Productivity Commission Progress Report

Impacts of Medical Technology in Australia

Submission from the Australian and New Zealand Society of Blood Transfusion

June 2005

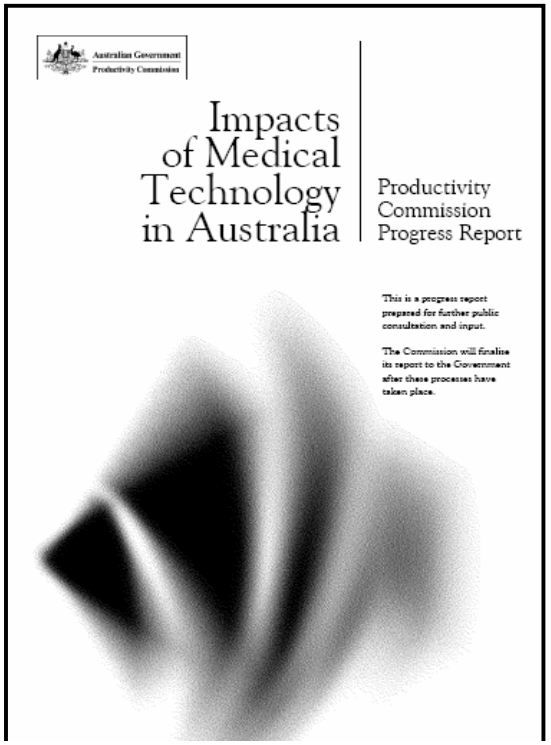
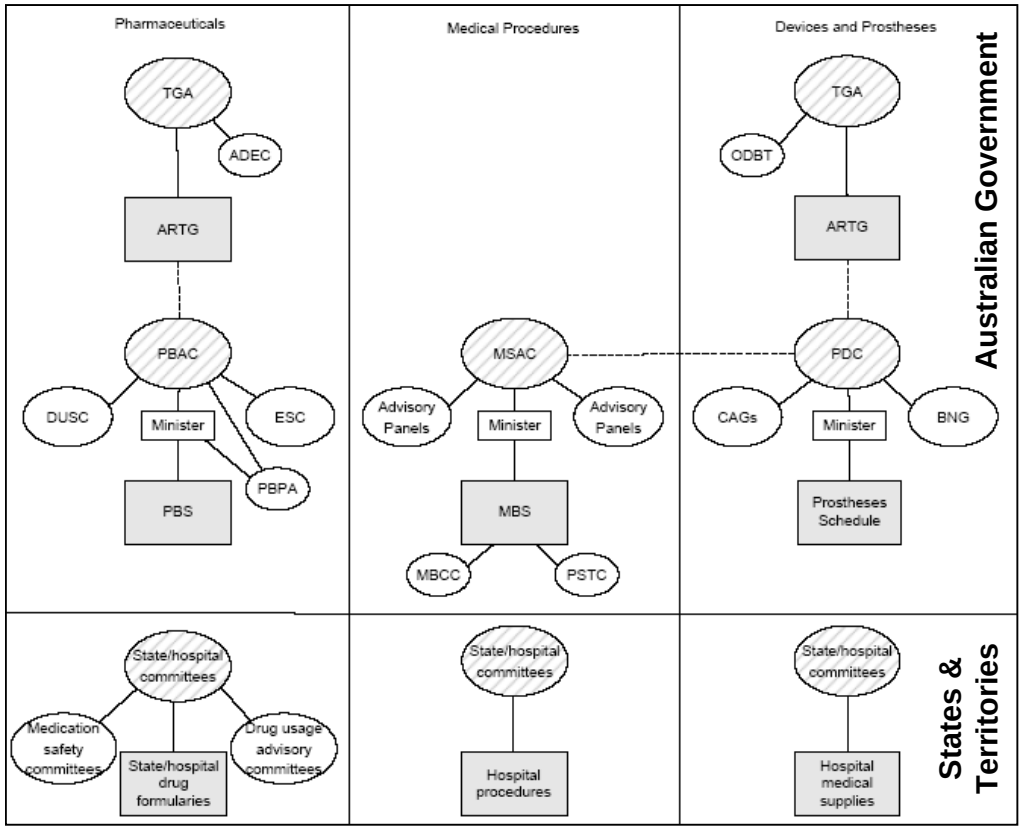
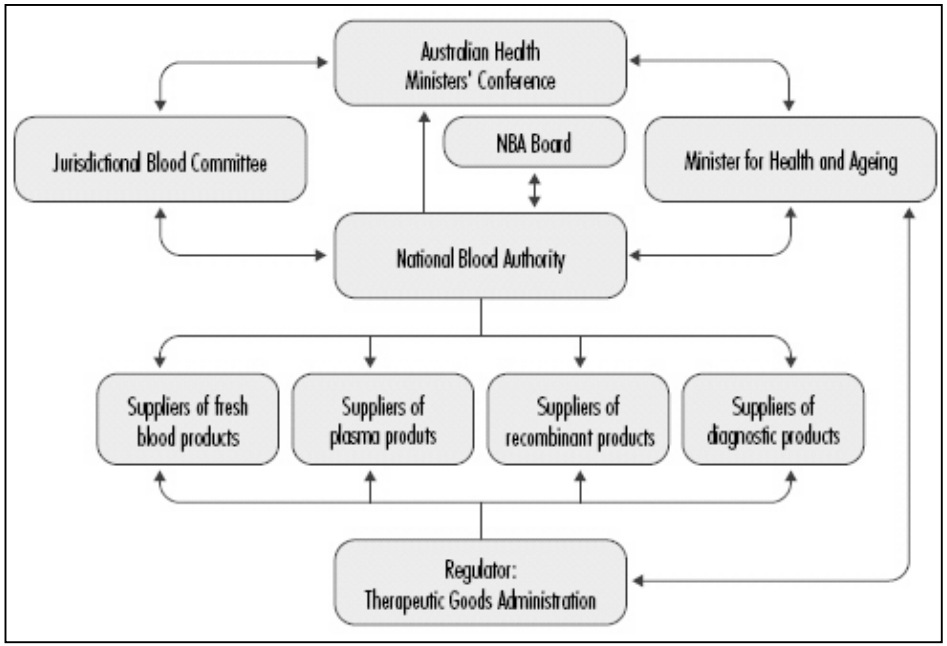


Figure 9 Some of the HTA agencies and committees in Australia with the inclusion of transfusion medicine





Preamble

There no is doubt that allogeneic blood transfusion has been one of the most significant medical advances during the 20th century. Massively bleeding patients survive, major surgical advances have been possible, haemophiliacs live longer and better lives and marrow failure from disease or myelosuppressive therapy can be survived. So what's the problem? Increasingly the view of many clinicians is that transfusion medicine has excessively focused on the blood component supply side of the system rather than from the demand/patient perspective. The blood supply agency naturally wants to "conserve" a precious and altruistically donated resource that should be "managed" appropriately. On the other hand the clinician wants to conserve and manage a patient's blood appropriately. The later should be the accepted "true" meaning of "blood conservation" and "blood management" The clinical focus should be on "what is best for the patient?" not, "what is best for the blood supply?" This is not to deny the importance of the multiple issues and challenges facing the provision of an adequate and safe blood supply but the primary focus must be on the needs of patients, with the supply chain appropriately responding to clinical needs.

Allogeneic blood transfusion is supportive therapy and may be administered to control the effects of, or to prevent problems, associated with a haemopoietic deficiency. Allogeneic transfusion, particularly in the peri-operative setting, should not be regarded as the first line of therapy for patients with haemopoietic defects. For most patients it is possible to minimise requirements for allogeneic blood components, or to correct or manage the effects of deficiencies in the haematopoietic system, without transfusing allogeneic blood components. Clearly, if allogeneic blood can be avoided the potential hazards need not be considered. For reasons that are not immediately apparent the transfusion of allogeneic blood has been regarded as the "default" decision when there is doubt about the possible benefits of allogeneic blood transfusion.

The benefits from transfusion have been assumed in most clinical circumstance and it is a sobering thought to consider that when there is no evidence to support the benefit of transfusion a patient is unnecessarily exposed to potentially major morbidity or even mortality. The decision-making process for blood component therapy can be difficult and much debate continues in relation to the indications for the use of various allogeneic blood components. However, there are good common sense and scientific reasons to adopt a non-transfusion default position when there is no evidence for potential benefit.

Improvements in assessment of cost effectiveness, equity of access and clinical governance will only make progress if a paradigm shift to patient-focused blood management occurs. What is medically appropriate for a patient should be based on sound evidence, the questions of affordability, cost effectiveness, equity etc, clearly impact on the availability and delivery of appropriate therapy, but do not alter what is scientifically best for the patient.

Patients think blood transfusion is special and beneficial, but have difficulty accepting small risks over which they have no control.

Blood Donors believe their contribution of blood is a gift to the community that will be used appropriately and safely to the benefit of those in need on an equitable non profit basis.

Clinicians think blood is ordinary, take blood transfusion for granted, benefit is assumed and risks regarded as minimal.

Governments view blood as a commodity and transfusion medicine as an expensive support service which should be regulated and funded in a "McDonaldised" manner.

These potentially disparate views on the same issue should be of concern to all health professions. With the increased range of pharmacological agents, surgical and anaesthetic techniques and development of recombinant blood components the armamentarium for avoiding or minimising allogeneic blood transfusion is substantial. What is now needed is a broad clinical commitment to blood conservation techniques in conjunction with more realistic costing and accountability for allogeneic blood products, as well as recognition that allogeneic transfusion remains a potentially hazardous procedure for the patient and should only be undertaken if there is likely to be benefit and improvement in clinical outcomes. Allogeneic donated blood is a scarce and expensive resource given in trust that it will be managed appropriately. The main hazards of allogeneic transfusion are now at the clinical practice end of the blood chain, not at the supply end. Blood management is logical, evidence is accumulating that the benefits of transfusion have been overrated, there are limitations of blood supply as well as medicolegal pressures. Compound on this patients want greater input and choice in decisions about their clinical management.

Responses to the Productivity Commission preliminary report

The preliminary report does not directly address transfusion, a key component of health care and expenditure. Transfusion medicine spreads across all specialties of medicine and is very depended on a wide range of technologies. The Society would like to recommend that transfusion medicine has a significant position in the final report. In order to make it easier for those preparing the report the Society's comments have been included in a table aligning them with the relevant preliminary findings of the commission.

Chapter & Title	Preliminary Finding	Transfusion Medicine & Blood Management
Chapter 2 **The market for medical technology**	**2** Key drivers of growing demand for advances in medical technology are income growth, community expectations, population ageing and disease prevalence and limits on consumer price signals, combined with the desire of and incentives facing medical practitioners to provide the best-available treatments. The use of medical technology will reflect 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 the availability of skilled labour.	➢ Donated blood components have never had a price signal to the consumer or the clinician. The only costs apparent to the private consumer are the pharmaceuticals, laboratory compatibility test and the clinician's administration charges. ➢ Blood transfusion is a support service in which the donated blood is only one component and probably the least costly component in the total transfusion process. ➢ Blood transfusion has never been accurately costed from the bottom up with an activity-based model. Each part of the process is costed separately and in many cases funded from different sources.
Chapter 3 **Aggregate impact of medical technology on expenditure**	**3** The Commission's modelling provides support for the proposition that medical technology has been a major driver of the growth in real healthcare expenditure over the past ten years. The mid-range estimate implies that technology has contributed around one-third of the growth in healthcare spending, though estimates range widely depending on the assumed income elasticity. Other important contributors to the increase in health expenditure over the period	➢ There has clearly been an increase in the expenditure on blood components, both donor sourced and recombinant. In particular there has been a substantial increase in demand for intravenous immunoglobulin. ➢ Expenditure on blood components should be looked at in the context of the clinical problem. Unfortunately, blood transfusion is the default therapeutic decision when transfusion may not be indicated or there are better and safer alternatives. Blood is perceived as free, there is fragmentation of

	include population and income growth, and to a lesser extent the limited past ageing of the population.	funding sources, poor knowledge at the workface about transfusion and alternatives and most cost effectiveness studies are invalid. ➢ There is an urgent need for patient-focused blood management within clinical practice and funding addressing the clinical problem, considering various management options, of which blood transfusion may be one and should only be used when safer and more effective alternatives have been considered.
Chapter 4 **Individual technology expenditure impacts**	**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, the increase in expenditure has been fuelled in part by increasingly expensive technologies such as prostheses. ➢ 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 have led to increased separations for some conditions, but have reduced the length of hospital stays.	➢ Increasingly there are recombinant blood components appearing on the market that are in some cases safer and more effective alternatives to donor sourced products. In some cases there is no donor equivalent available. ➢ Blood management alluded to in 3 above is proving to be effective in minimising blood transfusion, improving clinical outcomes and reducing ICU admissions and ICU and Hospital length of stay. ➢ Appropriate blood management should be practiced and costed as an integral part of any other modern technological intervention. Many advances in modern medicine have depended on blood transfusion for their development. ➢ Appropriate blood management can not only avoid or minimise the use of blood components, but can make procedures outpatient based, safer, and improve clinical outcomes

	➢ **4.2** Most major medical technological breakthroughs of the past decade have increased net health expenditure: ▪ For some, the 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 been accompanied by significant increases in the volume of treatment. ➢ **4.3** The division of funding responsibilities in the health sector influences expenditure on new technologies: ▪ The technology choices of individual agencies and institutions are often constrained by budget caps and, hence, they have little incentive to take into account impacts of their choices on their own future spending or on other parts of the health system. ▪ This creates a bias toward technologies which produce short-term cost savings in particular parts of the health system,	➢ In relation to blood components it is true to say that breakthroughs have resulted in increased costs on the supply side. Without appropriate activity and clinical problem based cost-effectiveness studies it has not been possible to identify the ultimate cost benefits and offsets. ➢ The blood supply is administered Nationally via the JBC and NBA ➢ The blood demand side is practiced in public and private hospitals ➢ The costs for various components of the blood demand and supply side for inpatients are fragmented as follows: **Supply** ▪ National (NBA) via the JBC driven State & Territory clinical supply plans

	possibly at the expense of more cost effective, but higher cost, technologies. ➢ **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, have increased spending on medical technologies by inducing faster technological diffusion and higher prices in the private sector. Diffusion in the private sector appears to place pressure on public hospitals to adopt the technology.	▪ Pharmaceutical industry for non NBA funded recombinant products **Demand** ▪ Public Hospitals – State transfusion expenditure is absorbed in numerous different hospital-based cost centres. Except for laboratory costs there are rarely specific transfusion administration cost centres at a patient/ward level. The administration, monitoring and adverse event management is probably the most costly component of the whole transfusion process. ▪ Private Hospitals • Health funds for hospital services • MBS for medical and pathology (Schedule) • Patient out-of-pocket ➢ As in 4.3 there is fragmentation of costs and currently no incentives for cost savings or the use of safer, better and cost-effective alternatives. Blood is perceived as free. As far as the Society is aware, no State or Territory has developed or proposed an effective way of addressing this issue. Considering that 30-40% of donor red cells are now administered in the private sector there needs to be an effective transfer of costs. At present the State and Territories are including the private sector in their clinical supply plans, but will probably be transferring the blood components "free" to the private health care sector.
Chapter 5 **Benefits of**	➢ **5.1** Although it is not possible to quantify and attribute benefits in overall terms, the available evidence suggests that specific advances in	➢ Interesting there is minimal evidence that the transfusion of red cells and possibly platelets have lead to improved outcomes in several clinical settings. Indeed evidence suggests that in many of the clinical

advances in medical technology	medical technology have delivered 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 living standards. ➢ **5.2** There is Australian and international evidence that those in more disadvantaged groups — lower income groups, those residing in rural and remote areas, Indigenous populations — are less likely to receive some types of services, encompassing both old and new technological interventions. Unequal access may be accentuated, at least initially, as new higher cost technologies are introduced.	circumstances red cell concentrates are used (ie surgery, ICU, critical bleeding, oncology) that many transfusions are inappropriate and may be responsible more problems than benefit. It is this evidence that is leading to a broad re-analysis of transfusion practices and a focus more on the clinical problem and transfusion alternatives rather than on the donor sourced allogeneic blood transfusion. ➢ Equity is an issue for transfusion medicine and this was one of the reasons for establishing a national structure (NBA/JBC) for the supply and safety of blood components. For several reasons many of the benefits in relation to equity have not been realised for several reasons: ▪ The clinical supply plans are State/Territory driven via JBC to NBA and national consensus is difficult to achieve at a JBC level. ▪ The State & Territory based blood services have restructured into the National Australian Red Cross Blood Service (ARCBS). This transformation has been a success story considering that blood banks in Australia had their origins in the State/Territory NGO sector (ie Red Cross) increasingly funded by State/Territory and Federal Government. There have been financial, governance, volunteerism and information technology issues that have presented ARCBS with enormous challenges. ▪ As a result of logistic, regulatory and financial constraints ARCBS has the same problems of equitable delivery of services as does the health sector in general. The supply of blood components should be viewed as an integrated part health

		delivery and not as a "pharmaceutical company". ARCBS's raw material is altruistically donated by members of the community and they expect it to be safely delivered to those in need, on an equitable basis. The "shareholders" in ARCBS are the Australian community and the organisation depends on economists and funders understanding that sustainability of the blood supply depends on social capital and understanding of the common good. These concepts have a value to the community that is above economic rationalism.
Chapter 6 **Cost effectiveness of advances in medical technology**	➢ **6.1** Cost effectiveness analysis is a useful technique for comparing technologies in a health technology assessment context. However, it is not possible to estimate the net impact of advances in medical technologies on the overall cost effectiveness of healthcare delivery since: ▪ overall benefits cannot be measured accurately or appropriately attributed; ▪ not all have been assessed for cost effectiveness; and ▪ those that have been assessed can reveal a wide variation in cost effectiveness.	➢ Cost effectiveness analysis has been lacking in transfusion medicine to the point that obviously illogical and questionable decisions have been made across the health sector. The focus of government has been exclusively on the safety and cost of the blood supply. Funding decisions have been made in the blood supply sector that cannot be justified on any economic grounds and would not even receive consideration if proposed in relation to any other health interventions. ➢ Attention to the demand side is essential with: ▪ Viewing transfusion medicine as an integrated supply-demand cooperative endeavour, integrated as part of the health system ▪ Clinical problem-based analysis ▪ Activity based costing ▪ Workface accountability for cost of supply ▪ Consideration of alternatives with appropriate cost-benefit analysis

Chapter 7 **Health technology assessment: Pharmaceuticals**	➢ **7.1** Whilst health technology assessment of pharmaceuticals is well-developed in Australia, some gaps in coverage remain: ▪ Existing horizon scanning units in Australia do not cover new and emerging pharmaceuticals (including drugs, vaccines and blood products). ▪ The PBAC does not assess all medicines used in hospital settings for clinical and cost effectiveness. This appears to have led to some duplication of HTA effort across and possibly within States. ▪ Once pharmaceuticals are listed on the PBS, there appears to be no systematic process for re-assessing their clinical and cost effectiveness by the PBAC.	➢ Currently transfusion medicine in Australia does not have an effective mechanism for integrating knowledge, education, opinion, research, horizon scanning and community involvement. It had been hoped that the new NBA/JBC structure would achieve this, however current experience indicates this is not the case. ➢ The top down "silo structure" for regulating and managing the blood sector is resulting in many important quality and safety issues stalling. Australia is falling behind acceptable international standards in important areas such as pre-storage leucodepletion of blood products, bacterial testing, haemovigilance and clinical practice guidelines. ➢ The future of transfusion medicine must been seen as part of a bigger picture. Donated allogeneic blood is only one aspect of managing a patient's blood. Integrated patient blood management programs involve: ▪ Clinical and diagnostic technologies to assist clinical decision making ▪ Pharmaceuticals • To minimise blood loss • Recombinant blood components (eg for bleeding disorders) • Blood substitutes (eg Haemoglobin based oxygen carriers) ▪ Anaesthetic/Surgical techniques & technology • To minimise blood loss

	➢ **7.2** There appear to be several areas in which pharmaceutical assessment processes potentially could be made more efficient and/or consistent with principles of good regulatory design: ▪ Unlike some overseas health technology assessment processes, the PBS listing process currently provides little opportunity for consultation with patient groups or the general public. ▪ The level of information disclosure by the TGA and PBAC regarding drug evaluations has been generally poor compared with other regulatory processes in Australia. Improved disclosure by the PBAC is expected to result from new arrangements under the Australia-United States Free Trade Agreement. ▪ A stated intent of restrictions on PBS listed items is to improve cost	• Perioperative autologous blood preparation and salvage techniques • Haemostatic "glues" ➢ Currently, the transfusion medicine sector does not have an effective integrated process for assessing and regulating the supply and demand side. Most decisions are made in "microenvironments" in which there is a lack of awareness of knowledge of the whole transfusion process. Most decisions are made on what is thought to be a rational economic basis. However in most circumstances decisions are made out of context, without valid cost effectiveness data and result in microeconomic decisions that are not aligned or, in many case incompatible, with the macroeconomics. ➢ There are aspects of the pharmaceutical assessment process that would offer benefits to the current NBA/JBC structure. This begs the question, why, when the supply of blood products was restructured, wasn't it included under the umbrella of PBS or alternatively have a similar structure? ➢ Many of the blood management aspects of patient's care fall under the pharmaceutical umbrella. ➢ Similar situation in transfusion medicine

	effectiveness based on clinical grounds. However, as the deliberations of the PBAC are not public, it is difficult to determine whether it has imposed restrictions on certain drugs for fiscal reasons. ▪ 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. ▪ 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 PBAC appears to give little or no weight to indirect benefits of medicines, such as hospital cost savings and gains in productive capacity. In part, this reflects unresolved issues in measuring benefits.	➢ This is so true of the current NBA/JBC structure ➢ Also relevant to transfusion medicine ➢ Also relevant to transfusion medicine

		➢ This is so true of the current economic model of transfusion medicine with top down control and lack of clinical activity-based costing
Chapter 8 **Health technology assessment procedures, devices and ICT**	➢ **8.1** Assessment of medical procedures and devices is less developed than for pharmaceuticals, with more substantial gaps in coverage: ➢ Because of the often incremental nature of past technological changes, some new technologies deemed to fit under existing MBS codes may not have been assessed. ➢ Existing MBS procedures are not subject to systematic re-assessment for clinical or cost effectiveness. While MSAC can undertake such re-assessments, its ability to do so is limited by its resources and the type of references its receives. ➢ 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.	➢ This is a problem area for the manufacturers of various transfusion related technology. There are a range of technologies used in transfusion medicine on both the supply and demand side. There are several near-patient technologies for blood conservation. It has been a constant source of frustration for clinicians and the commercial sector that it has been difficult, if not impossible, to make these safe, beneficial and cost-effective technologies available to patients. The reasons for this are outlined under comments above on Chapter 7, but the difficulties are even greater.

	➢ Unlike the PBAC and MSAC, a major focus of the new Prostheses and Devices Committee will be relative clinical efficacy rather than cost effectiveness. ➢ **8.2** The MSAC assessment process: ➢ appears lengthy, taking 13–15 months on average to complete evaluations, thus delaying access to new procedures and some devices; and ➢ like the PBAC process, allows little opportunity for consultation with patient groups or the general public. ➢ **8.3** Feasibility studies and trials used to evaluate HealthConnect appear to be deficient: ➢ costs have been assessed in isolation from the assessment of benefits; ➢ the examination of benefits has been limited in scope; ➢ trials have been uncoordinated; and ➢ implementation has preceded successful completion of trials. ➢ **8.4** Australia's HTA effort is fragmented along jurisdictional (national and State/Territory) and sectoral (public and private) lines. This has led to duplication of HTA effort which can create unnecessary costs and delays. ➢ There is potential for a nationally	

	co-ordinated approach to assessing technologies used in public hospital systems. ➢ **8.5** 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. ➢ **8.6** As different HTA agencies and committees examine particular types of medical technologies, conducting effective HTA of combined technologies such as new drug/device combinations can pose challenges and lead to delays. With greater technology convergence expected in future, coordination difficulties and delays are likely to be magnified	
Chapter 9 **Future advances in medical technology**	➢ **9.1** 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. Harnessing this potential will require planning, coordination and investment. ➢ New medical technologies in the pipeline have the potential to revolutionise the practice of medicine	Transfusion medicine is no exception in respect to ICT and the Society can only support the preliminary findings. The ARCBS has introduced a national system for managing the supply side of transfusion medicine. This project has been a major exercise and challenge to all involved. There have been difficulties and cost overruns in implementing the system. The Society feel ARCBS has been unfairly criticised when one considers the failure of many other health related IT systems at both State and Federal level.

	over the next 10 to 20 years. Many of these are likely to deliver significant benefits but, when combined with the pressures of an ageing population 9.2 and increasing community expectations, will do so at significant cost to governments, insurers and the wider community.	