

The impact of complexity on HIV clinical management and clinical research

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FOREWORD

The Australian Government has recently released a new National HIV/AIDS Strategyⁱ. It has an ambitious theme – “Revitalising Australia’s Response to HIV/AIDS”.

The release of the Strategy comes at a time of growing - if not unparalleled - complexity in HIV/AIDS treatment, care, research and prevention. So the Strategy’s theme is very appropriate, as the impact of complexity is an important reason why our HIV response needs revitalising. But with complexity also comes optimism as new treatments become available, scientific knowledge increases and mortality rates remain low.

As advocates, we find this a very stimulating time to be involved in HIV from a strategy and policy perspective: Australia needs to revitalise its HIV/AIDS response, but how this should be done is not always clear. This presents a challenge for all in the HIV sector.

We decided to write this paper with four aims in mind:

- to examine the growing complexity in HIV/AIDS and its impact on clinical management and clinical research.
- to propose possible changes to the HIV clinical management and clinical research models in light of these complexities.
- to suggest how NAPWA can best respond in a more complex treatment and clinical research environment.
- to stimulate wide discussion among the HIV partnership.

“Goal the of the 5th National HIV/AIDS Strategy:

To improve the health and well-being of PLWHA in Australia through equitable access to treatments and improved continuum of care in health and human services.”ⁱⁱ

With the release of the new National Strategy, the next challenge is how best to implement the Strategy’s priorities and objectives at both Commonwealth and State/Territory levels. We also hope this paper will make a contribution to that process as well.

This paper focuses on HIV clinical management and research, because they are core concerns for PLWHA and are being so manifestly affected by complexity. However, we recognise that clinical management and research is directly linked to the effectiveness of other services and programs – support, educational, cultural – in both medical and community settings. So it is essential that the impact of complexity is addressed across all HIV related programs and services accessed by HIV positive people in Australia.

In preparing this paper we talked to a range of physicians, general practitioners, researchers, academics, PLWHA and community advocates, as well as people in government and industry. These discussions were very helpful in clarifying our thinking on a range of issues. We greatly appreciate the time people gave to us.

This paper is intended for a wide audience – researchers, clinicians, PLWHA/community organisations, pharmaceutical companies, regulators and policy

makers. In particular, we want this paper to be accessible by people living with HIV, because this paper is ultimately about issues affecting their health and quality of life. To help with this, we spend some time explaining the background to issues.

This is a discussion paper, so the views expressed are ours and do not necessarily represent those of NAPWA or its members, at this time. We know that aspects of this paper may be controversial. However, if Australia is to address current complexities to strengthen treatment and research, then issues that are not necessarily easy do need to be talked about openly and constructively.

We hope this paper will help stimulate these discussions, leading to better outcomes to support the lives of people living with HIV in the years ahead.

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26 August 2005

SUMMARY OF KEY FINDINGS & PROPOSED STRATEGIC DIRECTIONS

BACKGROUND & APPROACH TO THIS PAPER

- This is a time of growing - if not unparalleled - complexity in HIV/AIDS treatment, care, research and prevention. This presents a challenge for all in the HIV sector.
- HIV clinical management and research are core concerns for PLWHA and are being manifestly affected by complexity. However, this is not always fully acknowledged or well articulated.
- HIV clinical management and clinical research are directly linked to the effectiveness of other services and programs – support, educational, cultural – in both medical and community settings. So it is essential that the impact of complexity is addressed across all HIV related programs and services accessed by HIV positive people in Australia.
- This discussion paper was written with four aims in mind:
 - to examine the growing complexity in HIV/AIDS and its impact on clinical management and clinical research.
 - to propose possible changes to the HIV clinical management and clinical research models in light of these complexities.
 - to suggest how NAPWA can best respond in a more complex treatment and clinical research environment.
 - to stimulate wide discussion among the HIV partnership.
- This paper is intended for a wide audience - researchers, clinicians, people living with HIV, PLWHA/community organisations, pharmaceutical companies, regulators and policy makers.

KEY FINDINGS & PROPOSED STRATEGIC DIRECTIONS

Part 1. Introduction

- A decade of treatment optimism and declines in HIV/AIDS mortality and morbidity have changed the expectations of many PLWHA about their lives and future. Many people with HIV/AIDS now expect they should be able to live as close as possible to a normal life - with longer term goals and expectations replacing short-term ones based around survival.
- It is important that clinical services and research are able to reflect these changed expectations about health and future that many PLWHA now have.

- There are more Australians living with HIV/AIDS than at any other time in the epidemic. This factor, together with –
 - increased complexity of HIV treatment, care and prevention;
 - the geographical spread of the HIV positive population from cities to regional and remote centres; and
 - the special needs of different affected populations,will place further pressure on clinical services and require that a range of other care, support and educational needs are capable of being met.
- A substantial proportion of PLWHA are now in or approaching middle age. Therefore PLWHA and their health providers need to consider a wide variety of health issues associated with longer life spans and ageing, as well as HIV itself.
- Complexities in HIV/AIDS not only affect doctors and researchers. For PLWHA, it can be very difficult to weigh up a range of complex factors they may need to take into account around health choices and participation in research.

Part 2. Complexity & HIV Clinical Management

Evolving Health Care Needs of PLWHA

- A range of health issues common in the general population which were not at the forefront in the pre-HAART era - such as ageing, heart disease, diabetes, arthritis, mental health - now require attention. Adding to the picture are increased complexities associated with HIV management itself, including ARV selection, as well as problems related to ARV toxicities.
- The bottom line is that long-term health management for many PLWHA is more complex than previously, encompassing not only HIV/AIDS itself but a range of other health challenges.

HIV Clinical Care and ARV Treatment – Delivery and Access

- The dramatic impact of ARV treatment on HIV morbidity and mortality has changed how HIV clinical care and ARV prescribing are organised and utilized. HIV related hospital admissions have declined sharply and the vast majority of PLWHA are now able to be cared for in ambulatory settings (hospital outpatient clinics; day treatment areas; GP practices; sexual health services; community health services;). This is a very different picture from ten years ago.
- However, while hospital admissions have declined, the length of stay can be significant – reflecting that HIV related hospital admissions can be very complex cases, with multiple problems related to HIV and other factors to be attended to.
- HIV clinical management and ARV prescribing have evolved to encompass a mix of specialist and generalist services, with hospital based physicians, sexual health physicians and general practitioners involved to varying degrees.

Impact on HIV Clinical Training & Antiretroviral Prescribing

- Currently there are 19 ARV drugs available in five different classes. The new drug pipeline contains about 15 new drugs which look promising. There are a host of others in very early development. Within another 5 years there may be some 30 ARV drugs available in six different classes.
- It is a major challenge for physicians and GPs working in HIV/AIDS to keep up to date with new drugs and new scientific knowledge and incorporate this into management of their patients. This applies even to the most experienced HIV clinicians.

Impact of Complexity on General Practice Viability

- HIV complexity is impacting on the viability of general practice based HIV clinical care in a number of ways.
- HIV patients usually need longer consultations, but general practice remuneration is very much geared to shorter consultations. Some doctors believe the new Medicare Chronic Diseases Management Plan item will be helpful, but will not in itself overcome the larger disincentives playing out. Time restraints are also a factor when trying to provide on-going and multi-focussed care in a single consultation, such as a discussion about specific drug interactions and managing side effects.
- Keeping up to date with developments in HIV treatment and care is a considerable task. Time involved in reading journals, attending scientific conferences, training courses sponsored by ASHM, pharmaceutical industry educational events, also impacts on general practice remuneration for training, even when certain sponsorships are provided. For practices with small HIV caseloads, the motivation and/or opportunity to acquire and put all this information into practical use is obviously limited.
- As a result of these factors, a number of GPs have given up their ARV prescribing rights, or are considering doing so, because they find it impossible to keep up to date. There are difficulties in recruiting new GPs to become ARV prescribers, even among high HIV caseload practices.

Re-defining ARV Prescribers & Upgraded Training

- In the current complex environment, management of HIV disease and ARV treatment requires not only substantial knowledge, but also an active PLWHA caseload. It is not in the best interests of PLWHA to have complex decisions about their HIV care and treatment made in low HIV caseload medical facilities, be they general practices, sexual health clinics or hospitals.
- Current training courses - while providing an excellent basic grounding in HIV medicine - are no longer sufficient to equip a doctor inexperienced in HIV to manage the complexities of ARV prescribing. Training and accreditation requirements for current ARV prescribers should be upgraded, in light of complexity.

- ASHM should continue to have the central role in this upgraded training framework, with the Commonwealth and State/Territory governments enhancing ASHM's capacity to do so.
- As part of upgraded training requirements, a minimum HIV caseload level for ARV prescribing accreditation should be introduced - set somewhere between 30 and 50 directly managed HIV patients. This change would be in the framework of a considerably strengthened model of co-managed care, described below.

Meeting HIV Clinical Management Needs - A Strengthened Model of Co-managed Care

- A likely trend of low HIV caseload general practices and other sites moving away from direct HIV management will create pressure on high caseload specialist HIV sites (hospital, public clinics and general practice). Should numbers of PLWHA increase, as is likely, this will add further pressure.
- The risk is that without policy intervention, HIV clinical management for a significant number of PLWHA may become increasingly difficult to access. There is also the issue of broader health care to be considered, which has become much more important as PLWHA live longer.
- To address these challenges, the future priority should be on –
 1. Expanding HIV specialist ambulatory care services in public hospitals and public clinics as necessary.
 2. Supporting existing high HIV caseload general practices to remain involved in HIV/AIDS, including support to mentor new HIV specialising GPs within these practices.
 3. Implementing a better defined, formal, and better resourced co-managed model of care between lower HIV caseload sites (in general practice, public clinics, hospitals) and high caseload HIV specialist sites (in general practice, public clinics, hospitals).
 4. Implementing strategies which maximise opportunities for non S100 GPs to participate in co-managing PLWHA health care with HIV specialist clinicians (located in general practice, public clinics, hospitals).
- Two key issues to be clarified in this co-management model are:
 - the level of HIV monitoring to be done in lower caseload general practices and other clinics and the level of training needed for this monitoring; and
 - whether a system of ARV prescribing limited to writing continuation scripts is needed for lower HIV caseload practices and other clinics.
- Immediate priority should be given to defining and implementing a better co-managed model of clinical care for PLWHA. There appears to be a lack of clarity in the nature of shared care arrangements between some specialist services and some GPs.
- There must be comprehensive planning, support, incentives and funding provided by Health Departments to make this model work.

- The changes proposed in Part 2 of this paper should not only help improve the overall quality of clinical and ARV management, but should also provide a reasonably equitable system of access for PLWHA in both urban and country areas. A much stronger emphasis on co-managed care should not only assist health care providers to manage the complexities of HIV disease, but also enable PLWHA to receive the broader health care they will need in the years ahead.

Quality Assurance

As complexity increases, so does the importance of quality assurance and clinical governance as they relate to HIV care. In this more complex HIV environment there is a need for Health Departments, Colleges, ASHM and NAPWA to review these areas.

Part 3. Complexity & Clinical Research

Issues Impacting on the Research Environment

- A key feature of Australian HIV research has been the strong partnership between PLWHA advocacy organisations, affected communities, researchers, the pharmaceutical industry and regulators. The partnership has lasted and delivered much to the Australian HIV response.
- Many of the issues described in Parts 1 and 2 of this paper impact on HIV related research. In addition, there are some specific problems to do with consultation, communication, funding, ethics and access, that if not addressed could undermine Australia's HIV clinical research environment.
- This is a very optimistic time in new ARV development. New drug development will generate more research about the drugs themselves and their strategic use in clinical management.
- Some of these studies will be specialised and may only involve relatively small numbers. Others may be multi-centre and multi-national, but the number of places allocated to Australia could be very limited. For many of these ARV development studies, a higher level of research expertise will likely be required of sites.
- Realistically, this will mean that the number of sites with the capacity (and in some cases the patient numbers) to do this specialised type of research will be limited. We are already seeing this trend in Australia, although its impact is not widely understood by PLWHA and some of their health providers.
- On the other hand, there should be opportunities for fairly wide participation in research looking at clinical events, adherence, or different clinical management approaches.

More Pharmaceutical Companies Entering the HIV Field

- A relatively small number of pharmaceutical companies operate in the HIV market, but this is changing. With more industry participation, additional efforts

will be needed to maintain Australia's relatively well coordinated, consultative and transparent research environment.

- There have already been some communication problems recently: some studies of new ARV drugs were set up without prior consultation or notice with the usual stakeholders, including the community.
- There is a need to look at mechanisms for supporting consultation and communication as more pharmaceutical companies enter the HIV field. Given growing complexities in HIV research and clinical care, plus the fact that personnel move in and out of the community, research and industry sectors, it is time to consider formalising aspects of the industry-PLWHA community relationship.
- Each of the pharmaceutical companies and NAPWA should consider an accord or memorandum of understanding, which would set out principles of communication and cooperation by which both sides would aim to operate. Also, regular roundtables between community and industry would be beneficial to exchange views and look at ways to cooperate.

More Industry Funded HIV Research in Private Practice

- There is a trend to more pharmaceutical industry funded clinical studies conducted outside the NCHECR network, including private practices with large HIV caseloads. Most of these studies involve new ARV agents, and are organised by overseas based pharmaceutical companies through their local offices or representatives. However, sometimes studies are negotiated directly between local researchers and off-shore pharma.
- With more research being done outside NCHECR - particularly in private practice – consultation channels between researchers and community should be clarified in the interests of all concerned.
- In the section above, an accord between NAPWA and pharmaceutical companies was proposed. A similar accord or memorandum of understanding between researchers and NAPWA would also be helpful, delivering benefits to both sides. Also, there should be a roundtable meeting between researchers, industry and community in the early stages of study planning.

Concentration of Research in a Smaller Number of Clinical Sites

- There is a trend towards concentration of research in a smaller number of clinical sites, particularly for pharmaceutical industry sponsored research. There are a variety of reasons for this.
- Equity of access to clinical trials is becoming more problematic as a result of this trend. As with the HIV clinical management model, we think some changes are needed.
- The first component of this would be better transparency and communication. The accords or memorandums of understanding proposed earlier would provide a strong foundation for this to occur. This paper proposes a strengthened co-

management model to provide shared care between GPs, public clinics, hospitals and HIV specialist HIV sites - this model could be adapted to include access to HIV clinical research sites as well.

- This model would not only apply to PLWHA in lower caseload clinics with little or no HIV research involvement. It would also involve HIV specialist sites who may not have a particular study, cooperating with ones that do.
- As for a shared clinical management model, this proposal will not work without planning, support, incentives and funding provided by Health Departments.

NCHECR & Cohesiveness of the NCHECR Research Network

- NCHECR has made an exceptional contribution to scientific knowledge and clinical management. The Centre and its leadership brings many direct and indirect benefits.
- There is wide support for the NCHECR. However, there were some concerns around direction, operations and communication which should be commented on. These include –
 - the direction of the research program, current and proposed;
 - the effectiveness of current mechanisms for stakeholder input into the formulation of NCHECR's research agenda;
 - lack of communication about some aspects of programs, plans and priorities;
 - the NCHECR cost structures for studies and the level of support provided to research network sites;
 - concerns that the NCHECR research network is becoming less cohesive, especially given current trends towards more industry supported research outside NCHECR.
- NCHECR is being affected by complexity like everyone else. It is therefore important that the concerns listed above are formally addressed, particularly in the areas of research program input and communication. Some re-appraisal of the NCHECR research network is probably needed, as new studies may not in themselves be enough to keep the network cohesive. NAPWA should use its good relationship with the Centre to assist in these areas.

Ethical & Transparency Issues

- Review of study proposals by Human Research Ethics Committees (HRECs) is a fundamental part of an ethical, transparent research framework. The work of HRECs has been a very important factor in Australia's long and impressive research record.
- HIV/AIDS is already a complex area for HRECs. However, new developments in HIV/AIDS science and treatments are further impacting on their work. Some HRECs regularly review HIV research proposals and are reasonably familiar with the area. Some may have members with HIV/AIDS expertise. Other HRECs may have very little experience with the area.

- Doubts were expressed about the capacity of some HRECs to review HIV studies as complexity increases. Also, as more studies are now emanating from GP practices - and people are living longer with HIV - consideration of primary care related issues have become very important. Linked to this is the ethical dilemma of being the principal medical carer, as well as the researcher.
- If there is no consultation by researchers or industry with community advocates prior to HREC application, the potential for ethical concerns increases. This is illustrated by two recent developments:
 1. Reports of very high payments to study participants and per-patient recruitment fees to doctors.
 2. A notable increase in promotional activities for research studies.
- In light of the more complex HIV research environment - and the ethical issues that have arisen recently over some studies - NAPWA should now seek a formal relationship with HRECs involved in reviewing HIV studies. This would provide a safeguard should there be a breakdown in consultation. It is also likely that NAPWA could from time to time assist HRECs with their work, given NAPWA's knowledge of HIV research and treatments and close links with PLWHAs and affected communities.
- Given the special nature of HIV/AIDS, the idea of having a national HIV/AIDS ethics committee should again be discussed.

Information to PLWHA about Research

- The number of available ARVs, the number of new agents in the pipeline and the number of studies looking at these agents and at other questions, is daunting. Added to this are more study advertisements appearing in community newspapers, more notices in clinics, etc. Unless this "information overload" is coordinated better, there is the likelihood that more PLWHA will opt out of research altogether. Informed consent to research could also become compromised by complexity and confusion.
- An HIV specific clinical trials site should be set up as soon as possible to provide more detailed information for PLWHA, other potential participants, clinicians, and researchers.

4. Complexity & NAPWA's Response

- The centrality of PLWHA in the planning of Australia's response to the epidemic is a fundamental principal of the National HIV/AIDS Strategy, which is widely accepted by stakeholders. The Strategy endorses NAPWA's role as the peak body representing PLWHA and its responsibilities to advocate on behalf of HIV positive people. The Australian government supports NAPWA in this role, including through funding for policy and advocacy work.
- Like everyone else, NAPWA is feeling the impact of increasing complexity in HIV/AIDS clinical management and research. There was wide support for the advocacy and policy work of NAPWA and its members. There were some criticisms and useful ideas about how NAPWA could operate better.

- In relation to clinical management and clinical research, seven areas were identified where NAPWA should consider new approaches to strengthen its work. They are:
 - i. Treatment Information for PLWHA.
 - ii. Clinical Trials Information for PLWHA and other stakeholders.
 - iii. Communication with other stakeholders.
 - iv. Communication with PLWHA and with NAPWA's member organisations.
 - v. Communication with Human Research Ethics Committees.
 - vi. Overseas Linkages.
 - vii. Building Capacity for Treatment & Research Advocacy.
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PART 1 – INTRODUCTION

1.1 Complexity in Context

There have been many twists and turns in the HIV epidemic. Who would have thought that 25 years after the first reports of AIDS, it would become a global catastrophe of such magnitude? Who would have thought that even now, so many countries are mishandling the problem, with disastrous effects on their citizens?

Australia has been more fortunate than most other countries. Strong leadership, especially in the early years of the HIV epidemic, together with the perseverance of scientists, researchers, health professionals, advocates and policy makers, has built and largely sustained an impressive HIV/AIDS response.

In research, there have been many obstacles to progress, not the least being the resilience of the virus itself. However, the tenacity of researchers has given us a remarkable amount of scientific knowledge about HIV/AIDS. This in turn has led to effective antiretroviral drugs. Scientific knowledge has also informed our treatment, care, support and prevention strategies.

In clinical care, many of those who were there in the early years of the epidemic in Australia are still involved. They have seen HIV clinical care evolve from being mostly about caring for the dying, to having potent drugs to use which are now helping many people to live long term with HIV/AIDS.

But if there is one lesson HIV has taught us, it is the danger of standing still. The prevention, care, support and treatment environment is constantly evolving. This has to be responded to, or there are setbacks. Strategies, policies and programs have to be regularly reviewed and updated, even though the temptation to leave things as they are is often understandable.

New complexities in the epidemic – cultural, social, educational, scientific, clinical – seem particularly evident at the moment. HIV clinical management and clinical research are being substantially influenced by complexity – however, this is not always fully acknowledged or well articulated.

Living with HIV/AIDS can be very daunting, not just in the health, treatment and research decisions PLWHA may need to make. For many, there are already years if not decades of living with loss and uncertainty to contend with. This may involve major life adjustments. Isolation, poverty and social ostracism are realities for some PLWHA. For newly infected people, coming to terms with living long-term with HIV can be very difficult.

This is a time of much optimism about HIV treatments, but there are difficulties associated with drug resistance, toxicities and unforeseen clinical problems associated with treatments. The nexus of which clinical problems might be caused by HIV itself as opposed to antiretroviral (ARV) drugs (or a combination of both) is not always clear. Other health issues associated with long term living must now be dealt with, as well as HIV itself.

There is an enormous amount of clinical research in progress and being planned. Many PLWHA want to contribute to research, but making informed choices about this is often much more complex. This can be frustrating for PLWHA as well as researchers and clinicians.

It is with this context in mind that we approached writing this paper.

1.2 Shared Environmental Factors

In the remainder of this Part, we discuss four environmental factors which need special explanation, as they have a dual impact on HIV clinical management and HIV clinical research, as well as on other areas of the HIV response. These are:

- Features of the Australian PLWHA Population.
- Ageing & the PLWHA Population.
- Changing Expectations of People with HIV/AIDS.
- Health, Treatment & Research Decision Making.

1.2.1 The Australian Population of People living with HIV/AIDS (PLWHA)

More Australians are now living with HIV/AIDS than at any other time in the epidemic. This is predominantly due to advances in antiretroviral treatment which have dramatically reduced HIV related morbidity and mortality. The other factor is a continuing level of new HIV infections, which have risen over the past 5 years.

Current estimates are that around 14,000 people are living with HIV/AIDS in Australia. Reported diagnoses of newly acquired HIV infection (within the previous year) increased from 170 cases in 1999 to 277 cases in 2003. These reported cases of newly acquired HIV infection represent a lower limit to the number of cases of HIV transmission that have actually occurred in Australia over this time.ⁱⁱⁱ

The distribution of PLWHA living in Australia varies considerably.^{iv} Most PLWHA live in capital cities, but PLWHA also live in regional centres and country areas and in some of these areas numbers are quite substantial (e.g. Cairns district Qld; Gold Coast Qld; NSW Hunter District; NSW Northern Rivers).

All States/Territories can expect increases in people living with HIV/AIDS over the next five years. In some States, the impact of these increases on clinical and other services may be quite substantial (e.g. it is estimated there will be an additional 2000 PLWHA in NSW by 2008, or between 11,500 and 12,000 in total^v).

Gay men continue to comprise the substantial majority of Australia's HIV/AIDS caseload. However, shifts in other populations appear to be occurring. While women represent a small number of the total number of newly diagnosed HIV infections, they are increasing as a proportion of the total.^{vi} People from culturally and linguistically diverse (CALD) backgrounds now make up a significant proportion of new diagnoses^{vii}. While the overall number of HIV infections among Indigenous people remains low, rates have tended to increase in recent years.^{viii} These and other populations such as injecting drug users and sex workers all have special needs related to living with HIV/AIDS.

The impact of more people living with HIV, together with –

- increased complexity of HIV treatment, care and prevention;
- the geographical spread of the HIV positive population from cities to regional and remote centres; and
- the special needs of different affected populations,

will place further pressure on clinical services and require that a range of other care, support and educational needs are capable of being met. More PLWHA potentially means more research participants, but on the other hand, if this is not well coordinated, there is the potential for PLWHA to feel they are being over-researched.

1.2.2 Ageing & the PLWHA Population

In the HIV Futures 4 study^x, the age of respondents ranged from 18 to 92 years, with a mean of 44.1 years (median 43 years). Respondents had been seropositive for an average of around 10 years. Other data show that most new HIV infections in Australia are occurring in people over 30 years of age^x.

Based on these figures, a substantial proportion of PLWHA are now in or approaching middle age. Until relatively recently, the impact of ageing was not a high priority issue, because many PLWHA died. However, ARV treatments have changed that. Now PLWHA and their health providers need to consider a wide variety of health issues associated with longer life spans and ageing, as well as HIV itself. This is not always easy, as HIV and its treatment adds additional complexity to a range of ageing related health problems.

“The changing natural history of HIV/AIDS and profile of the PLWHA population suggests that HIV/AIDS increasingly resembles a chronic disease, affecting people across a progressively increasing lifespan.”^{xi}

Age differences and ageing issues will also impact on the planning and conduct of HIV research.

1.2.3 Changing Expectations of People with HIV/AIDS

A decade of treatment optimism and declines in HIV/AIDS mortality and morbidity have changed the expectations many PLWHA have about their lives and future.

Today, many PLWHA expect to live as close as possible to a normal life. For many the focus has shifted from short term survival to living long-term, with all the associated health, social and economic challenges that involves. There is an emphasis on general health maintenance over the long term, rather than just on HIV itself. Expectations that may previously have been less prominent (financial security, employment and career, children, etc), may now be more to the forefront.

“Changes in care and support needs over recent years have been brought about by several factors including the development of long-term responses to HIV treatments, the longer life spans and ageing of people living with HIV and AIDS.”^{xii}

Of course, these expectations don't apply to all PLWHA. We know from studies like Futures 4^{xiii},

that a significant proportion of PLWHA are not experiencing good health and may also encounter poverty, social isolation or other problems. For these individuals, expectations may also have refocused to living longer term, but in a less optimistic light than for other PLWHA in better circumstances.

It is important that the organisation of clinical management and research reflects the changed expectations many PLWHA now have about their health and future. This is likely to mean more demands for health and support services, rather than less. However, the mix of these services and their utilization will likely be different.

1.2.4 Health, Treatment & Research Decision Making

A feature of the Australian response to HIV/AIDS has been efforts to empower PLWHA to make informed choices about their health and treatment. As part of this, PLWHA and their doctors have been encouraged to take a partnership approach to health decision making.

PLWHA organisations have established treatment information projects like the AIDS Treatment Project of Australia, and other initiatives designed to inform and support PLWHA around treatment, health, and research issues. The Commonwealth and State/Territory Governments and the pharmaceutical industry have supported PLWHA groups to do this important work.

Over the past several years there has been a quantum leap in new scientific information about HIV, new ARV treatments, and new factors to be considered in HIV care and living long term with HIV. As a result, sustaining a partnership approach to health decision-making is more of a challenge. For doctors, researchers and community groups, this means more time and effort is needed for patient education. For PLWHA, it can be very difficult to weigh up a range of complex factors they may need to take into account around health choices and participation in research.

PART 2 – COMPLEXITY & CLINICAL MANAGEMENT

2.1 *Evolving Health Care Needs of PLWHA*

In Part 1 we noted that most PLWHA are living much longer than in the pre-HAART era (pre-1995), with changed expectations about their health and future. A range of health issues common in the general population which were not at the forefront in the pre-HAART era - such as ageing, heart disease, diabetes, arthritis, mental health - now require attention. Some of these health issues are complicated by HIV disease and its treatment.

Adding to the picture are increased complexities associated with HIV management itself, including ARV selection, (e.g. the large number of approved ARVs; experimental drugs available pre-marketing; ARV resistance issues; questions about when to start and switch ARVs), as well as problems related to ARV toxicities.

The bottom line is that long-term health management for many PLWHA is more complex than previously, encompassing not only HIV/AIDS itself but a range of other health challenges.

“Given the improved survival among people living with HIV infection, it is imperative that all persons be managed according to standard practices appropriate for the individual's age and sex regardless of HIV status.”^{xiv}

2.2 *Overview of HIV Clinical Care Arrangements*

Before discussing possible changes to meet these evolving health care needs, it is necessary to consider -

- i. How HIV clinical care and ARV treatment are being delivered and accessed;
- ii. Antiretroviral treatment uptake;
- iii. The influence of PLWHA population levels and distribution; and
- iv. HIV clinical management training and ARV prescribing mechanisms.

These are key considerations in what should, and can, be done.

2.2.1 *HIV Clinical Care and ARV Treatment – Delivery and Access*

The dramatic impact of ARV treatment on HIV related morbidity and mortality has changed how HIV clinical care and ARV prescribing are organised and utilized.

HIV related hospital admissions have declined sharply and the vast majority of PLWHA are now able to be cared for in ambulatory settings (hospital outpatient clinics; day treatment areas; GP practices; sexual health services; community health services;). This is a very different picture from ten years ago.

However, while hospital admissions have declined, the length of stay can be significant – reflecting that HIV related hospital admissions can be very complex

cases, with multiple problems related to HIV and other factors (e.g. liver disease, cardiovascular complications) to be attended to.

HIV clinical management and ARV prescribing have evolved to encompass a mix of specialist and generalist services, with hospital based physicians, sexual health physicians and general practitioners involved to varying degrees^{xv}.

The pattern of HIV/AIDS clinical management and ARV prescribing in Australia can be summarised as follows:

- In *Western Australia, Tasmania, ACT and the Northern Territory*, most PLWHA access HIV clinical management and ARV treatment through a small number of public hospital and health department clinics (e.g. sexual health centres). A small number of GPs also provide HIV management and ARV prescribing, but the HIV caseload in these practices is understood to be low.
- In *South Australia*, the pattern is similar, but there is also one general practice clinic in Adelaide with a higher HIV caseload providing a specialist type HIV service.
- In *Queensland and Victoria*, the pattern is again similar, but there are more low HIV caseload GPs providing HIV management and ARV prescribing, and between 2 and 4 general practice clinics in Brisbane and Melbourne with moderate to higher HIV caseloads providing a specialist type HIV service. There are 24 Victorian based GPs with section 100 ARV prescribing rights.^{xvi}
- In *New South Wales*, there are a more public hospitals and health department clinics providing HIV management and ARV prescribing. There are around 45 general practice clinics with accredited ARV prescribers: most of these practices have low HIV caseloads, but there are 7 practices with high to very high HIV caseloads providing a specialist type HIV service. In total, there are 132 NSW based GPs with section 100 ARV prescribing rights. Of these, 50% manage five or fewer patients (27% of these manage one patient only) and 16% have thirty or more patients^{xvii}.

2.2.2 Antiretroviral Treatment Uptake

Estimates of the number of people taking ARVs vary. The National Centre in HIV Epidemiology and Clinical Research (NCHECR) estimates 50% of all Australian's with HIV were taking ARV treatment in 2003, slightly less than the 52% receiving ARV treatment in 2002^{xviii}. The Futures 4 Study^{xix} found 70% of respondents were taking ARVs. By comparison, a recent UK study found that 64% of adults with HIV were taking ARVs^{xx}. Any reduction in the level of ARV use in Australia is likely due to the shift in HIV treatment guidelines from early to deferred ARV treatment. However, very few if any PLWHA will be able to avoid ARV treatment at some stage.

A shift to deferred ARV treatment has not decreased the need for regular HIV clinical monitoring. All PLWHA require regular monitoring of immune function, viral load and other clinical markers of disease progression. A sizeable proportion of patients on ARV therapy experience treatment failure and/or treatment related toxicities,

requiring access to new ARVs¹, including experimental drugs through clinical trials and compassionate access programs².

2.2.3 Influence of PLWHA Population Levels & Distribution

PLWHA population levels and their distribution obviously influence the makeup of clinical and ARV treatment services. The distribution of PLWHA living in Australia varies considerably between the States/Territories.^{xxi} Most PLWHA live in capital cities, but there are PLWHA in regional centres and country areas and in some of these numbers are quite substantial (e.g. Qld Cairns district; Qld/NSW Gold Coast; NSW Hunter District; NSW Northern Rivers).

The *majority* of PLWHA in Australia access HIV monitoring and ARV treatment through –

- a relatively small number of hospital out-patient clinics specialising in HIV (around 10);
- a relatively small number of health department funded clinics with a strong HIV focus (e.g. various sexual health clinics; Albion Street Clinic) (around 7); and
- a relatively small number of city based, large HIV caseload, general practice clinics (around 10).

These facilities have large HIV caseloads and provide physicians and GPs who are often described as “HIV specialists”. It is this relatively small number of doctors who provide the majority of HIV clinical management and ARV prescribing.

A *minority* of PLWHA access facilities with low HIV caseloads for clinical management and ARVs – hospital out-patient clinics, government funded clinics, general practice clinics. The degree of available HIV expertise in these settings can be variable.

Most States/Territories have attempted to provide some degree of geographical spread of HIV monitoring and ARV prescribing services. Such measures are important for PLWHA living in outer urban, regional and remote centres, who would otherwise have to travel long distances for HIV clinical management and ARV treatment.

However, some PLWHA living outside major cities choose to travel to them for HIV care. Reasons may vary, but include issues of confidentiality, the complexity of their health situation, or their wish to receive HIV management through a specialist HIV clinic. On the other hand, not all PLWHA living in major cities choose high HIV caseload clinics or practices which specialise in HIV.

¹ The 5th National HIV/AIDS Strategy notes “*there are very serious limitations to HIV antiretroviral therapy and these have unique and urgent implications for people with HIV, as well as health care providers, carers and policy makers*”.

² Compassionate Access Programs are negotiated with pharmaceutical manufacturers to provide access to experimental drugs for PLWHA in urgent need of new treatment options.

2.2.4 *Training & ARV Prescribing Mechanisms*

- Hospital Settings & Public Clinics -

There is no HIV/AIDS specialty as such, either in Australia or elsewhere. Most of the hospital physicians managing HIV/AIDS are from infectious diseases and immunology specialties.

The Australian Medical Council and the Royal Australian College of Physicians have longstanding programs for training and continuing education of specialists within their fields. Specialists are required to complete CME requirements to retain accreditation. There is no specific HIV CME requirement as such.

However, within public hospitals there are systems of peer review and formalised audits aimed at advancing knowledge and maintaining clinical standards (we came across some excellent examples of this for HIV). Hospital specialists and other staff are supported by their institutions to attend courses, seminars and conferences. Involvement in research is encouraged and supported. So there is an inherent capacity for training and education, to benefit all specialties.

Public health system clinics, including sexual health centres, have similar systems for training, mentoring, evaluation and ongoing education.

A relatively small number of public hospitals provide specialist type HIV/AIDS care, with most being involved since the beginning of the epidemic. In our background discussions for this paper, most agreed these facilities provide high quality in-patient and ambulatory HIV/AIDS care and were capable of expansion, if necessary, to meet an increasing PLWHA population.

However, in hospitals and public clinics with low HIV caseloads, there were doubts about the capacity of some specialists, residents and other medical personnel to deal with the complexities of HIV/AIDS - especially in relation to ARV prescribing and management. Here a key test is how effectively systems of consultation with and referral to HIV specialist units are working.

Arguments have long been made that hospital specialists and other public health clinic staff managing HIV patients should be asked to complete the same Australasian Society for HIV Medicine (ASHM) type training and ARV prescribing accreditation requirements as GPs are. We agree this should be very strongly encouraged, even if it can't be mandated.

- General Practice -

General practitioners have played a vital role in Australia's HIV response since the beginning of the epidemic. Many of those first affected by AIDS in Australia were clients of city based GPs providing medical care for large numbers of gay men.

Twenty years on, most of this same small group of GPs remain involved and work in practices specialising in HIV care. Over time more GPs have become involved to varying degrees - often through Health Department initiatives to improve access to HIV care in outer-urban, regional and country areas.

Because of the cost and specialised nature of HIV ARV drugs, they are listed under section 100 of the National Health Act and are therefore not normally available through GPs and community pharmacies.³

With the availability of the first antiretroviral drug AZT in the late 1980s, many PLWHA were already being cared for in a small number of general practices, particularly in inner city Sydney. So a program was set up by the NSW Health Department, with Commonwealth cooperation, to enable AZT and other nucleoside drugs nearing approval (ddc, ddi, d4t) to be prescribed by those general practitioners.

The NSW program has been expanded to enable any interested GP to become an accredited section 100 HIV prescriber if they complete a designated training program and meet re-accreditation requirements each year (CME). ASHM became the body contracted to provide this training. Over time this training and accreditation system has been adopted by other States/Territories, with some variations.

2.3 Impact of Complexity on HIV Clinical Care

In the era of a few ARVs, no viral load testing, no resistance testing, and relatively short-term benefits from ARV therapy, the ARV prescribing mechanisms described above were practical and effective. They worked quite well even in low HIV caseload settings, because the knowledge level required to manage HIV patients was not too onerous. Also, the focus was often on palliative care rather than long-term living with HIV/AIDS.

However, from around 1995, there were dramatic advances in HIV treatments and scientific knowledge. The benefits of combining ARV drugs were proven and new drugs like protease inhibitors became available, along with viral load testing. Mortality and morbidity rates plummeted. The mantra of “hit hard and hit early”^{xxii} was taken up by many. The complexity of clinical management and ARV drug selection began to increase.

In the late 1990s to early 2000s, unpredicted effects of ARV therapy and HIV infection emerged. These included lipodystrophy, cardiovascular risks, diabetes risks and bone mineral density changes, among others. Issues of ARV drug resistance and cross-resistance became an increasing problem. Resistance testing and therapeutic drug monitoring began to be used. The terms “treatment failure” and “salvage therapy” became commonplace, as many PLWHA were not able to be stabilised on ARV treatment because of –

- toxicities and side effects;
- selection of sub-standard ARV regimens;
- ARV resistance and cross resistance; and
- treatment adherence problems.

These developments eventually led to a shift in treatment guidelines from early to deferred ARV treatment for PLWHA with asymptomatic HIV disease. So while falls in

³ Normally, section 100 drugs are provided through the hospital system and prescribed by specialists (or staff under their supervision).

morbidity and mortality are largely being sustained, this is within a more complex clinical management environment.

Adding to the picture is the growing number of ARV drugs. We currently have 19 ARV drugs available in five different classes. The new drug pipeline contains about 15 new drugs which look promising. There are a host of others in very early development. Within another 5 years there may be some 30 ARV drugs available in six different classes.

The challenge for physicians and GPs working in HIV/AIDS to keep up to date with new drugs and new scientific knowledge and incorporate this into management of their patients is substantial, to say the least. This was widely commented on in our discussions for this paper - even the most experienced clinicians talked about how complex HIV/AIDS had become for them.

2.4 Impact of Complexity on General Practice Viability

HIV complexity is impacting on the viability of general practice based HIV clinical care in a number of ways.

Firstly, HIV patients usually need longer consultations, but general practice remuneration is very much geared to shorter consultations. Recent increases in Medicare rebates simply maintain the disparity between short and long consultations. Some doctors believe the new Medicare Chronic Diseases Management Plan item will be helpful, but will not in itself overcome the larger disincentives playing out. Time restraints are also a factor when trying to provide on-going and multi-focussed care in a single consultation, such as a discussion about specific drug interactions and managing side effects.

Financial disincentives for GPs also impact on their capacity to offer bulk billing, which in turn affects a large number of PLWHA on benefits or low incomes.

Keeping up to date with developments in HIV treatment and care is also a considerable task. As well as time reading journals, etc, time involved in attending scientific conferences, training courses sponsored by ASHM, pharmaceutical industry educational events, also impacts on general practice remuneration for training, even when certain sponsorships are provided. For practices with small HIV caseloads, the motivation and/or opportunity to acquire and put all this information into practical use is obviously limited.

Growing complexity is now impacting on the GP based HIV care model. A number of GPs have given up their ARV prescribing rights, or are considering doing so, because they find it impossible to keep up to date. There are difficulties in recruiting new GPs to become ARV prescribers, even among high HIV caseload practices.

ASHM has tried to deal with these developments through additional support and training for GPs, including looking at videoconferencing, tele-medicine and on-line programs. However, there is only limited funding for this. We encourage ASHM's ongoing development of primary care education, training and support: The Primary Care Think Tank which ASHM held in Sydney earlier this year provided a welcome opportunity for discussion. Likewise, Health Departments and regional health

services are trying various strategies. But so far the above trends have not been reversed.

Given all these factors, a recent NSW Health Department review concluded it is not feasible to expect significant numbers of GPs across NSW to maintain interest and/or skills in HIV medicine.^{xxiii} We agree with this finding, which is clearly applicable to other States and Territories as well. However, we think that through a different model, maintaining a sufficient number of GPs in HIV care provision is definitely feasible.

2.5 Drawing the Line – Defining ARV Prescribers

We believe there should be changes in ARV prescribing accreditation requirements to address increasing complexity, as part of a re-structured HIV clinical management model.

Earlier we described ARV prescribing mechanisms in the States/Territories and the role of ASHM in implementing them. ASHM plays a key role in the Australian HIV response and we received many favourable comments about ASHM's training and educational efforts as we researched this paper. However, there is a broad view that current training courses - while providing an excellent basic grounding in HIV medicine - are no longer sufficient to equip a doctor inexperienced in HIV to manage the complexities of ARV prescribing. We also received comments that training and accreditation requirements for current ARV prescribers should be upgraded, in light of complexity.

We agree with these comments. We also believe ASHM should continue to have the central role in this upgraded training framework, with the Commonwealth and State/Territory governments enhancing ASHM's capacity to do so.

In the current complex environment, management of HIV disease and ARV treatment requires not only substantial knowledge, but also an active PLWHA caseload. It is not in the best interests of PLWHA to have complex decisions about their HIV care and treatment made in low HIV caseload medical facilities, be they general practices, sexual health clinics or hospitals. This view is supported by a range of findings that patient outcomes are better when managed by experienced HIV clinicians in higher caseload settings^{xxiv xxv}.

"Physicians caring for a low volume of HIV-infected patients are more likely to provide suboptimal care than those caring for a high volume."^{xxvi}

Australian ARV prescribing accreditation systems do not set a minimum HIV caseload for clinicians – there is no definition of what makes an HIV "specialist". In contrast, in the USA there are various health department directives, professional medical society guidelines, Medicaid related criteria, and even laws and regulations, which define HIV "specialists". These policies specify training levels and the number of HIV patients that health providers need to directly manage in order to qualify for this classification.^{xxvii xxviii} The minimum number of "directly managed HIV patients" stipulated varies between at least 20 patients and 50 patients.

As part of upgraded training requirements, we believe it is time to introduce a minimum HIV caseload level for ARV prescribing accreditation - set somewhere

between 30 and 50 directly managed HIV patients. This change would be in the framework of a considerably strengthened model of co-managed care, which we describe below.

2.6 Meeting HIV Clinical Management Needs

We recognise the introduction of more rigorous ARV prescribing accreditation would continue the trend of low HIV caseload general practices and other sites moving away from direct HIV management. But we think this is inevitable anyway.

This shift will create pressure on high caseload specialist HIV sites (hospital, public clinics and general practice). Should numbers of PLWHA increase, as is likely, this will add further pressure.

So how will these increases be accommodated?

In general practice, expansion of the number of HIV specialising general practices (who of course also provide primary care), seems unlikely (see section 2.4). It may be that current high caseload practices can accommodate some new HIV clients, but there are anecdotal reports that some practices are nearing capacity.

For hospital in-patient and out-patient services and public clinics, there is an inherent capacity for expansion of services, providing funding is available (realistically expansion would likely occur in the same hospitals and public clinics currently specialising in HIV). Most clinicians we spoke to were optimistic about attracting trainee hospital physicians into the HIV field. Even so, expansion in hospital settings and public clinics is about providing specialist HIV clinical services: it is not about primary care provision.

The risk is that without policy intervention, HIV clinical management for PLWHA living in regional and country areas will become increasingly difficult to access locally, necessitating travel to HIV specialist sites in major cities.

There is also the issue of broader health care to be considered, which has become much more important as PLWHA live longer. This issue affects both PLWHA in major cities as well as those in regional and country areas. We believe that many PLWHA are not clear about who has primary responsibility for their overall health care – is it their GP or HIV specialist? As a result, both HIV and non-HIV related problems may not always be managed effectively because neither health care providers or patients are clear about who is taking on the role of overall clinical management and coordination.

“People with HIV should have access to good quality primary healthcare provided by local networks, that are sensitive to the needs of those living with HIV.”^{xxix}

“HIV is increasingly managed as a chronic disease, with many more patients surviving for longer periods. This is shifting the emphasis of care towards partnership between specialist centres and primary care.”^{xxx}

2.7 A Strengthened Model of Co-managed Care

To address these challenges, we believe the future priority should be on –

1. Expanding HIV specialist ambulatory care services in public hospitals and public clinics as necessary.
2. Supporting existing high HIV caseload general practices to remain involved in HIV/AIDS, including support to mentor new HIV specialising GPs within these practices.
3. Implementing a better defined, formal, and better resourced co-managed model of care between lower HIV caseload sites (in general practice, public clinics, hospitals) and high caseload HIV specialist sites (in general practice, public clinics, hospitals).
4. Implementing strategies which maximise opportunities for non S100 GPs to participate in co-managing PLWHA health care with HIV specialist clinicians (located in general practice, public clinics, hospitals).

“Existing models of shared care for other chronic conditions need to be reviewed for their potential application to HIV medicine. In particular attention should be given to the relationship between the GP and specialist (clarification of respective roles and referral protocols) and the adequacy of Medicare rebates for care coordination.”^{xxxix}

In particular, we think immediate priority should be given to defining and implementing a better co-managed model of clinical care for PLWHA. Supporting this are two NSW Health Department reviews which comment on lack of clarity in the nature of shared care arrangements between specialist services and GPs⁴.

There are initiatives in Queensland, Victoria and NSW which should be considered in formulating this shared care model:

- Some clinicians in Queensland are discussing a shared care model which would provide “funnels of shared care” between GPs, clinics, hospitals and specialist HIV sites. This model would emphasise expert opinion and review; access to experimental HIV treatments; and research participation. Funding may be provided to enable patients to travel to expert HIV sites (intrastate and interstate) for expert review and/or clinical trials.
- In Victoria, the Victorian HIV Consultancy provides State-wide support to PLWHA, their carers and health professionals. There is a team of three: an infectious diseases physician, a clinical psychologist and a clinical nurse consultant. A multidisciplinary team approach is taken for the care of clients, including support of complex care clients integrating acute, continuing and palliative care.
- In NSW, the AIDS Council of NSW Enhanced Primary Care Project provides project officers to work with GPs in coordinating access to services for PLWHA living in inner-city Sydney. A similar project

⁴ A 2000 Review documented this problem and the 2005 HIV/AIDS Care & Treatment Needs Assessment noted (p54) that “no formal protocols appear to have been put in place, for instance to provide guidance on when referral is indicated. Consultations for this project suggested that little has changed, particularly around clinical trials, competition for the same patients, and hospital discharge summaries.”

operates in Northern NSW. A GP liaison officer also works in inner city Sydney to help coordinate care. Regional clinics supported by visiting HIV specialists operate in some country areas (e.g. Greater Murray area).

The recent NSW HIV/AIDS care and treatment needs assessment^{xxxii} also proposed several strategies that could help improve co-managed care, including:

- targeted recruitment of GPs to become involved in primary health care for PLWHA ;
- consistent referral of patients back to general practices for the patient's ongoing primary care needs;
- travel and accommodation assistance for GPs to attend HIV training courses on co-managing PLWHA health care with HIV specialists;
- more engagement with Divisions of General Practice; and
- exploring further strategies with ASHM, the RACGP, RACP and the ACSHP.

Two key issues which would need to be clarified in this co-management model include:

- i. the level of HIV monitoring to be done in lower caseload general practices and other clinics (e.g. should this include CD4 counts, viral load, and other monitoring tests?) and the level of training needed for this monitoring; and
- ii. whether a system of ARV prescribing limited to writing continuation scripts is needed for lower HIV caseload practices and other clinics.⁵

Most importantly, there must be comprehensive planning, support, incentives and funding provided by Health Departments to make this model work.

2.8 Quality Assurance

Most people involved in HIV/AIDS have from time to time heard complaints about alleged sub-optimal care and poor clinical decision-making. Some of this may derive from misinformation or even professional jealousy. However, mistakes and mismanagement do occur and these have resulted in detrimental outcomes for some PLWHA .

As complexity in HIV increases, so does the importance of quality assurance systems and review, such as clinical audits. Both doctors and patients benefit from these measures.

In researching this paper, we were updated on a number of strategies in hospitals and private clinics which provide a formal, rigorous way of reviewing HIV treatment and care decisions. However, in other settings caring for PLWHA (both public and private), quality assurance and review mechanisms are reportedly less rigorous.

⁵ There were various opinions on this. A two tiered prescribing system (initiating and changing Rx vs continuation prescribing) is operating for Roacutane in dermatology and MS Contin in pain management. However, most thought a two tiered system would not be necessary and that good communication systems between lower caseload providers and HIV specialists should ensure that PLWHAs did not encounter problems obtaining continuation ARV scripts.

It is beyond the scope of this paper to analyse quality assurance and clinical governance as they relate to HIV care. However, we do believe in this more complex HIV care environment that there is a need for Health Departments, Colleges, ASHM and NAPWA to review this issue and consider providing more specific quality assurance guidelines.

2.9 Conclusion

We believe that the changes proposed in this part of our paper will not only improve the overall quality of clinical and ARV management, but will also provide a reasonably equitable system of access for PLWHA in both urban and country areas. In particular, a much stronger emphasis on co-managed care should not only assist health care providers to manage the complexities of HIV disease, but also enable PLWHA to receive the broader health care they will need in the years ahead.

PART 3 – COMPLEXITY & CLINICAL RESEARCH

3.1 Introduction

An effective HIV research model is essential to optimize Australia's responses in clinical care, treatment, health promotion, and other areas.

Over the last 20 years, Australia has put in place good policies and programs to support this research effort. As a result, Australia has built an outstanding record in HIV research that is internationally recognised. Our contribution to HIV virology, immunology, clinical management, HIV prevention and social impacts is very substantial.

However, increasing complexities associated with HIV/AIDS described in Parts 1 and 2 of this paper are now impacting on HIV research, both here and in other countries. In this Part of our paper, we discuss these complexities and propose several changes we believe are needed to strengthen Australia's HIV clinical research model.

3.2 Australian Research Model & Environment

3.2.1 Partnership in Research

Before discussing complexities in research and possible solutions to them, it is important to look at the context of Australian HIV clinical research and consider how it is organised and accessed.

A key feature of Australian HIV research is the strong partnership between PLWHA advocacy organisations, affected communities, researchers, the pharmaceutical industry and regulators. This partnership didn't just happen – it had to be built. At times the partnership has been tested by conflict, especially in the early years of the epidemic with its crises, frustrations and despair. But the partnership has lasted and delivered much to the Australian HIV response.

3.2.2 The National HIV/AIDS Strategy

Each of Australia's National HIV/AIDS Strategies has supported a strong research effort. Commonwealth funding supports national HIV research centres in clinical/epidemiology; virology; and social research. The Centres have made major contributions to scientific knowledge, which is widely acknowledged internationally.

Additional Commonwealth Government funding has also been provided for commissioned research, competitive grants, and investigator initiated NHMRC grants.

"A 'research environment' should be fostered that effectively links researchers; health professionals; non-governmental organizations; people living with HIV; vulnerable groups; policymakers; and business. These partnerships are necessary to help ensure the relevance of research questions and to promote understanding of research processes. They also help ensure that ethical issues are fully addressed." xxxiii

In the 1980s, the National Centre in HIV Epidemiology and Clinical Research (NCHECR) began forming a research network of general practices, hospitals and other clinics throughout the States/Territories. This network is a vital component of NCHECR's operations and continues to deliver important benefits, including:

- providing a structure to encourage cooperation between researchers and community based organisations.
- developing research skills in general practice and other settings.
- facilitating reasonable equity of access to clinical research through sites in most States/Territories (an important way for PLWHA and their doctors to obtain access to some experimental treatments).

As well as consultation mechanisms within NCHECR itself⁶, the Commonwealth Health Minister's HIV/AIDS advisory committee (and its research sub-committees) have also provided opportunities for stakeholders to discuss research policy and participate in priority setting. Various State/Territory Health Departments have also encouraged this consultative approach.

3.2.3 Independent Research

High quality research has also been done outside the NCHECR and its network, with some researchers setting up their own collaborations. This kind of diversity and competition is obviously important. In most cases, these independent researchers and research groups have consulted PLWHA organisations about research proposals, to the benefit of both sides.

3.2.4 The Pharmaceutical Industry

The pharmaceutical industry is of course a key player in research. Industry sponsored trials of new therapies and new therapeutic approaches are very important for PLWHA and their doctors, especially where there is progressive disease and few or no treatment options available. Industry provides funding for investigator initiated studies conducted by NCHECR and to researchers based in hospitals, government funded clinics and private practice.

From NAPWA's perspective, relationships with industry are very important, particularly in areas of research planning; compassionate access to experimental drugs; drug approval and PBS listing; and support for education and information initiatives for PLWHA.

Despite conflicts over treatment access in the 1990s, relationships between industry and PLWHA organisations have been consistently attended to, and the relationship is generally characterised by a high level of communication and consultation, including in the very early stages of research development.

Industry also supports community based initiatives like the AIDS Treatment Project of Australia and the Treatment Officers Network, through educational grants. This helps provides PLWHA with the information to make informed choices about treatment and clinical trial participation.

⁶ e.g. the NCHECR system of research working groups; its scientific advisory committee; meetings with the Director and senior NCHECR staff.

Industry also benefits from community relationships: For example, reforms of the CTN/CTX clinical trial system and the drug approval process achieved through HIV community advocacy in the 1990s deliver many benefits for industry - beyond just HIV/AIDS itself. The community's continuing work around drug approval processes and PBS listing, as well as education and training for PLWHA and others, has flow on benefits to industry. Industry also benefits from consultation with community through information exchange that can inform their own work and practices.

A good feature of the Australian response has been the generally collegiate relationship between pharmaceutical companies operating in HIV. There are regular meetings between product managers which focus on areas where companies might work together to assist the Australian response – this might involve joint educational events, support for research studies, and strategic communications about scheduling of activities and events.

In working with other stakeholders, the pharmaceutical industry has made its own important contribution towards the effective, generally transparent and consultative research environment in Australia.

3.3 Impact of Complexity on HIV Clinical Research

Many of the changes and complexities associated with HIV/AIDS described in Parts 1 and 2 of this paper impact on HIV related research. In addition, there are some specific problems to do with consultation, communication, funding, ethics and access, that could undermine Australia's HIV clinical research environment if not addressed.

In preparing this paper, we identified seven areas of complexity affecting HIV clinical research which we think need responding to. These are:

- 1) The burgeoning new ARV drug pipeline.
- 2) More pharmaceutical companies entering the HIV field.
- 3) More industry funded HIV research in private practice.
- 4) Concentration of research in a smaller number of clinical sites.
- 5) NCHECR & Cohesiveness of the NCHECR research network.
- 6) Ethical and transparency issues.
- 7) Information to PLWHA about research and treatment options.

In the remainder of this section, we explore these issues and propose options for addressing them.

3.3.1 The Burgeoning new ARV drug pipeline

This is a very optimistic time in new ARV development. We have around 20 ARVs available now. It is quite probable we could have 30 ARVs available in 6 different classes within the next 5 years.

New drug development will generate more research about the drugs themselves and their strategic use in clinical management. So there should be good opportunities for Australian HIV research, providing we remain an attractive site and are competitive with other researchers in other countries.

However, the growing number of ARV drugs – approved and experimental – will make some clinical studies more complex, especially those involving highly ARV experienced patients. Also, unexpected toxicities and clinical events may yet unfold for some of these new drugs, particularly those in entirely new classes: This will have to be factored into study design and monitoring.

Some of these ARV studies will be specialised and may only involve relatively small numbers (e.g. pharmacokinetic studies). Others may be multi-centre and multi-national, but the number of places allocated to Australia could be very limited (especially in phase I/II type studies). For many of these ARV development studies, a higher level of research expertise will likely be required of sites.

Realistically, this will mean that the number of sites with the capacity (and in some cases the patient numbers) to do this specialised type of research will be limited. We are already seeing this trend in Australia, although we don't believe its impact is widely understood by PLWHA and some of their health providers.

On the other hand, there should be opportunities for fairly wide participation in research looking at issues like different clinical management approaches. These are the type of "real life" studies that can often be more reasonably picked up through the networks and which support standard clinical care procedures.

3.3.2 More Pharmaceutical Companies Entering the HIV Field

A relatively small number of pharmaceutical companies operate in the HIV market, but this is changing. More companies are getting involved and while there may not always be major windfalls with ARV drugs, there are obviously good returns to be made.

The entry of new pharmaceutical players has many positives. It demonstrates the importance and prestige industry places on being involved in HIV. Most importantly, competition leads to better drugs and more choice for consumers and their doctors.

The limited number of companies operating in HIV in Australia has made it somewhat easier to maintain good stakeholder relationships. However, more industry players could make the interactions between clinicians, researchers, regulators and PLWHA organisations more of a challenge. More effort and monitoring will be needed to maintain Australia's relatively well coordinated, consultative and transparent research environment.

Recent communication problems have emphasised this need: some studies of new ARV drugs have been set up without prior consultation with the usual stakeholders, including the community. HIV clinics and practices not involved in these studies were not aware of them either, thus limiting the possibility of involving patients in these trials (especially PLWHA patients with treatment failure requiring urgent access to new ARVs).

The companies concerned - either new to HIV in Australia or where the Australian company affiliate has not been directly involved in the Australian study activity - have not been aware of how the Australian HIV research model operates, especially apropos consultation with PLWHA and other community organisations. But steps

should be taken to avoid such incidents, which cause considerable friction and confusion among PLWHA organisations, other community organisations, clinicians and researchers.

We believe there is a need to look at how good consultation and communication can be fostered as more pharmaceutical companies enter the HIV field. From a NAPWA perspective, this would mean not only strengthening industry relationships here, but also building up the ones we have overseas.

Cooperation is often based around individual relationships in industry and in the community. However, given growing complexities in HIV research and clinical care, plus the fact that personnel move in and out of the community, research and industry sectors, we think it is time to look at formalising aspects of the industry-community relationship.

We propose that each of the pharmaceutical companies and NAPWA should consider an accord or memorandum of understanding, which would set out principles of communication and cooperation by which both sides would aim to operate. A clear description of the relationship and expectations on both sides would help sustain cooperation, communication and transparency over the long-term - beyond a reliance mainly around individual relationships themselves.

We also propose that regular roundtables between community and industry would be beneficial to exchange views and look at ways to cooperate. This would be in addition to ongoing one on one interactions between pharma and PLWHA advocates.

3.3.3 More Industry Funded HIV Research in Private Practice

In recent years there has been a trend to more pharmaceutical industry funded clinical studies conducted outside the NCHECR network, including private practices with large HIV caseloads.

There are several reasons for this trend, including – more pharma and therefore more trials; the large number of PLWHA in private practices; increased HIV research experience among some GPs; the initiative of researchers themselves; and from the pharma perspective, opportunities to have very targeted recruitment and site arrangements, which is likely to be more cost effective than involving sites with low patient numbers.

“Our results raise some significant concerns. The first is the apparent high level of industry-supported research being conducted by medical specialists working substantially or exclusively in private practice. Hard questions are now being asked about who oversees clinical research and the integrity of research publications and their authorship. We believe that professional organisations, institutions, and practitioners themselves, need to ensure that mechanisms are in place to ensure appropriate governance of clinical research when it is conducted substantially in the private arena.”^{xxxiv} ”

Most of these studies involve new ARV agents, and are organised by overseas based pharmaceutical companies through their local offices or representatives. However, sometimes studies are being negotiated directly between local researchers and off-shore pharma.

In section 3.3.2, we discussed the importance of industry consultation apropos research proposals. But we see this as a dual responsibility – for researchers, as well as pharma.

When studies operate through NCHECR, there are in-built consultation mechanisms, which generally work well. However, with more research being done outside NCHECR - particularly in private practice – consultation channels between researchers and community should be clarified in the interests of all concerned.

There are also some ethical questions associated with industry sponsored research in private practice which need to be acknowledged, such as the level of dependence on pharmaceutical industry funding by some private practices. Some practices freely admit that pharma funding is now important to their viability as HIV clinical practices.

As mentioned earlier, we very much support the participation of private practice based researchers in HIV. This helps build a diverse, dynamic and competitive research environment. However, as for institutional based research, good transparency and consultation measures are needed. In the previous section we suggested an accord between NAPWA and pharmaceutical companies. We believe that a similar accord or memorandum of understanding between researchers and NAPWA would also be helpful, delivering benefits to both sides.

We also propose that there should be a roundtable meeting between researchers, industry and community in the early stages of study planning. This would provide a forum to discuss the study itself, recruitment strategies and any potential ethical issues.

As we see it, these kinds of measures will all help to prevent confusion and conflict, which if left unaddressed will ultimately impact on the Australian research environment, making this country a less attractive place to do HIV research.

3.3.4 Concentration of research in a smaller number of clinical sites

Reasonable equity of access to clinical trails has been a feature of Australian HIV research – particularly for trials of experimental drugs. A range of research sites around the country have been involved - hospitals, health department clinics and private practices.

However, there is now a trend towards concentration of research in a smaller number of clinical sites, particularly for pharmaceutical industry sponsored research. There are a variety of reasons for this, including –

- The impact of complexity on HIV research itself.
- Patient numbers (some sites may just not have enough patients for a study).
- Differing levels of research expertise.
- Infrastructure issues (e.g. nursing, other staff, and in-house capacity to support research).
- Changed focus of the NCHECR research program.

For some industry funded studies, a relatively small number of participants may only be needed (or allocated to Australia in multi-centre trials). Also, the research itself is

often more complex than previously, especially in relation to early phase I/II studies, which may involve things like complex pharmacokinetic questions and new drug targets.

Understandably, pharmaceutical companies are selecting sites with a research track record as well capacity to meet recruitment targets.

Equity of access to clinical trials is becoming more problematic as a result of these trends. However, there are a few realities to be faced. Firstly, as with clinical management of HIV, it is not desirable to have research in the hands of people who are inexperienced and unsupported. Secondly, because of complexity and specialisation, the trend to less rather than more research sites is probably inevitable - and in some respects even desirable: Research that fails because of inexperience or other difficulties is bad for PLWHA and bad for Australia's reputation as an attractive research site.

So how do we find a reasonable balance between equity of access and research expertise? As with clinical management, we think a different model is needed to respond to this evolving research environment.

The first component would be better transparency and communication between industry, researchers and community on questions of site location, access and research expertise needed for studies. The accords or memorandums of understanding we proposed earlier would provide a strong foundation for this to occur.

In Part 2 of this paper we proposed a strengthened co-management model to provide shared care between GPs, public clinics, hospitals and HIV specialist HIV sites. This model could be adapted to include access to HIV clinical research sites.

This model would not only apply to PLWHA in lower caseload clinics with little or no HIV research involvement. It would also involve HIV specialist sites who may not have a particular study, cooperating with one that does. This would require rivalries and tensions that characterise some health professional relationships being put aside in the interests of patients.

As for a shared clinical management model, this proposal will not work without planning, support, incentives and funding provided by Health Departments. Funding would also be needed to assist some patients to travel to expert HIV research sites (intrastate and interstate), when necessary: planning and projections on recruitment profiles would be important in factoring these considerations into study operations.

Knowledge about which clinical studies are available would also be important. At present, this information is only available on an ad hoc basis (we think this can be improved - see section 3.3.7). Also, some kind of coordination mechanism will be needed to support links between study investigators, PLWHA and referring clinicians.

3.3.5 NCHECR & Cohesiveness of the NCHECR Research Network

The role of the NCHECR is a key issue to consider as we look at the impact of complexity on HIV research.

NCHECR has made an exceptional contribution to scientific knowledge and clinical management. The Centre and its leadership brings many direct and indirect benefits – the Centre’s work and reputation is a major factor in keeping Australia at the forefront of HIV research, with benefits flowing to clinicians, other researchers and PLWHA .

The NCHECR research network has been an important part of this success. Through NCHECR skills levels in HIV research have been built up in sites where there was relatively little experience in or capacity for clinical research. A reasonable coverage of research sites throughout NCHECR has meant that access to research has been possible for PLWHA in lower caseload areas. This can also assist access to experimental therapies – a special need for people with progressive HIV disease with few or no treatment options left.

The review of the 4th National HIV/AIDS Strategy and the quinquennial reviews have very favourably evaluated the NCHECR and the other National Centres. Recently, the Commonwealth Health Minister extended funding for the Centres to end 2008 in light of this.

The NCHECR is of immense value to the Australian response to HIV/AIDS, even more so in a time of growing complexity in clinical care and research. Community cooperation and consultation with NCHECR, and the other Centres, remains strong.

We found wide support for the NCHECR. However, there were some concerns around direction, operations and communication which we feel should be commented on. These include –

- the direction of the research program, current and proposed (including a shift away from doing pre-marketing related ARV studies, which seems at odds with the Centre’s terms of reference ⁷);
- the effectiveness of current mechanisms for stakeholder input into the formulation of NCHECR’s research agenda;
- lack of communication about some aspects of programs, plans and priorities; and
- the NCHECR cost structures for studies and the level of support provided to research network sites.

There were also concerns that the NCHECR research network is becoming less cohesive, especially given current trends towards more industry supported research outside NCHECR. An irony here is that some researchers who have enhanced their research skills through the NCHECR network may now feel they do not need it as much, or at all.

The fact that processes for MACASHH to provide research oversight have not been finalised yet; that the NCHECR scientific advisory committee is only now being reconstituted by the Commonwealth Department of Health & Ageing; and that the system of NCHECR working groups is not particularly effective, has probably not helped NCHECR’s consultation and communication efforts. The addition of Hepatitis and STI research into the Centre’s brief may also have had an impact.

⁷ *NCHECR Terms of Reference – To review, evaluate, co-ordinate, participate in and provide assistance for, clinical trials of therapeutic substances for the treatment of HIV/AIDS.*

All research programs have ebbs and flows. Currently, the NCHECR program is very full and this has limited the number of new HIV trials that can be taken on, but we are aware that new studies and initiatives (like INSIGHT) are on the horizon.

The NCHECR is being affected by complexity like everyone else. It is therefore important that the concerns mentioned here are formally addressed, particularly in the areas of research program input and communication. Some re-appraisal of the NCHECR research network is probably needed, as new studies may not in themselves be enough to keep the network cohesive. We believe that NAPWA should use its good relationship with the Centre to assist in these areas.

3.3.6 Ethical and transparency issues

The pressures to advance HIV scientific knowledge and develop better treatments are immense, as the health and lives of many millions of people are at risk. These pressures impact on all research stakeholders – researchers, clinicians, the pharmaceutical industry, policy makers, regulators, patient advocates and research participants. Added to this is the complexity associated with HIV/AIDS, not only from a scientific point of view, but also because of multifarious social and cultural factors associated with the epidemic.

The confluence of these factors in the HIV research environment underlines the importance of ethics and transparency to all stakeholders. Without this, there are many potential pitfalls for research participants, health consumers and researchers themselves.

Review of study proposals by Human Research Ethics Committees (HRECs) is a fundamental part of an ethical and transparent research framework. The work of HRECs has been a very important factor in Australia's long and impressive research record.

As with researchers, clinicians and consumers, levels of understanding about HIV and HIV research issues will vary among HRECs. Some HRECs regularly review HIV research proposals and are reasonably familiar with the area. Some may have members with HIV/AIDS expertise. Other HRECs may have very little experience with the area.

HIV/AIDS is already a complex area for HRECs. However, new developments in HIV/AIDS science and treatments are further impacting on their work. Our discussions with ethicists and HREC members confirmed this view.

"When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship." xxxv

In our background discussions, doubts were expressed about the capacity of some HRECs to review some HIV studies as complexity increases. Also, as more studies are now emanating from GP practices - and people are living longer with HIV - consideration of primary care related issues have become very important. Linked to

this is the ethical dilemma of being the principal medical carer, as well as the researcher.

If there is no consultation by researchers or industry with community advocates prior to HREC application, the potential for ethical concerns increases. This is illustrated by three recent developments:

1. The first is reports of very high payments to study participants and per-patient recruitment fees to doctors. PLWHA groups were not consulted about these studies prior to ethics application, either by the researchers or the pharmaceutical companies involved. On the other hand, these studies have been through HREC review. This is very concerning, given the ethical implications that arise.
2. Multiple studies with high payment structures could create a perception of competition and possible conflict of interest for investigators recruiting to these studies.
3. The other development is the notable increase in advertisements appearing in gay community newspapers for research studies. Some of these advertisements are very large and are run repeatedly. The text for these advertisements has likely been HREC approved, but the size, graphics, frequency and their impact does not appear to have been considered with reference to any interested group or agency. We think that HRECs should require the full recruitment plan for studies, not just advertisement texts. If these promotional trends continue, the result is likely to be less recruitment, not more, because people are becoming bombarded in a confusing manner with study information in community media, newsletters, notice boards in clinics and other settings.

Over the past 20 years of HIV research, NAPWA and other community groups have rarely had to intervene at the HREC level. Most of the time, consultation by pharmaceutical companies and researchers has been very good, enabling differences over ethical and other concerns to be sorted out. We would hope that this approach will continue, and we believe that measures suggested in this paper, such as accords, would strengthen this.

"In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail." xxxvi

However, in light of the more complex HIV research environment - and the ethical issues that have arisen recently over some studies - we believe that NAPWA should now seek a formal relationship with HRECs involved in reviewing HIV studies. This would provide a safeguard should there be a breakdown in consultation. It is also likely that NAPWA could from time to time assist HRECs with their work, given NAPWA's knowledge of HIV research and treatments and close links with PLWHAs and affected communities.

"By 2003, ensure that all research protocols for the investigation of HIV-related treatment including anti-retroviral therapies and vaccines based on international guidelines and best practices

This kind of relationship is consistent with principles outlined in the NHMRC Statement on Ethical Conduct in Research (and Commentary)^{xxxix} as well as United Nations and World Health Organization policy statements on the advantages of HRECs having links with community advocates.

Given the special nature of HIV/AIDS, the idea of having a national HIV/AIDS ethics committee has been proposed from time to time. However, this has not been progressed for two main reasons. The first being that it would not obviate the need for most researchers to seek ethics approval from their linked institutions (e.g. their hospital or university). The other reason was that most research was conducted through the NCHECR and its networks, or by other institutions with close links to PLWHA advocacy organisations. This close liaison, plus oversight by the National HIV/AIDS Ministerial Advisory Committee (through a dedicated clinical trials/treatments sub-committee), was usually able to take care of most conflicts, including ones concerning ethical questions.

We believe it is time that some streamlining of the number of HRECs reviewing HIV clinical studies should be examined⁸. We also suggest that the idea of a national HIV/AIDS ethics committee should be reconsidered: Having one committee with recognised HIV expertise that all stakeholders had confidence in would have many advantages, including for those institutional HRECs who will still need to review studies, but who may not have HIV expertise readily available.

It is possible that a current HREC, such as the RACGP's National Research and Evaluation Ethics Committee, could take on a national role in HIV. The RACGP's HREC already considers HIV studies and has the obvious advantage of being familiar with primary care issues. We think that GPs involved in HIV research should be encouraged to use the College's HREC, because of its expertise in looking at research in the context of primary practice.

A full discussion of ethical issues in a more complex HIV research environment is beyond the scope of this paper. More work may be needed. However, we believe the initiatives we have proposed here, together with ongoing dialogue with ethicists, can to a large measure address ethical concerns and help maintain stakeholder confidence in Australian HIV research.

3.3.7 Information to PLWHA about Research and Treatment Options

A goal of the National HIV/AIDS Strategy is to provide information to and support for PLWHA in making decisions about their health. How this is best done is not always easy, because PLWHA obtain information about HIV treatment not just from health professionals, but from a diverse range of other sources, including community organisations, peers, the internet, newspapers and HIV newsletters.^{xi}

In Part 1 we discussed how complexity in HIV/AIDS can make it more difficult for PLWHA to make informed choices about their clinical care, treatment choices and participation in research. For HIV clinical research, this is made even more difficult if transparency, consultation and communication between stakeholders is lacking. The breakdowns we described earlier have caused confusion among PLWHA. They have also hampered the work of NAPWA and the community treatment officers network,

⁸ 20 different HRECs were involved in the CREST study.

because there has been little or no information to initially give PLWHA contacting community organisations about some studies.

The number of available ARVs, the number of new agents in the pipeline and the number of studies looking at these agents and at other questions, is daunting. Added to this are more study advertisements appearing in community newspapers, more notices in clinics, etc. Unless this “information overload” is addressed, there is the likelihood that some PLWHA will opt out of research altogether. Informed consent to research could also become compromised by complexity and confusion. In relation to this we should note comments about the Australian PLWHA population possibly becoming over-researched, especially in some high caseload practices and clinics.

The measures we propose to improve consultation and communication with researchers and industry should assist with these challenges. However, we think that other measures are needed. We have looked at the NHMRC sponsored clinical trials site which is now in the early stages of being set up. This is an important development and we understand that registration of all studies will eventually become compulsory. This register would provide a simplified point of access to research information for consumers, researchers and clinicians.

“Research misconduct and bias in intervention research could be markedly reduced if ongoing initiatives to register all trials at their inception, and ensure public access to trial protocols and all data generated by a trial, become successful.”^{xli}

However, the register has inherent limitations, especially the level of information that can be provided about studies, their aims and objectives. This is understandable given the register will have to encompass all Australian research.

Therefore we suggest that a specific HIV clinical trials site be set up, potentially by NAPWA, as soon as possible to provide more detailed information for PLWHA, other potential participants, clinicians, and researchers. This site should be user friendly and widely advertised through community newspapers, PLWHA and AIDS Council networks and newsletters, and through clinics and GP practices. Formal linkage with the NHMRC site, the NCHCR site, and with overseas HIV clinical trials registries should be explored.

Other initiatives which could assist PLWHA with their decisions about treatment, care and research decision making are discussed further in Part 4.

3.4 Sustaining the Research Environment

The efforts of stakeholders to create an environment conducive to high quality research has delivered many benefits to Australia’s HIV response. Although Australia’s model is not perfect, it is widely admired. We continue to be regarded as a very attractive place to do HIV/AIDS research.

However, our research environment could be seriously undermined if communication and cooperation between stakeholders becomes frayed. Other countries are improving their research effort and providing much stronger competition. And, as well as our advantages, Australia has some inherent

disadvantages from the point of view of HIV clinical research – a small population; a relatively small number of PLWHA; inadequate government funding for research; and a smaller pharmaceutical market by comparison with many other countries⁹.

The issues discussed in this part of our paper provide opportunities as well as threats. If they are not responded to, there is the potential for Australia's HIV clinical research environment to be seriously undermined, to the detriment of researchers, clinicians and PLWHA. On the other hand, there is the opportunity to actually strengthen our research effort by addressing them. We hope this section of the Paper makes a useful contribution to this process.

⁹ Pharmaceutical companies operating in Australia employ approximately 14,000 people, have a turnover of more than \$5 billion - about 1% of the global market - and export medicines valued at more than \$2 billion. Source: Medicines Australia (2005). <http://www.medicinesaustralia.com.au/>

PART 4 – COMPLEXITY & NAPWA’S RESPONSE

4.1 Role of NAPWA in Health, Treatment & Research

The centrality of PLWHA in the planning of Australia’s response to the epidemic is a fundamental principal of the National HIV/AIDS Strategy^{xliii}, which is widely accepted by stakeholders. This approach has contributed greatly to Australia’s successes in treatment, care, prevention and research.

The Strategy endorses NAPWA’s role as the peak body representing PLWHA and its responsibilities to advocate on behalf of PLWHA. The Australian government supports NAPWA in this role, including through funding for policy and advocacy work.

NAPWA participates in the Ministerial Advisory Committee on HIV, Sexual Health and Hepatitis C (MACASHH); the Intergovernmental Committee on HIV, Hepatitis C and Related Diseases (IGCAHRD); and other governmental advisory committees, as well as the National research centres’ scientific advisory committees and working groups. NAPWA’s members are significantly involved in State/Territory HIV strategy and policy planning.

“This Strategy recognises the overriding importance of the participation of PLWHA in policy and program development, implementation, monitoring and evaluation. This participation is necessary for the effectiveness of responses, because it ensures that policies and programs are informed by the experiences of PLWHA, are responsive to need, and take adequate account of the full range of personal and community effects of policy directions.” xliii

Policy and advocacy on health, treatment and research is at the core of NAPWA’s work, because these issues are paramount for our members. This is reflected in the high priority given to this area by the NAPWA CEO, as well as through the work of the NAPWA Health Policy Analyst, and other NAPWA staff. NAPWA’s Health, Research & Treatments Portfolio provides strategic advice and carries out a large amount of policy and advocacy work for NAPWA.

In treatment education, NAPWA auspices the AIDS Treatment Project of Australia (ATPA), which has been very successful in supporting PLWHA to make informed choices about their health and treatment. The ATPA also provides training courses for others involved in the HIV sector, including the pharmaceutical industry.

4.2 NAPWA’s Response to Complexity

Like everyone else, NAPWA is feeling the impact of increasing complexity in HIV/AIDS clinical management and research. In preparing this paper we thought it essential to look at how NAPWA can strengthen it’s work to respond to this challenge.

Most people we spoke to were very supportive of the advocacy and policy work of NAPWA and its members. There were some criticisms, as should be expected, and useful ideas put forward about how we could operate better.

In relation to clinical management and clinical research, we identified seven areas where NAPWA should consider new approaches to strengthen its work. They are:

- i. Treatment Information.
- ii. Clinical Trials Information.
- iii. Communication with other stakeholders.
- iv. Communication with PLWHA and NAPWA members.
- v. Communication with Human Research Ethics Committees.
- vi. Overseas Linkages.
- vii. Building Capacity for Treatment & Research Advocacy

These areas are discussed below.

4.2.1 Treatment Information for PLWHA

The provision of community based treatment information for PLWHA is sometimes ad hoc. There are full-time treatment officers in Victoria, NSW and Queensland. In other States/Territories, the provision of treatment information is only part of a wider set of duties in various staff positions. Many clinicians and other health professionals have only limited time to provide treatment and research information.

NAPWA supports a network of community based workers involved in the provision of treatments related information and/or support to PLWHA in their respective jurisdictions - and provides regular meetings which offer training and information updates. Even so, there are often fairly big gaps in treatment and research knowledge between workers in the network (known as the TON – treatment officers network). Also access to these workers can be limited when the treatment provision role is only part-time.

With growing complexity in treatments and research, we believe it may be time to consider a dual level approach to treatments information provision. This could involve locally based treatment officers and/or support workers referring PLWHA with complex inquiries onto a dedicated treatments information telephone line, auspiced by NAPWA. This national, free-call information line could be staffed on a rostered basis by full-time treatment officers and others with high level treatment information experience around the country. A website based question/answer treatments information service could also be set up by NAPWA to complement other support initiatives and assist people with information access options.

This would not mean the end of the TON, nor discontinuation of treatment information responsibilities among PLWHA groups and AIDS Councils – rather the opposite. We see the TON network as being crucial in providing information on locally based clinical services and local sites for HIV research participation. The upgraded system we propose would streamline treatment information access for PLWHA and provide a formalised referral path for complex inquiries, particularly in States/Territories with part-time workers and/or support officers wishing to have specialised referral options as back up for their work.

4.2.2 Clinical Trials Information

In Part 2 we suggest a HIV specific clinical trials website could be set up by NAPWA to provide information on research for PLWHA, other potential participants, clinicians,

and researchers. This website should be user friendly and widely advertised through community newspapers, PLWHA newsletters, and AIDS Council networks and publications, as well as clinics and GP practices. Formal linkage with the NHMRC clinical register website and with overseas HIV clinical trials registries should be explored. There is also the possibility that information about social and other research related to HIV could be part of this website directory.

A link to the treatments information line proposed in section 4.2.1 could be provided for research inquiries, as well as contact details for the specific study coordinators and/or investigators.

4.2.3 Communication with Non-Government Stakeholders

There are clear processes for NAPWA to communicate with governments and with HIV community based organisations. However, the best way of communicating with other members of the HIV partnership is not always as straightforward.

Our discussions for this paper underscored the value of organising time to talk with other stakeholders about work, problems being faced and new approaches. This is particularly so for our partners in research, clinical care and industry, where much of NAPWA's work is focused. Unfortunately, opportunities to do this are rare because of the pace and volume of work in the HIV sector.

We believe NAPWA needs to communicate with stakeholders in a more regular, structured way because of increasing complexities in HIV: Here the accords we propose with researchers and industry could spell out how this should best occur. Communication with other health professionals is also important: Here roundtables, forums hosted by NAPWA and other initiatives should be considered, as well as one on one meetings.

In this paper we argue for better consultation with NAPWA about research proposals. In turn, this will require NAPWA ensuring it is able to respond in a timely and coordinated way to requests for input from researchers and industry - and inform stakeholders of the appropriate consultative processes they should use within NAPWA.

4.2.4 Communication with PLWHA and NAPWA members

It is essential that NAPWA engage with it's members about growing complexities in HIV/AIDS clinical care and research, and changes that might be needed to address them. This paper is designed to stimulate these discussions, but a communication strategy will be needed to facilitate this. We propose to continue these discussions through the NAPWA membership and it's governance mechanisms. We also believe it is crucial to inform PLWHAs about growing complexity in clinical care and research and the implications this may have.

4.2.5 Communication with Human Research Ethics Committees

In the previous section we proposed formal relationships be established between some HRECs and NAPWA. There are already indications this would be welcomed. However, mechanisms will need to be in place so NAPWA is able to respond promptly to invitations from HRECs for input.

The possibility of NAPWA providing an independent sounding-board for potential research participants may also merit consideration. This might be particularly useful where there is a dual doctor-researcher relationship with the patient. How this might be facilitated and resourced needs further thought. Another proposal put forward has been for an information sheet to be prepared for research participants, which would also provide clarification about patient payments, recruitment Q&A points and where to obtain further independent information.

4.2.6 Overseas Linkages

The increasing number of pharmaceutical companies involved in HIV means NAPWA will need to make new industry relationships overseas, as well as in Australia. Some new drugs are being developed by companies with no local representation. For drugs which look particularly important, NAPWA should establish links with overseas companies as early as possible. Again this will have planning and resource implications.

NAPWA already has an extensive links with overseas treatment advocates, treatment information organisations, global and regional PLWHA networks, as well as relationships within WHO and UNAIDS. The importance of these relationships increases as treatments and research advocacy becomes more complex.

4.2.7 Building Capacity for Treatment & Research Advocacy

NAPWA like everyone else faces budget constraints and a broad and increasingly complex set of operations and responsibilities. However, even so, we think it essential that NAPWA's capacity in treatment and research policy and advocacy is strengthened, so it is able to respond to the complexities discussed in this paper.

This will likely involve staffing and resource implications. It will also mean efforts to involve more volunteers in NAPWA's treatments work - and ensuring support for them to do so. The complex nature of HIV treatments policy and advocacy work will not make this easy, but it is important that new advocates are brought into this increasingly demanding area of NAPWA's work.

These issues will need to be discussed within NAPWA itself and with NAPWA's members. NAPWA's Strategic Plan gives strong priority to treatment and research advocacy – so the key question will be how best to provide an enhanced capacity

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- ^{xxxv} World Medical Association Declaration Of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2004) (Paras 23, 28).
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- ^{xxxvii} Declaration of Commitment on HIV/AIDS: Adopted by the UN General Assembly Special Session on HIV/AIDS (June 2001) (para 74). Australia co-facilitated the development of this Declaration.
- ^{xxxviii} The WHO Global Health Sector Strategy for HIV/AIDS also calls for the "establishment of mechanisms for ethical review of research proposals, which includes involvement of PLWHA and caregivers." (p34-35).
- ^{xxxix} NHMRC Statement on Ethical Conduct in Research and the Commentary (Australia): www.nhmrc.gov.au/publications. See also the special appendix to the Commentary which deals with HIV/AIDS research.
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