NATIONAL ASSOCIATION OF PEOPLE LIVING WITH HIV/AIDS
PO BOX 51 NEWTOWN NSW 2042 AUSTRALIA
TELE: + 61 2 9557 8825 **FAX:** + 61 2 9557 9461
EMAIL admin@napwa.org.au

Submission from
the National Association of People Living with HIV/AIDS (NAPWA)

to the

PRODUCTIVITY COMMISSION PROGRESS REPORT ON THE IMPACTS OF MEDICAL TECHNOLOGY IN AUSTRALIA

JULY 2005

Who we are

NAPWA is the peak, community-based organisation advocating for and providing policy advice on behalf of the 14,000 Australians currently living with HIV/AIDS. In partnership with the Australian Federation of AIDS Organisations (AFAO), NAPWA works to ensure a national continuum of community-based advocacy and service delivery, from prevention, to care and support. Our 20 years of engagement, aligned with the singular challenge that HIV has offered, has given us a significant depth of experience in and with health delivery in Australia, and also with the full range of stakeholder interests engaged in its provision.

Background to the submission

Overall, NAPWA believes this Progress Report is a thorough and perceptive document which, from our perspective, clearly identifies the major issues and what is at stake in terms of the availability of and access to new and emerging medical technologies in Australia.

We hope that the comments we make below will contribute further to the breadth of this document and discussions about the future of medical technologies.

Needless to say, NAPWA has a major responsibility to ensure that appropriate medical technologies, including diagnostic procedures, tests, and medical devices, are available to the 14,000 Australians living with HIV, in a way which reflects the highest level of research and clinical knowledge of HIV.

Some examples of emerging medical technologies and devices increasingly important in HIV/AIDS clinical management include:

- new kinds of diagnostic testing (e.g. rapid testing for HIV antibodies);
- immunological tests (such as tests allowing the measurement of specific immunological markers for clinical monitoring);
- tests used in clinical monitoring (for example, assays which can indicate whether HIV treatments are at clinically appropriate levels in the blood stream);
- HIV genotypic and phenotypic resistance tests (which can establish whether a person is resistant or sensitive to particular HIV medicines);
- medical devices, such as polylactic acid, which can be used surgically to correct facial fat wasting (atrophy), a common side effect of some HIV medications;
- a range of technologies and tests which may applicable to the clinical management of other common side effects of HIV or HIV treatment, such as cardiovascular problems, metabolic disturbances and diabetes, opportunistic infections, or cancers.

Because of the complex nature of HIV disease and HIV drug side effects, there are a wide range of technologies regularly used. Clinical research and guidelines change rapidly as knowledge expands.

NAPWA's major interest in this report is to protect and sustain timely, appropriate and equitable access to this range of technologies – within, of course, the obvious constraints of best clinical practice.

With this in mind, we have made comments focused on the following areas:

- **Approval processes, mechanisms, clinical evidence and the assessment of cost-benefit assessments**
- **Current costs to government and community**
- **Expectations of community and clinicians**
- **Community input**

2. Approval processes and mechanisms; clinical evidence; assessing costs and benefits

NAPWA has always emphasised the importance of timely access to new technologies and medications, since many people living with HIV or AIDS are often in precarious or fluctuating clinical situations.

We were pleased to see that the Commission has therefore had a strong focus on approval processes and mechanisms, such as the Medicare Services Advisory Committee (MSAC), and would concur with many of the major problems and impediments to these processes identified.

From NAPWA's perspective, however, we would take some of these analyses one step further, and believe what is needed is a radical re-thinking of the ways in which regulatory bodies consider the effectiveness and cost-benefits of new technologies.

Over the past few years, genotypic resistance tests have become increasingly important in HIV management. In these tests, HIV is analysed for particular genetic changes that can make HIV resistant to particular treatments.

The tests are complex and need to be carefully interpreted, but they are now widely considered a routine part of clinical care for HIV. US, European and draft Australian treatment guidelines recommend when and how they should be used. They are a standard tool in HIV clinical research, and HIV drug developers always try to incorporate some understanding of genotypic resistance in their clinical trials.

Over two years ago, an application went to the Medicare Services Advisory Committee (MSAC). An expert subcommittee, after more than a year of deliberation, recommended to the MSAC that HIV resistance tests be included on the Medicare schedule. However, the MSAC did not accept this recommendation, and refused a Medicare item number for this test.

It appears that MSAC was not convinced that the evidence demonstrated cost-effectiveness. However, community advocates and those involved in the process felt that it was a case in point highlighting some of the limitations of the particular process.

NAPWA and others are of the opinion that MSAC's view of what constitutes acceptable evidence of clinical efficacy and cost-effectiveness is narrow and inflexible. The use of HIV genotypic resistance testing in defined patient populations is well-documented in a wealth of peer-reviewed scientific and clinical literature on HIV, and international guidelines have explicit recommendations as to how and when these tests can be of best use in clinical management. Resistance testing is also a part of most major international clinical trials protocols.

In determining that there was insufficient evidence to support a listing, the MSAC in fact overturned the advice of its own expert panel, which had advised that predicted improvements in survival and quality of life were sufficient to justify the additional cost. This suggests, at the very least, some serious flaws in the process, and certainly, a worrying lack of transparency.

Further, if the MSAC cannot agree with the interpretation of its expert committee, despite being advised it was both best practice, and cost-effective, this may suggest some more fundamental disagreements as to what truly constitutes evidence of cost-effectiveness, and on what basis this is assessed and understood – and NAPWA believes that this is a problem which extends well beyond the single case in point, and surely affects the outcomes for the listing of other emerging technologies.

napwa
is the peak non-government
organisation representing PLWHA
community based groups
in Australia

These kinds of problems have been identified in the Progress Report. In our opinion, however, there is latitude and reason to take these observations further, and to consider what implications they may have for practice.

Some of the questions we believe urgently need exploring are:

- Just what is the relationship between "quality of life", as measured, for example, using standardised instruments in clinical research, and "productivity"? Of course, these effects are difficult to quantify, but we don't believe the answer is to ignore them altogether, in favour of narrower albeit more comfortable definitions. To do so, we believe, risks rendering important new technologies with real clinical value and agreed uses effectively unavailable to a broad range of health care consumers.
- How can funders and policy-makers more effectively capture relevant cost offsets when considering cost-effectiveness? So, to return for a moment to the example above, there is evidence that HIV resistance tests, appropriately used, can help improve the rational use of HIV antiviral treatments, by eliminating the use of treatment combinations to which HIV is resistant, and which we would therefore expect not to work. This is obviously useful for patients, but has the real benefit of ensuring that expensive HIV antiviral treatments being paid for under the Pharmaceutical Benefits Scheme can be more wisely used and effectively targeted. It is difficult to provide an exact estimate of the economic effects of this. However, no one in this case disputed the clinical evidence, so it would be rational to infer that this would represent savings to the PBS.
- How can bodies such as the MSAC, which decide on new technologies, ensure that there is appropriate and reasonable guidance offered to sponsors as to the level of evidence required for listing to be considered? Currently, guidelines exist, however, it would seem to us that it would be valuable to provide more information as to what is – and is not – considered "admissible" economic evidence, rather than offering post-hoc analyses once a submission has been rejected. This is particularly important given the lengthy timelines for consideration of new technologies through the current MSAC process: in the case of HIV resistance tests, more than two years.
- There should be some clear guidance as to what weight clinical practice and guidelines can be expected to have. No doubt there are some who would have reservations about this, fearing it may lead to pressure from clinicians to simply adopt the "newest and latest" technologies and developments. However, NAPWA believes that the evidence gained through the use of emerging technologies in routine clinical practice can be extremely valuable in adding to a true picture of how technologies are likely to be used in practice. It is often the gradual experience of applying new technologies in the clinic which leads, for example, to clearer understanding of their rational and appropriate use – including, most importantly, when technologies should not be used, or those circumstances where they are less likely to be effective. In the case of HIV resistance assays, the result of clinical experience has been to use this technology in more targeted and specific ways,

rather than the opposite – and had there been scope in the process to make this point, or to appraise the committee of new and emerging evidence throughout the lengthy assessment period, we believe this may have allayed any fears this technology was likely to be inappropriately used or to lead to cost blowouts.

- Is there currently an imbalance between economic prudence, and the case for a wider availability of new technologies which may represent significant advances in quality of life or productivity? Again, it is difficult to determine this only through abstract economic models. NAPWA does feel, however, that economic prudence does tend to prevail sometimes at the expense of improvements in quality and quantity of life for individual or particular patient groups. Again, we feel this is a problem which cannot be ignored. The challenge for regulators is surely to ensure that those bodies set up as the gatekeepers and independent umpires providing advice to government do not inadvertently or otherwise become captured by a political or policy imperative to reduce costs – at any cost. Health consumers do have a right to expect that the case for new technologies has been fairly considered and heard. To many health consumers, the reality seems to be that decisions about technologies which may have a fairly direct effect on their lives are being made by nameless and faceless committees – and according to principles and models which to many remain a mystery. This is not an appeal for a process devoid of rigor or an argument for throwing economic analysis out the window. Rather, we are suggesting that the requirements for "evidence" of "cost-effectiveness", when applied in their strictest and narrowest definitions, risks overlooking other, very real, "values" in new technologies.

3. Current costs to government and community

Unsurprisingly, cost-shifting and Commonwealth-State funding arrangements are a focus of the Progress Report. However, NAPWA would like to emphasise one particular feature of these arrangements that surely has implications when assessing "productivity", and it is the question of who pays and how.

When new technologies come onto the market, they may be initially supported through means such as 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.

Over time, technologies do begin to find their rational place in clinical use, and often, initial surges in consumer or clinician demand for "the latest" technologies subside, as they get incorporated into best practice.

This was certainly the case with HIV resistance tests, which have been funded to date through a range of mechanisms, including research monies through hospitals and laboratories.

Part of the reason we believe that the evidence of how technologies are applied in routine clinical practice should be of great importance to funders is that in many cases, even if the procedure or test is not funded through Medicare, it would be expected that there would still be ongoing, clinically justified demand for it. In this case, the question must surely be, Who is paying for it, and is this the wisest and most productive use of that money? NAPWA is aware of many emerging procedures and tests which are supported primarily through monies scrimped together, more or less transparently, through hospital budgets, related research programs, or other means. Though for obvious reasons this is not always talked about, we believe that agencies regulating and advising on the funding and availability of new technologies need to give serious consideration to this problem, given that, one way or the other, someone is paying the price.

We believe this would also be a welcome win for the much-vaunted principle of "transparency", forcing a more rational consideration of who is best placed and should be paying for, new technologies. The right answer may not, in fact, always be "The Commonwealth government". However, NAPWA feels this is an important issue which cannot be simply avoided or swept under the carpet, if consumers, industry and government alike are to have faith in the rational allocation of healthcare resources. It may well be true that "consumers are willing to pay for good health" (Progress Report, p. 11) – but we already do pay, through the tax system, and so consumers have a right to expect that the systems put in place to ensure the most rational and productive use of healthcare resources funded through State or Federal budgets are just that. For all the sophistry, smoke and mirrors which can obscure debates about the funding of new technologies, the bottom line is that, in the end, someone pays: we need to be sure it is the most appropriate outcome.

4. Community and clinician expectations of new technologies

The Report also has a strong focus on the so-called 'demand drivers' for the uptake of new technologies, and health consumers have been identified as a factor influencing the rate at which new technologies are adopted. This is certainly partly true, but we'd like to caution against what we see as a common misapprehension – that consumers drive an often-inappropriate use of new technologies.

We note that at least one submission referred to in the report suggested that this demand may be driven by factors such as advertising or indirect promotion, with the implication that the consumer's desire for a particular technology may sometimes be clinically inappropriate.

While we do accept that the uptake of some new technologies may be in part driven by consumer demand, we'd make two important points in relation to this.

The first is that clinicians themselves also play a pivotal role in the demand for or use of new technologies or healthcare innovations. Shifting the blame entirely to consumers, assumed here to exercise limited discretion or sophistication around the adoption of new technologies, overlooks the important role clinicians can and should play in 'brokering' the use of emerging technologies, and ensuring they are appropriately used – a responsibility which is particularly serious where consumers are directly paying for a test, device or procedure.

The second, and perhaps more important point, is 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.

In particular, 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.

On the other hand, there are often very real and clear reasons for the uptake of particular technologies. In the case of HIV, one example is the use of polylactic acid for the surgical correction of facial fat wasting caused by HIV medications. There is no doubt that this procedure, currently not funded by Medicare and available under limited circumstances in only one state, has generated an enormous amount of interest and enthusiasm from people living with HIV / AIDS. However, this seems perfectly rational and justifiable given the very real stigma experienced by HIV positive people who may have severe facial fat loss as a direct and well-documented side effect of drug treatment for HIV infection.

It's also worth noting that other factors may drive the demand for what may be the questionable application of particular technologies – and that these pressures may actually come from government, policy-makers, or clinicians. One example of this is recent debates which have emerged as to whether HIV testing should be routinely offered to all pregnant women in Australia. Some clinicians and policy-makers have argued in favour of this measure, which it is estimated may prevent an estimated xx HIV infections in children each year. However, others have countered that this would be an expensive exercise which cannot be justified, and that the more appropriate and cost-effective response would be to invest in training and support mechanisms for clinicians so that HIV testing is offered to women on the basis of a proper risk assessment.

napwa
is the peak non-government
organisation representing PLWHA
community based groups
in Australia

5. Consumer input into regulatory processes

Finally, we'd like to draw attention to the question of community and consumer involvement in deliberations and decision-making about the uptake of new technologies.

NAPWA has a strong track record of robust involvement in policy-making, research and service delivery for people with HIV, and believe that our experiences demonstrate the value of consumer consultation and input.

In general, however, consumer input into discussions around the effects of new medical technologies is at best patchy and at worst, non-existent. Certainly, there is consumer representation within the MSAC process, but we believe that, like PBAC, the effectiveness of this role is to some extent hampered by confusion as to its ambit and scope, and what kinds of consultation are permissible within the constraints of in-confidence proceedings.

In addition, as with the pharmaceuticals approval system, there is no real capacity for consumer groups to provide direct evidence or advice on the relative value of new technologies. In the past, this has been resisted due to concerns that "subjective" or "emotive" evidence derived directly from practical consumer experiences might run counter to the principles of objective analysis and unbiased evidence obtained, for example, through that gold standard, the randomised controlled trial. But NAPWA feels very strongly that this is short-sighted, and that the value of evidence direct from health consumers is often under-estimated in favour of that obtained through research – which is, of course, also open to particular kinds of biases and agendas. Certainly, this has been an important principle governing our interaction with HIV researchers, government and policy-makers.

We'd encourage the Commission to take a strong stance on the importance of community and consumer involvement in deliberations on new technologies: as the Progress Report notes, in other systems, such as the UK's NICE, this principle is well-established, and consumer input is much more systematically and extensively engaged. It may be worth elaborating further on overseas models, to contribute to the discussions around how procedural transparency, fairness and equity for health consumers in Australia can be guaranteed not just in theory – but in practice.

We hope that the above comments and observations are helpful to the Commission, and would be pleased to discuss any of these matters further. We congratulate the Commission on their exhaustive and expansive work in this area, and look forward to the final report.

napwa
is the peak non-government
organisation representing PLWHA
community based groups
in Australia