', *Cancer Treatment Reviews*, vol. 29, pp. 151–60.
- Lipscomb, J., Weinstein, M.C. and Torrance, G.W. 1996 'Time preference', in Gold, M.R., Russell, L.B., Siegel, J.E. and Weinstein, M.C. (eds), *Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 214–46.
- Litster, S. 2005, 'Video age just the tonic', *Townsville Bulletin*, 7 February, p. 30.
- Lleyland-Jones, B., Gelmon, K., Ayoub, J.P., Arnold, A., Verma, S., Dias, R. and Ghahramani, P. 2003, 'Pharmacokinetics, safety and efficacy of trastuzumab administered every three weeks in combination with paclitaxel', *Journal of Clinical Oncology*, vol. 21, pp. 3965–71.
- Lofgren, H. 2002, *Generic Drugs: International Trends and Policy Developments in Australia*, Centre for Strategic Economic Studies, Victoria University of Technology, Working Paper no. 10, Melbourne.
- Lopert, R. and Henry, D. 2002, 'The Pharmaceutical Benefits Scheme: economic evaluation works ... but is not a panacea', *Australian Prescriber*, vol. 25, pp. 126–7.
- Lotan, Y., Cadeddu, J. and Gettman, M. 2004, 'The new economics of radical prostatectomy: cost comparison of open, laparoscopic and robot assisted techniques', *Journal of Urology*, vol. 142, pp. 1431–5.
- Luce, B.R., Manning, W.G., Siegel, J.E. and Lipscomb, J. 1996, 'Estimating costs in cost-effectiveness analysis', in Gold, M.R., Russell, L.B., Siegel, J.E. and Weinstein, M.C. (eds), *Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 176–213.
- McAlister, F.A., Laupacis, A., Wells, G.A. and Sackett, D.L. 1999, 'Users' guides to the medical literature: XIX. Applying clinical trial results. B: Guidelines for determining whether a drug is exerting (more than) a class effect', Prepared for the Evidence-Based Medicine Working Group, *Journal of the American Medical Association*, vol. 282, no. 14, pp. 1371–7.

-
- McCabe, B. 2005, 'Let's get serious about selling health', *The Australian*, p. C02.
- McCarty, C.A. 2002, 'Cataract in the 21st century: lessons from previous epidemiologic research', *Clinical and Experimental Optometry*, vol. 85, no. 2, pp. 91–6.
- , Keeffe, J.E. and Taylor H.R. 1999, 'The need for cataract surgery: projections based on lens opacity, visual acuity, and personal concern', *British Journal of Ophthalmology*, vol. 83, pp. 62–5.
- McCarty, C.A., Mukesh, B., Fu, C. and Taylor, H. 1999, 'The epidemiology of cataract in Australia', *American Journal of Ophthalmology*, vol. 128, no. 4, pp. 446–65.
- McClellan, M. and Kessler, D. (eds) 2002, *Technological Change in Health Care: A Global Analysis of Heart Attack*, University of Michigan Press, USA.
- McCredie, M., Bell, J., Lee, A. and Rogers, J. 1996, 'Differences in patterns of care of prostate cancer, New South Wales, 1991', *Australian New Zealand Journal of Surgery*, vol. 66, no. 11, pp. 727–30.
- McDaid, D. 2000, *ASTEC Report on Canada*, ASTEC Project, LSE Health, London School of Economics.
- , Cookson, R. and the ASTEC Team 2001, *Evaluation Activity in Europe: An Overview*, ASTEC Project, LSE Health, London School of Economics.
- McEwen, J. 2004, 'What does TGA approval of medicines mean?', *Australian Prescriber*, vol. 27, no. 6, pp. 156–7.
- McGregor, M. 2003, 'Cost–utility analysis: use QALYs only with great caution', *Canadian Medical Association Journal*, vol. 168, no. 4, pp. 433–4.
- McIntosh, E., Donaldson, C. and Ryan, M. 1999, 'Recent advances in the methods of cost–benefit analysis in healthcare', *Pharmacoeconomics*, vol. 15, no. 5, pp. 357–67.
- McManus, P., Donnelly, N., Henry, D., Hall, W., Primrose, J. and Linder, J. 1996, 'Prescription drug utilisation following patient co-payment changes in Australia', *Pharmacoepidemiology and Drug Safety*, vol. 5, pp. 385–92.
- McManus, P., Mant, A., Mitchell, P., Britt, H. and Dudley, J. 2003, 'Use of antidepressants by general practitioners and psychiatrists in Australia', *Australian and New Zealand Journal of Psychiatry*, vol. 37, no. 2, pp. 184–9.
- McManus, P., Mant, A., Mitchell, P. and Dudley, J. 2004, 'Length of therapy with selective serotonin reuptake inhibitors and tricyclic antidepressants in Australia', *Australian and New Zealand Journal of Psychiatry*, vol. 38, no. 6, pp. 450–4.

-
- McManus, P., Mant, A., Mitchell, P.B., Montgomery, W.S., Marley, J. and Auland, M.E. 2000, 'Recent trends in the use of antidepressant drugs in Australia, 1990–1998', *Medical Journal of Australia*, vol. 173, no. 9, pp. 458–61.
- McMurray, A., Grant, S., Griffiths, S. and Letford, A. 2002, 'Health-related quality of life and health service use following total hip replacement surgery', *Journal of Advanced Nursing*, vol. 40, no. 6, pp. 663–72.
- McMurray, J. 1999, 'The health economics of the treatment of hyperlipidemia and hypertension', *American Journal of Hypertension*, vol. 12, no. 10, October, Part 2, pp. s99–s104.
- McNeil, J. 1998, Aligning evidence with research, paper Presented at the Evidence-Based Health Advice Workshop organised by the Menzies Foundation in association with the Health Advisory Committee of the NHMRC, Melbourne, 4–5 November.
- , Nelson, M.R., and Tonkin, A.M. 2003, 'Public funding of large-scale clinical trials in Australia', *Medical Journal of Australia*, vol. 179, no. 10, pp. 519–20.
- Macken, J. 2005, 'Bitter pills depress our happy drug euphoria', *Australian Financial Review*, 18 June, p. 19.
- Mahon, J.L., Bourne, R.B., Rorabeck, C.H., Feeny, D.H., Stitt, L. and Webster-Bogaert, S. 2002, 'Health-related quality of life and mobility of patients awaiting elective total hip arthroplasty: a prospective study', *Canadian Medical Association Journal*, vol. 167, no. 10, pp. 1115–21.
- Makinen, T., Tammela, T.L.J., Hakama, M., Stenman, U. H., Rannikko, S., Aro, J., Juusela, H., Maattanen, L. and Auvinen, A. 2003, 'Tumor characteristics in a population-based prostate cancer screening trial with prostate-specific antigen', *Clinical Cancer Research*, vol. 9, pp. 2435–9.
- Malek, M. 2001, 'Implementing QALYs', Aventis 'What is...?' Bulletins series, vol. 2, no. 9, May, <http://www.evidence-based-medicine.co.uk/ebmfiles/ImplementQALYs.pdf> (accessed 18 July 2005).
- Maley, J. 2005, 'Looking at chronic illness from an adult's point of view', *Sydney Morning Herald*, 25 April, p. 5.
- Manning, W.G., Fryback, D.G. and Weinstein, M.C. 1996 'Reflecting uncertainty in cost-effectiveness analysis', in Gold, M.R., Russell, L.B., Siegel, J.E. and Weinstein, M.C. (eds), *Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 176–213.
- Manning, W., Newhouse, J., Duan, N., Keeler, E., Leibowitz, A. and Marquis, M. 1987, 'Health insurance and the demand for medical care: evidence from a randomised experiment', *American Economic Review*, vol. 77, pp. 251–77.

-
- Mant, A., Rendle, V.A., Hall, W.D., Mitchell, P.B., Montgomery, W.S., McManus, P.R. and Hickie, I.B. 2004, 'Making new choices about antidepressants in Australia: the long view 1975–2002', *Medical Journal of Australia*, vol. 181, no. 7, pp. s21–s24.
- March, L.M. and Bagga, H. 2004, 'Epidemiology of osteoarthritis in Australia', *Medical Journal of Australia*, vol. 180, 1 March, suppl., pp. s6–s10.
- March, L.M., Cross, M.J., Lapsley, H., Brnabic, A.J.M, Tribe, K.L., Bachmeier, C.J.M., Courtenay, B.G. and Brooks, P.M. 1999, 'Outcomes after hip and knee replacement surgery for osteoarthritis', *Medical Journal of Australia*, vol. 171, no. 5, pp. 235–8.
- Marosszeky, N. 2003, *Instrument Review for SF-12*, Australian Health Outcomes Collaboration, Centre for Health Service Development, University of Wollongong, <http://www.uow.edu.au/commerce/ahoc/sf12review.html> (accessed 2 March 2005).
- Marshall, T. 2003, 'Coronary heart disease prevention: insights from modelling incremental cost effectiveness', *British Medical Journal*, vol. 327, no. 7426, pp. 1264–8.
- Martin, Z. 2005, 'RFID tags help identify patients before surgery', *Health Data Management*, July, <http://www.healthdatamanagement.com/html/current/PastIssueStory.cfm?PostID=19807&PastMonth=July&PastYear=2005> (accessed 28 June 2005).
- Mathers, C. 2002, 'Health expectancies: an overview and critical appraisal', in Murray, C.J.L., Saloman, J.A., Mathers, C.D. and Lopez, A.D. (eds), *Summary Measures of Population Health Concepts, Ethics, Measurement and Applications*, World Health Organization, Geneva, pp. 177–204, http://whqlibdoc.who.int/publications/2002/9241545518_Chap4.1.pdf (accessed 15 March 2005).
- 1999, *Alternative Methods to Measure Burden of Disease*, [http://www.skyaid.org/Skyaid%20Org/Medical/Burden of Disease Methods.htm](http://www.skyaid.org/Skyaid%20Org/Medical/Burden%20of%20Disease%20Methods.htm) (accessed 23 February 2005).
- , Vos, T. and Stevenson, C. 1999, *The Burden of Disease and Injury in Australia*, AIHW Cat. no. PHE 17, AIHW, Canberra.
- Mathur, S. 2002, *Epidemic of Coronary Heart Disease and its Treatment in Australia*, Cardiovascular Disease Series no. 20, AIHW Cat. no. CVD 21, AIHW, Canberra.
- Meadows, M. 2002, 'Bringing real life to the table: patient reps help FDA review products', *FDA Consumer Magazine*, Jan-Feb, www.fda.gov/fdac/features/2002/102_real.html (accessed 19 May 2005).

-
- Medicines Australia 2002, *A Prescription for the Future Health of Australia*, Canberra.
- MedlinePlus 2003, *Rhabdomyolysis*, National Library of Medicine (US), <http://www.nlm.nih.gov/medlineplus/aboutmedlineplus.html> (accessed 11 February 2005).
- Medscape 2004, 'Drug-eluting stents: A mechanical and pharmacological approach to coronary artery disease', US, http://www.medscape.com/content/2004/00/49/58/495864/495864_tab.html (accessed 27 January 2005).
- MEDTAP International 2004, *The Value of Investment in Health Care*, Full Report, Bethesda, MD, United States, http://www.medtap.com/Products/HP_FullReport.pdf (accessed 29 June 2005).
- Meijer, W.E.E., Heerdink, E.R., Leufkens, H.G.M., Herings, R.M.C, Egberts, A.C.G. and Nolen, W.A. 2004, 'Incidence and determinants of long-term use of antidepressants', *European Journal of Clinical Pharmacology*, vol. 60, pp. 57–61.
- Melton, L. 2004, 'Don't go breaking my heart', *New Scientist*, 25 November, pp. 39–41.
- Meltzer, D. 1997, 'Accounting for future costs in medical cost-effectiveness analysis', *Journal of Health Economics*, vol. 16, no. 1, pp. 33–64.
- Melzer, D., Raven, A., Detmer, D., Ling, T., Zimmermann, R. and Jillions, D. 2003, *My very own medicine: what must I know?: Information policy for pharmacogenetics*, University of Cambridge, Report for the Wellcome Trust, July.
- Merck & Co. Inc. 2004, DOV Pharmaceutical and Merck announce agreement to develop and commercialize novel depression compounds, Whitehouse Station, www.merck.com/newsroom/press_releases/research_and_development/2004_0805.html (accessed 21 December 2004).
- Meskan, T. 2004, 'DESigs on better outcomes', *Managed Healthcare Executive*, vol. 14, no. 6, pp. 30–4.
- Messori, A., Santarlasci, B., Trippoli, S. and Vaiani, M. 2003a, 'Polypill to fight cardiovascular disease', *British Medical Journal*, vol. 327, no. 7418, pp. 808–9.
- 2003b, 'Questionable cost-effectiveness of statins for primary prevention of cardiovascular events' (electronic response to Wald and Law 2003), *British Medical Journal*, <http://bmj.com/cgi/eletters/326/7404/1407#34612>, (accessed 1 March 2005).
- MHRA (Medicines and Healthcare Products Regulatory Agency) 2005, *About the MHRA*, www.mhra.gov.uk/aboutmhra/aboutmhra.htm (accessed 24 June 2005).

-
- Miles, J. 2005, 'Genetic screening', *The Advertiser*, 14 June, p. 21.
- Miraculins 2005, *Miraculins Positive Results of Study to Improve the Diagnosis of Prostate Cancer*, Media release, 30 March, http://www.miraculins.com/press_mar30_2005.htm (accessed 7 July 2005).
- Mitchell, P., Cumming, R., Attebo, K. and Panchapakesan, J. 1997, 'Prevalence of cataract in Australia, The Blue Mountains Eye Study', *Ophthalmology*, vol. 104, no. 4, pp. 581–8.
- Mitchell, S. 2005, 'Hospital of future goes remote', *The Australian*, 2 August, p. 31.
- MOGA (Medical Oncology Group of Australia), 2002, *Submission to the Interdepartmental Committee Reviewing the Pharmaceutical Benefits Scheme*, August, http://www.racp.edu.au/moga/PBSsub_Aug02.pdf (accessed 29 August 2005).
- Mohr, P., Mueller, C., Neumann, P., Franco, S., Milet, M., Silver, L. and Wilensky, G. 2001, *The Impact of Medical Technology on Future Health Care Costs*, Report prepared for Health Insurance Association of America and Blue Cross and Blue Shield Association, Project HOPE, Centre for Health Affairs.
- Moise, P. and Jacobzone, S. 2003, 'Population ageing, health expenditure and treatment: an ARD perspective', in *A Disease-based Comparison of Health Systems*, OECD, Paris.
- Molloy, F. 2005, 'Mine of information', *Sydney Morning Herald*, 15 January, p. 5.
- Moncrief, M. 2005, 'Privacy fears over computer system for health records', *The Age*, 30 January, p. 7.
- Mont, M.A., Ragland, P.S., Biggins, B., Friedlander, G., Patel, T., Cook, S., Etienne, G., Shimmin, A., Kildey, R., Rueger, D.C. and Einhorn, T.A. 2004, 'Use of bone morphogenetic proteins for musculoskeletal applications', *Journal of Bone and Joint Surgery (American volume)*, Boston, vol. 86, pp. 41–55.
- More, E. and McGrath, M. 2000, *Health and Industry Collaboration — the PeCC Story*, Department of Communications, Information Technology and the Arts, Canberra, May, http://www.dcita.gov.au/ie/publications/2000/may/health_and_industry_collaboration_-_the_pecc_story (accessed 10 March 2005).
- Morgan, J., Thornton, B., Peacock, J., Hollingsworth, K., Smith, C., Mehmet, C. and Argenziano, M. 2005, 'Does robotic technology make minimally invasive cardiac surgery too expensive? A hospital cost analysis of robotic and conventional techniques', *Journal of Cardiac Surgery*, vol. 20, no. 3, pp. 246–52.
- Morrison, C., Woodward, M., Leslie, W. and Tunstall-Pedoe, H. 1997, 'Effect of socioeconomic group on incidence of management of and survival after

-
- myocardial infarction and coronary death: analysis of community coronary event register', *British Medical Journal*, vol. 314, pp. 541–6.
- Mowatt, G., Bower, D.J., Brebner, J.A., Cairns, J.A., Grant, A.M. and McKee, L. 1997, *When and How to Assess Fast-Changing Technologies: A Comparative Study of Medical Applications of Four Generic Technologies*, NHS R&D HTA Programme, York.
- MPA (Medical Products Agency) 2005a, *About the Medical Products Agency*, Uppsala, http://www.mpa.se/eng/about_mpa/index.shtml (accessed 28 June 2005).
- 2005b, *Swedish Medical Products Agency—A Centre of Regulatory Excellence*, Uppsala http://www.mpa.se/eng/about_mpa/index.shtml (accessed 28 June 2005).
- MSAC (Medical Services Advisory Committee) 2005, *Drug-Eluting Stents, Assessment Report — MSAC Application 30*, Commonwealth of Australia, Canberra, forthcoming.
- 2004a, *Annual Report 2002-03*, Department of Health and Ageing, Canberra.
- 2004b, *Funding of New Medical Technologies and Procedures: Application and Assessment Guidelines*, Department of Health and Ageing, Canberra.
- 2003, *Annual Report 2001-02*, Department of Health and Ageing, Canberra.
- 2002, *Coated Stents for Coronary Arteries*, Horizon Scanning Briefing No. 2, February, Commonwealth of Australia, Canberra.
- 2001, *Annual Report 2000-01*, Department of Health and Ageing, Canberra.
- 2000, *Annual Report April 1998 – June 2000*, Department of Health and Ageing, Canberra.
- MTG (The Medical Technology Group) 2003, *Making the Economic Case for Medical Technology*, MTG, London, <http://www.eucomed.be/docs/Making%20the%20Economic%20Case%20for%20Medical%20Technology.pdf> (accessed 10 February 2005).
- Muller, N. 2005, 'Terminal illness', *The Courier-Mail*, 8 August, p. 17.
- Murphy, A.M., McKiernan, J.M., and Olsson, C.A., 2004, 'Controversies in prostate cancer screening', *Journal of Urology*, vol. 172, November, pp. 1822–4.
- Murphy, K. and Topel, R.H 2003, 'The economic value of medical research', in Murphy, K. and Topel, R.H (eds), *Measuring the Gains from Medical Research*, University of Chicago Press, Chicago, pp. 41–73.
- Murray, C.J. and Lopez, A.D. 1996. *The Global Burden of Disease: A Comprehensive Assessment of Mortality and Disability From Diseases, Injuries*

and Risk Factors in 1990 and Projected to 2020, Global Burden of Disease and Injury Series, Volume 1, Burden of Disease Unit, Harvard University, Cambridge, Massachusetts.

Murray, C.J.L., Saloman, J.A. and Mathers, C.D. 2002, 'A critical examination of summary measures of population health', in Murray, C.J.L., Saloman, J.A., Mathers, C.D and Lopez A.D. (eds), *Summary Measures of Population Health Concepts, Ethics, Measurement and Applications*, World Health Organization, Geneva, pp. 13–40.

Murray, D. 2004, 'A painful decision', *The Australian*, 23 October, pp. C32–C33.

Murthy, N.R.V. and Ukpolo, V. 1994, 'Aggregate health care expenditure in the United States: evidence from cointegration tests', *Applied Economics*, vol. 26, pp. 797–802.

Mushkin, S.J. and Landefeld, J.S. 1979, *Biomedical Research: Costs and Benefits*, Ballinger Publishing Company, Cambridge, Massachusetts.

Nader, C. 2005, 'Olivia's high-tech step forward', *The Age*, 12 July, p. 6.

National Asthma Council Australia 2002, *Asthma Management Handbook*, South Melbourne, <http://www.nationalasthma.org.au/publications/amh/print/AMH2002.pdf> (accessed 30 March 2005).

National Cancer Institute 2005a, *Genetic Testing for Breast Cancer Risk*, www.nci.nih.gov/cancertopics/genetic-testing-breast/ (accessed 29 March 2005).

— 2005b, *Herceptin Combined with Chemotherapy Improves Disease-Free Survival for Patients with Early-Stage Breast Cancer*, <http://www.nci.nih.gov/newscenter/pressreleases/herceptinCombination2005> (accessed 2 June 2005).

National Health Performance Committee 2003, *National Report on Health Sector Performance Indicators*, AIHW Cat. no. HWI 78, AIHW, Canberra.

National Institute of Health (US) 2004, *NIH Consensus Statement on Total Knee Replacement*, NIH consensus and state-of-the-science statements, <http://consensus.nih.gov/cons/117/TKRStatementPrintFinal.pdf> (accessed 10 February 2005).

National Institute for Health Care Management 2002, *Changing Patterns of Pharmaceutical Innovation*, Research Report, Washington D.C..

NBCC (National Breast Cancer Centre) 2004, *Screening and Early Detection*, August, <http://www.nbcc.org.au/bestpractice/screening/index.html>, (accessed 1 July 2005).

-
- 2001, *A Guide for Women with Metastatic Breast Cancer*, iSource National Breast Cancer Centre, http://www.nbcc.org.au/resources/documents/MCG_metastaticguide.pdf (accessed 2 June 2005).
- NCCH (National Centre for Classification in Health) 2005, *ICD-10-AM Fifth Edition Discussion Paper: Drug Eluting Stents*, Sydney.
- Neal, D.E. and Donovan, J.L. 2000, 'Prostate cancer: to screen or not to screen?', *The Lancet Oncology*, vol. 1, September, pp. 17–24.
- NEC (Nordic Evaluation Committee) 2003, *External Evaluation of DACEHTA*, National Board of Health, Copenhagen.
- NEHTA (National E-Health Transition Authority) 2005a, *About NEHTA*, http://www.nehta.gov.au/index.php?option=com_content&task=view&id=1&Itemid=69 (accessed 29 March 2005).
- 2005b, *Welcome to NEHTA*, <http://www.nehta.gov.au> (accessed 29 March 2005).
- 2004, *Fact Sheet*, http://www.nehta.gov.au/index.php?option=com_docman&task=cat_view&gid=91&Itemid=53 (accessed 28 March 2005).
- Neumann, P.J., Sandberg, E.A., Bell, C.M., Stone, P.W. and Chapman, R.H. 2000, 'Are pharmaceuticals cost-effective? A review of the evidence', *Health Affairs*, vol. 19, no. 2, pp. 92–109.
- Neurocrine Biosciences Inc. 2004, CRF receptor antagonist: Anxiety/Depression, San Diego, www.neurocrine.com/html/clin_anxietyDepression.html (accessed 23 December).
- Newby, D.A., Fryer, J.L. and Henry, D.A. 2003, 'Effect of computerised prescribing on use of antibiotics', *Medical Journal of Australia*, vol. 178, no. 5, pp. 210–13.
- Newhouse, J.P. 1992, 'Medical care costs: how much welfare loss?', *Journal of Economic Perspectives*, vol. 6, no. 3, pp. 3–21.
- 1977, 'Medical care expenditure: a cross national survey', *Journal of Human Resources*, vol. 12, no. 1, pp. 115–25.
- Neyt, M., Albrecht, J., Clarysse, B. and Cocquyt, V. 2005, 'Cost-effectiveness of Herceptin: a standard cost model for breast-cancer treatment in a Belgian university hospital', *International Journal of Technology Assessment in Health Care*, vol. 21, no. 1, Winter, pp. 132–7.
- NHC (National Health Committee) (NZ) 2005, *Decision-Making about New Health Interventions*, Report to the New Zealand Minister of Health, Wellington.

NHF (National Heart Foundation of Australia) and The Cardiac Society of Australia and New Zealand 2001, 'Lipid management guidelines — 2001', *Medical Journal of Australia*, vol. 175, no. 9, suppl., pp. s55–s90.

NHMRC (National Health and Medical Research Council) 2005, *NHMRC Standards and Procedures for Externally Developed Guidelines*, <http://www.nhmrc.gov.au/publications/synopses/nh56syn.htm> (accessed 30 March 2005).

—— 2005b, *National Health and Medical Research Council statement on animal-to-human transplantation (xenotransplantation) research*, 10 March.

—— 1999, *A Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines*, AusInfo, Canberra.

—— and NBCC (National Breast Cancer Centre) 2000, *Advice about Familial Aspects of Breast Cancer and Ovarian Cancer — A Guide for Health Professionals*, October, http://www.nbcc.org.au/bestpractice/resources/BOG_BreastOvarianGuideCompl.pdf (accessed 28 June 2005).

NHS (National Health Service) (UK) 2004, *Hip Replacement: An Operation to Replace your Hip with an Artificial One*, NHS Direct Online <http://www.besttreatments.co.uk/btuk/pdf/18618.pdf> (accessed 16 March 2005).

—— 2003, *National Service Framework for Coronary Heart Disease*, <http://www.wales.nhs.uk/sites/page.cfm?orgid=376&pid=1965> (accessed 28 January 2005).

NHSC (National Horizon Scanning Centre) (UK) 2003, *Licofelone for Osteoarthritis*, New and Emerging Technology Briefing, January.

NHSU (National Horizon Scanning Unit) 2004, *Operations Manual*, Adelaide Health Technology Assessment, Department of Public Health, University of Adelaide.

NICE (National Institute of Health and Clinical Excellence) 2005a, *About Technology Appraisals*, <http://www.nice.org.uk/page.aspx?o=251107> (accessed 26 July 2005).

—— 2005b, 'Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block', *Technology Appraisal*, no. 18, NHS, UK, February.

—— 2004a, *Annual Report 2003-04*, London, <http://www.nice.org.uk/page.aspx?o=212708> (accessed 10 February 2005).

—— 2004b, *Guide to the Methods of Technology Appraisal*, NICE, London, <http://www.nice.org.uk/page.aspx?o=201974> (accessed 10 February 2005).

-
- 2004c, *A Guide to NICE*, NICE, London, <http://www.nice.org.uk/page.aspx?o=113719> (accessed 10 February 2005).
- 2004d, Invitation to participate in the appraisal of statins, April, http://www.nice.org.uk/pdf/Statins_final_scope.pdf (accessed 9 February 2005).
- 2003, *Guidance on the Use of Coronary Artery Stents*, Technology appraisal no. 71, NHS, UK.
- 2002a, *Full Guidance on the Use of Trastuzumab for the Treatment of Advanced Breast Cancer*, Technology appraisal no. 34, NHS, UK.
- 2002b, *NICE Recommends the Selective Use of Metal on Metal Hip Resurfacing*, Media release no. 2002/32, 19 June.
- 2000, *The Effectiveness and Cost Effectiveness of Different Prostheses for Primary Total Hip Replacement*, http://www.nice.org.uk/embcats.aspx?page=oldsite/appraisals/hip_patient.htm (accessed 10 February 2005).
- and Secta 2004, *Costing and Clinical Guidelines: Familial Breast Cancer*, NICE, May, <http://www.nice.org.uk/pdf/CG014report.pdf> (accessed 27 August 2005).
- NICS (National Institute of Clinical Studies) 2003, *Evidence — Practice Gaps*, Report, vol. 1, Melbourne.
- Nielsen, C.P., Kristensen, F.B and Vestergaard, M. 2000, *ASTEC Report on Denmark*, ASTEC Project, LSE Health, London School of Economics.
- NIH (National Institute of Health) (US) 2004, *NIH Consensus Statement on Total Knee Replacement*, NIH Consensus and State-of-the-Science Statements, <http://consensus.nih.gov/cons/117/TKRStatementPrintFinal.pdf> (accessed 10 February 2005).
- Nikolaou, K., Poon, M., Sirol, M., Becker, C.R. and Fayad, Z.A. 2003, 'Complementary results of computed tomography and magnetic resonance imaging of the heart and coronary arteries: a review and future outlook', *Cardiology Clinics*, vol. 21, no. 4, pp. 639–55.
- Noble, T. 2004, 'Cancer gene test first', *The Age*, 17 February.
- NOIE (National Office for the Information Economy) 2002a, 'Appendix A: case studies', *Broadband in Health: Drivers, Impediments and Benefits*, Department of Communications, Information Technology and the Arts, Canberra, August, http://www.dcita.gov.au/ie/publications/2002/august/broadband_in_health_drivers_impediments_and_benefits/appendix_a_case_studies (accessed 10 February 2005).
- 2002b, 'Drivers of Broadband in Health', *Broadband in Health: Drivers, Impediments and Benefits*, Department of Communications, Information

-
- Technology and the Arts, Canberra, August, http://www.dcita.gov.au/ie/publications/2002/august/broadband_in_health_drivers,_impediments_and_benefits/drivers_of_broadband_in_health (accessed 10 February 2005).
- 2002c, 'Executive Summary', *Broadband in Health: Drivers, Impediments and Benefits*, Department of Communications, Information Technology and the Arts, Canberra, August, http://www.dcita.gov.au/ie/publications/2002/august/broadband_in_health_drivers,_impediments_and_benefits/executive_summary (accessed 10 February 2005).
- 2002d, 'Impediments', *Broadband in Health: Drivers, Impediments and Benefits*, Department of Communications, Information Technology and the Arts, Canberra, August, http://www.dcita.gov.au/ie/publications/2002/august/broadband_in_health_drivers,_impediments_and_benefits/impediments (accessed 10 February 2005).
- 2002e, 'Introduction', *Broadband in Health: Drivers, Impediments and Benefits*, Department of Communications, Information Technology and the Arts, Canberra, August, http://www.dcita.gov.au/ie/publications/2002/august/broadband_in_health_drivers,_impediments_and_benefits/introduction (accessed 10 February 2005).
- Noonan, G. 2004, 'Nuclear reactor is redundant, say doctors', *Sydney Morning Herald*, 31 August, p. 4.
- Nord, E., Menzel, P. and Richardson, J. 2003, 'The value of life: individual preferences and social choice. A comment to Magnus Johannesson', *Health Economics*, vol. 12, pp. 873–7.
- Nordhaus, W.D. 2003, 'The health of nations: the contribution of improved health to living standards' in Murphy, K. and Topel, R.H (eds), *Measuring the Gains from Medical Research*, University of Chicago Press, Chicago, pp. 9–40.
- Nowak, R. 2005, 'Smart bombs to blast tumours', *New Scientist*, 8 January, p. 19.
- NPS (National Prescribing Service) 2003, *Progress, Achievements and Future Directions*, Evaluation Report no. 6, Sydney.
- NSWtag (New South Wales Therapeutic Advisory Group) 2004, *Annual Report 2003-04*, Sydney.
- O'Dea, J. and Kilham, R. 2002, 'The inverse care law is alive and well in general practice', *Medical Journal of Australia*, vol. 177, no. 2, pp. 78–9.
- OECD (Organisation for Economic Cooperation and Development) 2005a, *Health Technologies and Decision Making*, OECD Health Project, Paris, forthcoming.
- 2005b, *Purchasing Power Parity — Comparative Price Levels*, OECD, Paris.
- 2005c, *Economic Survey of Australia, 2004*, Summary, OECD, Paris.

-
- 2005d, *Health Data 2005*, June 2005, OECD, Paris.
- 2004, *Health Data 2004*, 3rd edn, OECD, Paris.
- 2001, *Measuring Expenditure on Health-related R&D*, OECD, Paris.
- Office of the Federal Privacy Commissioner 2004, *HealthConnect Interim Research Report and Draft Systems Architecture*, Submission to HealthConnect Program Office, Sydney.
- Okunade, A.A. and Murthy, V.N.R. 2002, 'Technology as a "major driver" of health care costs: a cointegration analysis of the Newhouse conjecture', *Journal of Health Economics*, vol. 21, pp. 147–59.
- Oliver, A., Mossialos, E. and Robinson, R. 2004, 'Health technology assessment and its influence on health-care priority setting', *International Journal of Technology Assessment in Health Care*, vol. 20, no. 1, pp. 1–10.
- Oliver, S.E., May, M.T. and Gunnell, D. 2001, 'International trends in prostate cancer mortality in the "PSA era"', *International Journal of Cancer*, vol. 92, pp. 893–8.
- Olsen, O. and Gotzsche, P. 2001, 'Cochrane review on screening for breast cancer with mammography', *The Lancet*, vol. 358, pp. 1340–2.
- Olson, R.J., Mamalis, N., Werner, L. and Apple, D.J. 2003, 'Perspective: cataract treatment in the beginning of the 21st century', *American Journal of Ophthalmology*, vol. 16, no. 1, pp. 146–54.
- Oncology Business Week 2005, 'Endocare, Inc. device company announces data in study of prostate cancer treatment', <http://proquest.umi.com/pqdweb?did=818578081&sid=1&Fmt=3&clientId=61469&RQT=309&VName=PQD> (accessed 26 April 2005).
- Orvain, J., Xerri, B. and Matillon, Y. 2004, 'Overview of health technology assessment in France', *International Journal of Technology Assessment in Health Care*, vol. 20, no. 1, pp. 25–34.
- Oxley, H. and MacFarlan, M. 1994, *Health Care Reform: Controlling Spending and Increasing Efficiency*, Economics Department Working Paper no. 149, OECD, Paris.
- Paltiel, A.D., Fuhlbrigge, A.L., Kitch, B.T., Liljas, B. and Weiss, S.T. 2001, 'Cost-effectiveness of inhaled corticosteroids in adults with mild-to-moderate asthma: results from the asthma policy model', *Journal of Allergy and Clinical Immunology*, vol. 108, no. 1, pp. 39–46.
- Pammolli, F., Riccaboni, M., Ogialoro, C., Magazzini, L., Baio, G. and Salerno, N. 2005, *Medical Devices Competitiveness and Impact on Public*

Health Expenditure, Study prepared for the Directorate General Enterprise of the European Commission, July.

Panchapakesan, J., Mitchell, P., Tumuluri, K., Rochtchina, E., Foran, S. and Cumming, R. 2003, 'Five year incidence of cataract surgery: the Blue Mountains Eye Study', *British Journal Ophthalmology*, vol. 87, pp. 168–72.

Panzarino, P.J. and Nash, D.B. 2001, 'Cost-effective treatment of depression with selective serotonin reuptake inhibitors', *American Journal of Managed Care*, vol. 7, no. 2, pp. 173–84.

Parkes J., Chase, D., Grace, A., Cunningham, D. and Roderick, P. 2005, 'Inequity of use of implantable cardioverter defibrillators in England: retrospective analysis', *British Medical Journal*, vol. 330, pp. 454–5.

Parkin, D., McGuire, A. and Yule, B. 1987, 'Aggregate health care expenditures and national income: is health care a luxury good?', *Journal of Health Economics*, vol. 6, no. 2, June, pp. 109–27.

Parnell, S. 2004, 'Major overhaul for medical IT', *The Courier-Mail*, 12 July, p. 3.

Patterson, K. (Minister for Health and Ageing) 2003a, *HealthConnect Trial Extended in Northern Territory*, Media release, 8 July.

—— 2003b, *HealthConnect trial extended in Tasmania*, Media release, 4 July.

—— 2003c, *Medicare — for all Australians*, Commonwealth of Australia, May.

—— 2003d, *Stage two reforms to drive private health fund efficiency*, Media release, 3 April.

—— 2002, *Green Light for HealthConnect Trials*, Media release, 24 June.

Pauly, M.V. 1996, 'Valuing health care benefits in money terms', in Sloan, F.A. (ed.), *Valuing Health Care Costs, Benefits and Effectiveness of Pharmaceuticals and other Medical Technologies*, Cambridge University Press, Cambridge, pp. 99–124.

Payne, N. and Saul, C. 1997, 'Variation in use of cardiology services in a health authority: comparison of coronary artery revascularisation rates with prevalence of angina and coronary mortality', *British Medical Journal*, vol. 314, pp. 257–61.

PBAC (Pharmaceutical Benefits Advisory Committee) 2003, *PBAC Outcomes — "Subsequent" Decisions not to Recommend*, September, <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-listing-pbacrec-sep03-reject2.htm> (accessed 21 March 2005).

PC (Productivity Commission) 2005a, *Economic Implications of an Ageing Australia*, Research Report, Productivity Commission, Canberra.

-
- 2005b, *Review of National Competition Policy Reforms*, Report no. 33, Canberra.
- 2004, *ICT Use and Productivity: A Synthesis from Studies of Australian Firms*, Commission Research Paper, Canberra.
- 2001a, *International Pharmaceutical Price Differences*, Research Report, Canberra.
- 2001b, *Cost Recovery by Government Agencies*, Report no. 15, Canberra.
- and Melbourne Institute of Applied Economic and Social Research 2002, *Health Policy Roundtable*, Conference Proceedings, Canberra.
- 1999, *Policy Implications of the Ageing of Australia's Population*, Conference Proceedings, Canberra.
- Peacock, S., Chan, C., Mangolini, M. and Johansen, D. 2001, *Techniques for Measuring Efficiency in Health Services*, Staff working paper, Productivity Commission, Canberra.
- Pearson, J.D., Luderer, A.A., Metter, E.J., Partin, A.W., Chan, D.W., Fozard, J.L. and Carter, H.B. 1996, 'Longitudinal analysis of serial measurements of free and total PSA among men with and without prostatic cancer', *Urology*, vol. 48, December, pp. 4–9.
- Pell, J., Pell, A., Norrie, J., Ford, I., Cobbe, S. and Hart, J. 2000, 'Effect of socioeconomic deprivation on waiting time for cardiac surgery: retrospective cohort study', *British Medical Journal*, vol. 320, pp. 15–19.
- Perry, S. and Thamer, M. 1999, 'Medical innovation and the critical role of health technology assessment', *Journal of the American Medical Association*, vol. 282, no. 19, pp. 1869–72.
- Petersen, C. 1999, 'HMOs get what they pay for with HIV treatment', *Managed Healthcare*, vol. 9, no. 11, pp. 40–2.
- Petrou, S. 2003, *What are Health Utilities?*, Aventis 'What is...?' Bulletins series, vol. 1, no. 4, May, <http://www.evidence-based-medicine.co.uk/ebmfiles/Whatarehealthutil.pdf> (accessed 18 July 2005).
- Pharmafocus 2003, 'NICE to review statins', *News Story*, 4 April, http://www.pharmafocus.com/cda/focusH/1,2109,21-0-0APR_2003focus_news_detail-0-76210,00.html, (accessed 9 February 2005).
- PharmaMar 2005, *Aplidin commences phase II clinical trials in prostate and bladder cancers*, Media release, 17 February, http://www.pharmamar.com/en/press/news_release.cfm?newsReleaseID=106&year=2005 (accessed 9 August 2005).

-
- Phelps, C.E. 1992, *Health Economics*, HarperCollins, New York.
- Phelps, M.E. 2002, 'Molecular imaging with positron emission tomography', *Annual Review of Nuclear and Particle Science*, vol. 53, pp. 303–38.
- PHIAC (Private Health Insurance Administration Council) 2005a, *Statistical Trends in Membership and Benefits*, Canberra, <http://www.phiac.gov.au/statistics/trends/index.htm> (accessed 31 March 2005).
- 2005b, *Annual Coverage Survey*, <http://www.phiac.gov.au/statistics/survey/aust.htm> (accessed 28 March 2005).
- 2004, *Operations of the Registered Health Benefits Annual Report 2003-04*, PHIAC, Canberra.
- Philipson, G. 2005, 'PCs in health: keep taking the tablets', *The Age*, 19 April, p. 5.
- Phillips, C. and Thompson, G. 2001, *What is a QALY?*, Hayward Medical Communications, Kent, United Kingdom, May, <http://www.evidence-based-medicine.co.uk> (accessed 23 February 2005).
- Phillips, K.A., Shlipak, M.G., Coxson, P., Heidenreich, P.A., Hunink, M.G., Goldman, P.A., Williams, L.W., Weinstein, M. C. and Goldman, L. 2000, 'Health and economic benefits of increased beta-blocker use following myocardial care', *Journal of the American Medical Association*, vol. 284, no. 21, pp. 2748–54.
- PhRMA (Pharmaceutical Research and Manufacturers of America) 2004, 'New medicines in development', www.innovation.org/future/new-meds.php (accessed 27 January 2004).
- 2001, *Pharmaceutical Industry Profile 2001*, Washington.
- Pilote, L., Joseph, L., Belisle, P. and Penrod, J. 2003, 'Universal health insurance coverage does not eliminate inequities in access to cardiac procedures after acute myocardial infarction', *American Heart Journal*, vol. 146, no. 6, pp. 938–40.
- Pinnock, C., Weller, D. and Marshall, V. 1998, 'Self-reported prevalence of prostate-specific antigen testing in South Australia: a community study', *Medical Journal of Australia*, vol. 169, no. 1, pp. 25–8.
- Pirani, C. 2005, 'Public hospital queues swell', *The Australian*, 21 March, pp. 1–2.
- Pirotta, M.V., Cohen, M.M., Kotsirilos, V. and Farish, S.J. 2000, 'Complementary therapies: have they become accepted in general practice?', *Medical Journal of Australia*, vol. 172, no. 3, pp. 105–9.
- Pirraglia, P.A., Rosen, A.B., Hermann, R.C., Olchanski, N.V. and Neumann, P. 2004, 'Cost–utility analysis studies of depression management: A systematic review', *American Journal of Psychiatry*, vol. 161, no. 12, pp. 2155–62.

-
- Pollard, R. 2005a, 'Culture of negligence a danger to patients', *Sydney Morning Herald*, 15 January, p. 3.
- 2005b, 'Drug ad pop-ups ruled out of order', *Sydney Morning Herald*, 26 July, p. 3.
- 2005c, 'Electric schemes', *Sydney Morning Herald*, 13 June, p. 15.
- Pompidou, A. 2002, 'Dissemination and use of new technologies through telemedicine for elderly people', *Biotechnology and Healthy Ageing*, Policy Implications of New Research, OECD, Paris, pp. 139–41.
- Population Health Division 2004, *The Health of the People of NSW, Report of the Chief Health Officer 2004*, NSW Department of Health, Sydney.
- Pountney, M. 2004, 'Drug's banning overdue', *Herald Sun*, 26 October, p. 12.
- Prieto, L. and Sacristán, J.A. 2003, 'Problems and solutions in calculating quality-adjusted life years (QALYs)', *Health and Quality of Life Outcomes*, vol. 1, <http://www.hqlo.com/content/pdf/1477-7525-1-80.pdf> (accessed 12 July 2005).
- Prosser, L.A., Stinnett, A.A., Goldman, P.A., Williams, L.W., Hunink, G.M., Goldman, L. and Weinstein, M.C. 2000, 'Cost effectiveness of cholesterol-lowering therapies according to selected patient characteristics', *Annals of Internal Medicine*, vol. 132, no. 10, 16 May, pp. 769–79.
- PSA Rising: Prostate cancer survivor news, info and support 2003, 'Bostwick Laboratories announces uPM3 (TM) test, first genetic test for prostate cancer', <http://psa-rising.com/wiredbird/bostwicklabs92303.php> (accessed 19 May 2005).
- PWC (PriceWaterhouseCoopers) 1999, *HealthCast 2010, Smaller World, Bigger Expectations*, November.
- Pyne, C. (Parliamentary Secretary to the Minister for Health and Ageing) 2005a, *Australia and Canada Forge Links to Regulate Medicines*, Media release no. CP013/05, 16 March.
- 2005b, *Australia and New Zealand Agree to Defer Start-Up Date for Joint Therapeutic Products Regulation*, Media release no. CP002/05, 9 February.
- Queensland Health 2004, *Queensland Hospitals Standard Drug List*, December Version, Brisbane.
- Radiation Oncology Inquiry Committee 2002, *A Vision for Radiotherapy, Report of the Radiation Oncology Inquiry*, Commonwealth of Australia, Canberra.
- Ramchandani, P., Murray, B., Hawton, K. and House, A. 2000, 'Deliberate self poisoning with antidepressant drugs: a comparison of the relative hospital costs of cases of overdose of tricyclics with those of selective-serotonin re-uptake inhibitors', *Journal of Affective Disorders*, vol. 60, no. 2, pp. 97–100.

- Rang, H.P., Dale, M.M., Ritter, J.M. and Moore, P.K. 2003, *Pharmacology*, 5th edn, Churchill Livingstone, Edinburgh.
- RANZCP (Royal Australian and New Zealand College of Psychiatrists) 2002, *Telepsychiatry*, Position Statement no. 44, October.
- Reginster, J.Y., Deroisy, R., Rovati, L.C., Lee, R.L., Lejeune, E., Bruyere, O., Giacobelli, G., Henrotin, Y., Dacre, J.E. and Gossett, C. 2001, 'Long term effects of glucosamine sulphate on osteoarthritis progression: a randomised, placebo-controlled clinical trial', *The Lancet*, vol. 357, 27 January, pp. 251–6.
- Reinecke, I. 2005, e-Health — Getting There from Here, Presentation to Health-e-Nation 2005, Sydney, 9 March.
- 2004, Managing Information in Health, Presentation to National Health Information Summit, Melbourne, 7 December.
- Revicki, D.A., Brown, R.E., Palmer, W., Bakish, D., Rosser, W.W., Anton, S.F. and Feeny, D. 1995, 'Modelling the cost effectiveness of antidepressant treatment in primary care', *Pharmacoeconomics*, vol. 8, no. 6, pp. 524–40.
- Richards, D. 2005, 'Your life history, online', *Sydney Morning Herald*, 16 June, p. 4.
- 2004, 'There's new hope for the despairing', *Australian Financial Review*, 18 September, p. 22.
- Richardson, J. 1988, 'Medical technology and its diffusion in Australia', *International Journal of Technology Assessment in Health Care*, vol. 4, pp. 407–31.
- 1990, *Economic Assessment of Health Care: Theory and Practice*, National Centre for Health Program Evaluation, Working Paper no. 1, Paper presented to the 1990 Social Issues Conference, Melbourne, 10 August.
- Richardson, J. and Robertson, I. 1999, 'Ageing and the Cost of Health Services' in *Policy Implications of the Ageing of Australia's Population*, Productivity Commission and Melbourne Institute, March, Canberra.
- Rihmer, Z. 2001, 'Can better recognition and treatment of depression reduce suicide rates? A brief review', *European Psychiatry*, vol. 16, no. 7, pp. 406–9.
- Riley, J. 2005, 'Feds fund pharmacy broadband', *The Australian*, 10 February, <http://australianit.news.com.au/common/print/0,7208,12199062%5E15306%5E%5E%5Enbv%5e,00.html> (accessed 10 February).
- Ringel, J.S., Hosek, S.D., Vollard, B.A. and Mahnovski, S. 2002, *The Elasticity of Demand for Health Care: A Review of the Literature and Its Application to the Military Health System*, Report prepared by the US National Defence Research

Institute and RAND Health for the US Office of the Secretary of Defence, RAND Health.

- Rob, M.I., Corben, P. and Rushworth, R.L. 1998, 'The impact of new technology on cholecystectomy rates in New South Wales', *Journal of Quality Clinical Practice*, vol. 18, pp. 263–74.
- Roberts, J. 1998, Sensitivity of elasticity estimates for OECD health care spending: analysis of a dynamic heterogenous data field, Paper prepared for the Seventh European Workshop of Econometrics and Health Economics, STAKES, Helsinki, Finland, 9–12 September.
- Robertson, I. and Richardson, J. 2000, 'Coronary angiography and coronary artery revascularisation rates in public and private hospital patients after acute myocardial infarction', *Medical Journal of Australia*, vol. 173, pp. 291–5.
- Rochtchina, E., Mukesh, B., Wang, J.J., McCarty, C., Taylor, H. and Mitchell, P. 2003, 'Projected prevalence of age-related cataract and cataract surgery in Australia for the years 2001 and 2021: pooled data from two population-based surveys', *Clinical and Experimental Ophthalmology*, vol. 31, pp. 233–6.
- Rose, E. 2004, 'Digital images cut travel time', *Herald Sun*, 15 September, p. 36.
- Rosenberg, L.E. 2002, 'Exceptional economic returns on investments in medical research', *Medical Journal of Australia*, vol. 177, no. 7, pp. 368–71.
- Royal Adelaide Hospital 2004, *RAH gets \$3 million da Vinci Robotic Surgical System thanks to the generosity of the Pickard Foundation*, Media release, 10 September.
- RS and RSA (Royal Society and Royal Academy of Engineering) 2004, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*, The Royal Society, London, <http://www.nanotec.org.uk/finalReport.htm> (accessed 7 March 2005).
- Sacks, F.M., Pfeffer, M.A., Moya, L.A. and Rouleau, J.L. 1996, 'The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels', *The New England Journal of Medicine*, vol. 335, no. 14, pp. 1001–9.
- Sakr, W.A., Haas, G.P., Cassin, B.F., Pontes, J.E. and Crissman, J.D. 1993, 'The frequency of carcinoma and intraepithelial neoplasia of the prostate in young male patients', *Journal of Urology*, vol. 150, no. 1, pp. 379–85.
- Sambamoorthi, U., Olfson, M., Walkup, J. and Crystal, S. 2003, 'Diffusion of new generation antidepressant treatment among elderly diagnosed with depression', *Medical Care*, vol. 41, no. 1, pp. 180–94.

-
- Sanders, J.M. 2002, 'Challenges, choices and Canada', *International Journal of Technology Assessment in Health Care*, vol. 18, no. 2, pp. 199–202.
- Sansom, L. 2004, 'The subsidy of pharmaceuticals in Australia: processes and challenges', *Australian Health Review*, vol. 28, no. 2, pp. 194–205.
- Santini, M. and Ricci, R. 2003, 'A trial fibrillation: the role of atrial defibrillation', *Journal of International Cardiac Electrophysiology*, vol. 9, pp. 229–33.
- SBU (Swedish Council on Technology Assessment in Health Care) 2005, *About SBU*, <http://www.sbu.se/www/index.asp> (accessed 28 June 2005).
- 2004, 'Drug eluting stents in coronary arteries', Sweden, <http://www.sbu.se/www/index.asp> (accessed 16 March 2005).
- Schurmann, D.J. and Smith, R.L. 2004, 'Osteoarthritis: current treatment and future prospects for surgical, medical and biologic intervention', *Clinical Orthopaedics and Related Research*, vol. 427, pp. s183–s189.
- Scott, A. 2005, Point of use implant data capture: the Canberra hospital, Presentation to the 7th Annual Health Congress, Sydney, 24 February.
- SCRGSP (Steering Committee for the Review of Government Service Provision) 2005, *Report on Government Services 2005*, Productivity Commission, Canberra.
- 2003, *Overcoming Indigenous Disadvantage: Key Indicators 2003*, Productivity Commission, Canberra.
- Seagrave, P. 2005, 'E-health standards work well' in 'You said IT — Letters to the Editor', *The Australian*, 26 July, p. 34.
- Seale, J.P., Gebiski, V.J. and Keech, A.C. 2004, 'Generalising the results of trials to clinical practice', *Medical Journal of Australia*, vol. 181, no. 10, pp. 559–60.
- Sears, J. 2005, 'High-speed skill online. Doctors have a new virtual bedside manner', *CSIRO Solve, A CSIRO Review of Scientific Innovations for Australian Industry*, Issue 2, February, CSIRO, Canberra, p. 10.
- Segal, L., Day, S.E., Chapman, A.B. and Osborne, R.H. 2004, 'Can we reduce the disease burden from osteoarthritis?', *Medical Journal of Australia*, vol. 180, no. 5, suppl., pp. s11–s17.
- Segal, L. and Richardson, J. 1994, *Efficiency in Resource Allocation*, National Centre for Health Program Evaluation, Working Paper no. 34, April.
- Senate Community Affairs Legislation Committee 2003, Examination of Budget Estimates 2002-03, Additional Information Received Health and Ageing Portfolio, Supplementary Budget Estimates 2002-03, 21 November 2002, Question: E02-060, outcome 8.

-
- Shactman, D., Altman, S.H., Eilat, E., Thorpe, K.E. and Doonan, M. 2003, 'The outlook for hospital spending', *Health Affairs*, vol. 22, no. 6, pp. 12–26.
- Shenfield, G., Le Couteur, D. and Rivory, L. 2002, 'Clinical pharmacology', *Medical Journal of Australia*, vol. 176, no. 1, p. 9.
- Simes, R.J. 2002, 'Clinical trials and "real-world" medicine', *Medical Journal of Australia*, vol. 177, no. 8, pp. 407–8.
- Simoens, S., Villeneuve, M. and Hurst, J. 2005, *Tackling Nurse Shortages in OECD Countries*, OECD Health Working Papers no. 19, Paris.
- Simpson, K. and Dunn, A. 2005, 'Now for research to create organs', *The Sunday Age*, 27 March, pp. 1–2.
- Skaer, T.L., Sclar, D.A., Robison, L.M., Galin, R.S., Legg, R.F. and Nemic, N.L. 1995, 'Economic evaluation of amitriptyline, desipramine, nortriptyline, and sertraline in the management of patients with depression', *Current Therapeutic Research*, vol. 56, no. 6, pp. 556–7.
- Skatssoon, J. 2005, 'Put paid to the puffer', *Sydney Morning Herald*, 24 February.
- 2004, 'Class of happiness', *Sydney Morning Herald*, 21 August, p. 12.
- Slevin, T.J., Donnelly, N., Clarkson, J.P., English, D.R. and Ward, J.E. 1999, 'Prostate cancer testing: behaviour, motivation and attitudes among Western Australian men', *Medical Journal of Australia*, vol. 171, no. 4, pp. 185–8.
- Smith, D.H. and Gravelle, H. 2000, *The Practice of Discounting Economic Evaluation of Health Care Interventions*, University of York Centre for Health Economics Technical Paper Series, October.
- Smith, D.P. and Armstrong, B.K. 1998, 'Prostate-specific antigen testing in Australia and association with prostate cancer incidence in New South Wales', *Medical Journal of Australia*, vol. 169, no. 1, pp. 17–20.
- Smith, I. 2001, 'Efficacy and safety of herceptin in women with metastatic breast cancer: results from pivotal clinical studies', *Anti-Cancer Drugs*, vol. 12, suppl. 4, pp. s3–s10.
- Smith, R. 2004, 'Healthy opportunities from small technologies', Healthy Opportunities from Small Technologies conference, 9–10 December 2004, Melbourne.
- Smith, S. 2001, The macro picture: medical innovation and growth in health care costs, HealthCare Financing Administration paper presented at The National Academies Board on Science, Technology and Economic Policy, 'Technological Innovation in a Changing Medical Marketplace', 14 June.
- Smith, W. 2005, 'Sweet cell of success', *The Australian*, 22 March, p. 11.

-
- Solomon, M.J. and McLeod, R.S. 1998, 'Surgery and the randomised controlled trial: past, present and future', *Medical Journal of Australia*, vol. 169, no. 7, pp. 380–3.
- Solomon, R. and Donnenfeld, E.D. 2003, 'Recent advances and future frontiers in treating age-related cataracts', *Journal of the American Medical Association*, vol. 290, no. 2, pp. 248–51.
- Souetre, E. Lozet, H. and Cimarosti, I. 1997, 'Predicting factors for absenteeism in patients with major depressive disorders', *European Journal of Epidemiology*, vol. 13, no. 1, pp. 87–93.
- South Eastern Sydney Area Health Service 2001, 'Information for GPs, Familial Breast Cancer', *Cancer Control Bulletin*, Issue 19, October/November.
- Stafford, A. 2005a, 'Alarm sounds on ads in doctors' software', *Australian Financial Review*, 29 January, p. 6.
- 2005b, 'Blood set to flow at health meeting', *Australian Financial Review*, 27 January, p. 3.
- 2005c, 'Hospitals splurge on equipment to lure doctors', *Australian Financial Review*, 15 July, p. 8.
- 2005d, 'System is headache for doctors', *Australian Financial Review*, 9 August, p. 8.
- Stebbing, J., Copson, E. and O'Reilly, S. 2000, 'Herceptin (trastuzumab) in advanced breast cancer', *Cancer Treatment Reviews*, vol. 26, pp. 287–90.
- Steel, M., Smyth, E., Vasen, H., Eccles, D., Evans, G., Moller, P., Hodgson, S., Stoppa-Lyonnet, D., Change-Claude, J., Caligo, M., Morrison, P. and Haites, N. 1999, 'Ethical, social and economic issues in familial breast cancer: a compilation of views from the EC Biomed II Demonstration project', *Disease Markers*, vol. 15, pp. 125–31.
- Steenland, K., Rodriguez, C., Mondul, A., Calle, E.E. and Thun, M. 2004, 'Prostate cancer incidence and survival in relation to education (United States)', *Cancer Causes and Control*, vol. 15, pp. 939–45.
- Steketee, M. 2005, 'Obscene bills of health', *The Australian*, 26 February, p. 32.
- Stevens, A. and Milne, R. 2004, 'Health technology assessment in England and Wales', *International Journal of Technology Assessment in Health Care*, vol. 20, no. 1, pp. 11–24.
- Stocks, N.P., Ryan, P., McElroy, H. and Allan, J. 2004, 'Statin prescribing in Australia: socioeconomic and sex differences', *Medical Journal of Australia*, vol. 180, no. 5, pp. 229–31.

-
- Sugar, A. 2000, 'Ophthalmic surgery', *Journal of American College of Surgeons*, vol. 190, no. 2, pp. 179–82.
- and Scherzer, R.M. 1999, 'Clinical course of phacoemulsification wound burns', *Journal of Cataract Refract Surgery*, vol. 25, pp. 688–92.
- Sweeny, K. 2002a, *Trends in the Use and Costs of Pharmaceuticals Under the Pharmaceutical Benefits Scheme*, Centre for Strategic Economic Studies, Victoria University, Working paper no. 5.
- 2002b, *Technology Trends in Drug Discovery and Development: Implications for the Development of the Pharmaceutical Industry in Australia*, Pharmaceutical Industry Project Equity, Sustainability and Industry Development Working Paper no. 3, Centre for Strategic Economic Studies, Victoria University of Technology, Melbourne.
- Tan, A.G., Wang, J.J., Rochtchina, E. and Jakobsen, K.B. and Mitchell, P. 2004, 'Increase in cataract surgery prevalence from 1992–1994 to 1997–2000: analysis of two population cross-sections', *Clinical Experimental Ophthalmology*, vol. 32, pp. 284–8.
- Taylor, H.R. 2000, 'Cataract: how much surgery do we have to do?', *British Journal of Ophthalmology*, vol. 84, pp. 1–2.
- 1997, *Eye Health in Aboriginal and Torres Strait Islander Communities*, The Report of a review commissioned by the Commonwealth Minister for Health and Family Services, the Hon. Dr. Michael Wooldridge, MP, <http://iris.medoph.unimelb.edu.au/new/hrtreview/reviewmain.html> (accessed 30 April 2005).
- Taylor, H., West, S., Rosenthal, F., Munoz, B., Newland, H., Abbey, H. and Emmett, E. 1988, Effect of ultraviolet radiation on cataract formation, *New England Journal of Medicine*, vol. 319, no. 22, pp. 1429–33.
- Taylor, R., Stubbs, J., Langlands, A. and Boyages, J. 1999, 'Predictors of mastectomy for women with breast cancer in the greater western region of Sydney', *The Breast Journal*, vol. 5, no. 2, pp. 116–21.
- TCSDD (Tufts Center for the Study of Drug Development) 2005, *Outlook 2005*, Tufts Center for the Study of Drug Development, Boston.
- Teachers' Union Health 2004, Rate rise Q&A's, Queensland, Australia, <http://www.tuh.com.au/content/?id=594> (accessed 13 January 2005).
- TECH (Technological Change in Health Care) Research Network 2001, 'Technological change around the world: evidence from heart attack care', *Health Affairs*, vol. 20, no. 3, May/June, pp. 25–42.

-
- Tengs, T. and Berry, D. 2000, 'The cost effectiveness of testing for the BRCA1 and BRCA2 breast-ovarian cancer susceptibility genes', *Disease Management and Clinical Outcomes*, vol. 1, Winter, pp. 15–24.
- Tengs, T.O. and Wallace, A.W. 2000, 'One thousand health-related quality-of-life estimates', *Medical Care*, vol. 38, no. 6, pp. 583–637.
- Tennent, T.D. and Goddard, N.J. 2000, 'Current attitudes to total hip replacement in the younger patient', *Annals of the Royal College of Surgeons England*, vol. 82, no. 1, pp. 33–8.
- Teplensky, J.D., Pauly, M.V., Kimberly, J.R., Hillman, A.L. and Schwartz, J.S. 1995, 'Hospital adoption of medical technology: an empirical test of alternative models', *Health Services Research*, vol. 30, no. 3, August, pp. 437–65.
- Terada, M. 2002, 'Government science and health policy strategies in Japan', in *Biotechnology and Healthy Ageing, Policy Implications of New Research*, OECD, Paris, pp. 143–5.
- TGA (Therapeutic Goods Administration) 2005, Australian Drug Evaluation Committee (ADEC), <http://www.tga.gov.au/docs/html/adece/adece.htm> (accessed 28 March 2005).
- 2004a, *Access to Unapproved Therapeutic Goods via the Special Access Scheme*, DoHA, Canberra.
- 2004b, *Potential Safety Risks with Celebrex*, Media release, 20 December, Canberra.
- 2004c, *Australian Regulatory Guidelines for Prescription Medicines*, DoHA, Canberra.
- 2003, *Australian Medical Devices Guidelines: An Overview of the New Medical Services Regulatory System*, guidance document no. 1, version 1.6, DoHA, Canberra.
- The Age* 2005, 'Dangers in using dead men's sperm', Editorial, 28 April, p. 24.
- The Canberra Times* 2005, 'The artificiality of debating serious Medicare issues', Editorial, 7 May, p. B11.
- The Cancer Council Australia 2005, *Prostate Cancer Position Statement*, May, http://www.cancer.org.au/documents/Pos_State_Prostate_cancer_screening_MAY2005.pdf (accessed 11 August 2005).
- The Economist*, 'The no-computer virus', Special Report: IT in the health-care industry, 30 April, pp. 55–7.
- The Lancet* 2004, 'OTC statins: a bad decision for public health', vol. 363, no. 9422, 22 May, p. 1659.

-
- Thompson, A. and Temple, N.J. 2004, 'The case for statins: has it really been made?', *Journal of the Royal Society of Medicine*, vol. 97, October, pp. 461–4.
- Thompson, I.M. and Optemberg, S.A. 1995, 'An overview cost–utility analysis of prostate cancer screening', *Oncology*, vol. 9, no. 11, pp. 141–5.
- Thorpe, K.E., Curtis, C.S., Howard, D.H. and Joski, P. 2005, 'The rising prevalence of disease: effects on private health insurance spending', *Health Affairs*, <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w5.317> (accessed 3 August 2005).
- Thorpe, K.E., Florence, C.S. and Joski, P. 2004, 'Which medical conditions account for the rise in health care spending', *Health Affairs*, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.437v1> (accessed 4 April 2005), pp. W4-437-W4-445.
- Thurect, L., Harding, A. and Walker, A. 2004, Equity and hospitals: do usage and treatment costs vary with socioeconomic status and locality?, NATSEM conference paper no. CP2004_10, September, <http://www.natsem.canberra.edu.au/publication.jsp?titleID=CP0410> (accessed 27 August 2005).
- Tobert, J. 2003, 'Lovastatin and beyond: the history of the HMG-COA reductase inhibitors', *Nature Reviews Drug Discovery*, vol. 2, no. 7, pp. 517–26.
- Tracy, R. 2003, 'Emerging relationships of inflammation, cardiovascular disease and chronic diseases of ageing', *International Journal of Obesity*, vol. 27, pp. s29–s34.
- Turini, M., Redaelli, A., Gramegna, P. and Radice, D. 2003, 'Quality of life and economic considerations in the management of prostate cancer', *Pharmacoeconomics*, vol. 21, no. 8, pp. 527–41.
- UK Department of Health 2004, *Heart Drug Available without Prescription*, Reference no. 2004/0186, 12 May, http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4082004&chk=z/YiI3 (accessed 8 February 2005).
- UK DH (Department of Health) 2004, *Policy Appraisal and Health: A Guide from the Department of Health*, revised draft, November, <http://www.dh.gov.uk/assetRoot/04/09/54/14/04095414.pdf> (accessed 12 July 2005).
- UK Treasury (Great Britain H.M. Treasury) 2003, *The Green Book Appraisal and Evaluation in Central Government*, Treasury Advice: TSO, London, January, <http://greenbook.treasury.gov.uk/> (accessed 12 July 2005).
- University of British Columbia 2003, 'Do statins have a role in primary prevention?', *Therapeutics Letter*, no. 48, April–June, <http://www.ti.ubc.ca/pages/letter48.htm> (accessed 29 August 2005).

-
- University HealthSystem Consortium 2005, *Clinical Technology Advisory*, http://www.uhc.edu/results_list.asp?folder=WEB/About_UHC/CP/ (accessed 27 July 2005).
- University of Melbourne 2005, *Solving the Hospital Crisis with Models*, Media release, Melbourne, 3 June.
- Urological Society of Australasia 2005a, Brachytherapy for Prostate Cancer, <http://www.urosoc.org.au/info/screeningprostate.html> (accessed 8 June 2005)
- 2005b, Screening for Prostate Cancer, <http://www.urosoc.org.au/info/screeningprostate.html> (accessed 8 June 2005).
- US Food and Drug Administration Centre for Drug Evaluation and Research 1999, *From Test Tube to Patient: Improving Health Through Human Drugs*, Special Report, September.
- US Preventive Services Task Force 1989, *Guide to Clinical Preventive Services: An Assessment of the Effectiveness of 169 Interventions*, Williams and Williams, Baltimore.
- Van Doorslaer, E. and Masseria, C. 2004, 'Income-related inequality in the use of medical care in 21 OECD countries', in OECD, *Towards High-Performing Health Systems*, Policy Studies, OECD, Paris.
- Vastag, B. 2004, 'Knee replacement underused, says panel: useful option when nonsurgical therapies fail', *Journal of the American Medical Association*, Chicago, vol. 291, no. 4, pp. 413–15.
- VDHS (Victorian Department of Human Services) 2004, Burden of Disease — DALY (YLD & YLL) Worksheets, <http://www.health.vic.gov.au/healthstatus/bod/daly.htm> (accessed 16 February 2005).
- 1999, *Victorian Burden of Disease Study: Morbidity, Epidemiology Section, Health Intelligence and Disease Control*, Public Health and Development Division, Victorian Government Department of Human Services, Melbourne, <http://www.health.vic.gov.au/healthstatus/downloads/morbidity.pdf> (accessed 16 February 2005).
- VDUAC (Victorian Drug Usage Advisory Committee) 2004, *Annual Report 2003-04*, Melbourne.
- VicTag (Victorian Therapeutics Advisory Group) 2004, *Hospital Price and Resources Allocation Review: Good Practice Model for Controlling Pharmaceutical Costs in Hospitals*, Final Report prepared for the Department of Human Services, Melbourne.

-
- Victora, C., Vaughan, J., Barros, F., Silva, A. and Tomasi, E. 2000, 'Explaining trends in inequities: evidence from Brazilian child health studies', *The Lancet*, vol. 356, pp. 1093–8.
- Victorian Family Cancer Genetics Service, http://www.cancervic.org.au/cancer1/professionals/family_cancer/risk.htm#familyHistory (accessed 28 June 2005).
- Victorian Government 2005, Better Health Channel, [http://www.betterhealth.vic.gov.au/bhcv2/bhcpdf.nsf/ByPDF/Gene_therapy/\\$File/Gene_therapy.pdf](http://www.betterhealth.vic.gov.au/bhcv2/bhcpdf.nsf/ByPDF/Gene_therapy/$File/Gene_therapy.pdf) (accessed 23 February 2005).
- Viney, R. and Savage, E. 2003, *Modelling preferences for health care*, Centre for Health Economics Research and Evaluation, Faculty of Business, University of Technology, Sydney, Paper presented to the Labour Econometrics Workshop Melbourne, August.
- Viscusi, W.K. 1996, 'Discounting health effects for medical decisions', in Sloan, F.A. (ed.), *Valuing Health Care Costs, Benefits and Effectiveness of Pharmaceuticals and other Medical Technologies*, Cambridge University Press, Cambridge, pp. 125–47.
- 1993, 'The value of risks to life and health', *Journal of Economic Literature*, vol. XXXI, December, pp. 1912–46.
- and Aldy, J.E. 2003, 'The value of a statistical life: a critical review of market estimates throughout the world', *Journal of Risk and Uncertainty*, vol. 27, no. 1, pp. 5–76.
- Vision 2020 Australia 2004, *The Right to Sight: Australia's plan for eliminating avoidable blindness and reducing the impact of vision loss*, Submission to the Australian Health Ministers' Conference prepared by Vision 2020 Australia on behalf of the Australian Eye Health sector, July, http://www.v2020australia.org/docs/National_Vision_Plan.pdf (accessed 10 January 2005).
- Wahlqvist, P. 2001, 'Symptoms of gastroesophageal reflux disease, perceived productivity, and health-related quality of life', *The American Journal of Gastroenterology*, vol. 96, no. 8, suppl., pp. s57–s61.
- Wainberg, S. and Husted, J. 2004, 'Utilisation of screening and preventive surgery among unaffected carriers of a BRCA1 or BRCA2 gene mutation', *Cancer Epidemiology Biomarkers and Prevention*, vol. 13, no. 12, pp. 1989–95.
- Wald, N.J. and Law, M.R. 2003, 'A strategy to reduce cardiovascular disease by more than 80 per cent', *British Medical Journal*, vol. 326, pp. 1419–25.
- Walker, A. 2004, Impact of health on the ability of older Australians to stay in the workforce — with possible contributions to economic sustainability, Online conference paper CP0412, December, <http://www.natsem.canberra>.

-
- edu.au/publications/papers/cps/cp04/2004_012/Walker_Newcastle%20Conf%20ppr_final.pdf (accessed 11 March 2005).
- 2001, Health inequalities and income distribution Australia 1977 to 1995, Paper prepared for the 7th annual national health outcomes conference, 27–8 June, Canberra, http://www.natsem.canberra.edu.au/publications/papers/cps/cp01/2001_002/cp2001_002.pdf (accessed 5 April 2005).
- Wang, A.J. 1998, 'Key concepts in evaluating outcomes of ATP funding of medical technologies', *Journal of Technology Transfer*, vol. 23, no. 2, pp. 61–5.
- Wanless, D. 2001, *Securing our Future Health: Taking a Long-Term View*, Interim Report, HM Treasury, London.
- Wanner, C., Krane, V., März, W., Olszewski, M., Mann, J.F.E., Ruf, G. and Ritz, E. 2005, 'Atorvastatin in patients with type 2 diabetes mellitus undergoing hemodialysis', *New England Journal of Medicine*, vol. 353, no. 3, pp. 238–48.
- Ware, J.E. 2002, *SF-36 Health Survey Update*, <http://www.sf-36.org/tools/sf36.shtml> (accessed 2 March 2005).
- Ware, R.E., Francis, H.W. and Read, K.E. 2004, 'The Australian Government's review of positron emission tomography: evidence-based policy-making in action', *Medical Journal of Australia*, vol. 180, no. 12, pp. 627–32.
- Weedon, D. 1999, 'Health technology assessment in Australia', *Medical Journal of Australia*, vol. 171, no. 10, pp. 551–2.
- Weil, R.J. 2004, *The Future of Surgical Research*, Public Library of Science Medicines, vol. 1, no. 1, <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0010013> (accessed 21 March 2005).
- Weinstein, M. 2005, *Spending health care dollars wisely: can cost-effectiveness analysis help?*, Sixteenth annual Herbert Lourie memorial lecture on health policy, Policy Brief no. 30/2005, Syracuse University, NY.
- Weissleder, R. and Mahmood, U. 2001, 'Molecular imaging', *Radiology*, no. 219, pp. 316–33.
- Weksler, M.E. 2002, 'Rapporteur's scientific summary', in *Biotechnology and Healthy Ageing, Policy Implications of New Research*, OECD, Paris, pp. 19–22.
- Wells, V.M., Hearn, T.C., McCaul, K.A., Anderton, S.M., Wigg, A.E.R. and Graves, S.E. 2002, 'Changing incidence of primary total hip arthroplasty and total knee arthroplasty for primary osteoarthritis', *The Journal of Arthroplasty*, vol. 17, no. 3, pp. 267–73.
- WHO (World Health Organization) 2002, *Genomics and World Health*, Report of the Advisory Committee on Health Research, World Health Organisation, Geneva.

-
- 2000, *Disability Adjusted Life Years (DALY)*, http://www3.who.int/whosis/burden/gbd2000docs/DALY_about.doc (accessed 17 February 2005).
- Whynes, D.K., Neilson, A.R., Walker, A.R. and Hardcastle, J.D. 1998, 'Faecal occult blood screening for colorectal cancer: is it cost-effective?', *Health Economics*, vol. 7, no. 1, pp. 21–9.
- Wilde, A. 2004, 'Shrinking distances', *Sydney Morning Herald*, 9 September, p. 7.
- Wise, P. 1999, 'Efficacy and justice: the importance of medical research and tertiary care to social disparities in infant mortality', *Journal of Perinatology*, vol. 19, no. 6, pp. s24–s27.
- Wong, K. 2004, 'Hunt on for nuke dump site', *Australian Financial Review*, 16 July, p. 21.
- Woodhead, B. 2005a, 'Complaints made about NSW Health', *Australian Financial Review*, 27 April, p. 62.
- 2005b, 'Hospital communications struggle for funds', *Australian Financial Review*, 5 April, p. 36.
- 2005c, 'On a mission for better health care', *Australian Financial Review*, 5 April, p. 36.
- 2005d, 'Qld goes slow on health data', *Australian Financial Review*, 26 April, p. 40.
- 2005e, 'Qld Health seeks a second opinion', *Australian Financial Review*, 7 March, p. 13.
- 2005f, 'Qld Health to test troubled software', *Australian Financial Review*, 1 April, p. 74.
- 2005g, 'Queensland Health cures systems' woes', *Australian Financial Review*, 16 March, p. 51.
- 2004a, 'Canberra-made clinical tool gets world attention', *Australian Financial Review*, 21 September, p. 34.
- 2004b, 'Health system gets shot in the arm', *Australian Financial Review*, 26 October, p. 33.
- 2004c, 'Help closer at hand at wireless hospital', *Australian Financial Review*, 15 October, p. 68.
- 2004d, 'Queensland Health faces delays, cost blowouts', *Australian Financial Review*, 14 December, p. 25.
- 2004e, 'NSW Health seeks federal funds', *Australian Financial Review*, 16 December, p. 35.

-
- Yi, Q., Flanagan, S. and McCarty, D. 2001, 'Trends in health service delivery for cataract surgery at a large Australian ophthalmic hospital', *Journal of Clinical and Experimental Ophthalmology*, vol. 29, pp. 291–5.
- Yong, P., Milner, P., Payne, J., Lewis, P. and Jennison, C. 2004, 'Inequalities in access to knee joint replacements for people in need', *Annals of the Rheumatic Diseases*, vol. 63, no. 1, pp. 1483–9.
- Younan, C., Mitchell, P., Cumming, R. and Rochtchina, E. 2002, 'Socioeconomic status and incident cataract surgery: the Blue Mountains Eye Study', *Clinical and Experimental Ophthalmology*, vol. 30, pp. 163–7.
- Yusuf, S. 2002, 'Two decades of progress in preventing vascular disease', *The Lancet*, vol. 360, no. 9326, 6 July, pp. 2–3.
- Zhao, Y., Guthridge, S., Magnus, A. and Vos, T. 2004, 'Burden of disease and injury in Aboriginal and non-Aboriginal populations in the Northern Territory', *Medical Journal of Australia*, vol. 180, no. 10, pp. 498–502.
- Zubrick, S., Lawrence, D., Silburn, S., Blair, E., Milroy, H., Wilkes, T., Eades, S., D'Antoine, H., Read, A., Ishiguchi, P. and Doyle, S. 2004, *The Western Australian Aboriginal Child Health Survey: the Health of Aboriginal Children and Young People*, Telethon Institute for Child Health Research, Perth.