

## [30 years of AIDS]

# ***Revolutionising HIV Prevention and Maximising Treatment Impact in Australia***

## **[Meeting our Commitment to Implement the 2011 United Nations Declaration on HIV/AIDS]**

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### **1. INTRODUCTION**

The global fight against AIDS is at another crossroad. On the one hand, we now have the knowledge and the means to drive down new HIV infection rates, accelerate progress in reducing illness and deaths from HIV and for the first time contemplate the prospect of a world without AIDS.

On the other hand, there is weariness and complacency after 30 years of the epidemic, plus a global financial crisis impacting national budgets, just at the very time when fully investing in HIV prevention and treatment can dramatically change the course of the epidemic.

*30 years of AIDS -*

- *30 million lives lost.*
- *34 million people living with HIV.*
- *7000 new infections every day, mostly among young people.*
- *For every one person put on HIV treatment, another two become infected.*

*[Source: UNAIDS, 2011]*

How the world reacts to this dilemma will affect the lives of many millions of people around the world. Once again we need the kind of leadership and community resolve seen at other key moments in the epidemic's history, so we make the right decisions in this challenging, but exciting time.

#### **1.1 Aim of Paper**

This paper proposes that Australia implement a series of new policy and program actions, supported by bold time-bound targets for achieving them, to revitalize our response to HIV. These actions are based on important developments in HIV prevention and treatment which this paper highlights, as well on the measures endorsed by all countries under the 2011 United Nations Declaration on HIV/AIDS<sup>1</sup>.

This paper focuses on HIV prevention and treatment in Australia, particularly among men who have sex with men, as this population remains overwhelmingly the most affected by HIV in Australia and at high risk of new HIV infections.

This focus on prevention and treatment does not diminish the importance of other challenges, including promoting human rights and addressing discriminatory

policies, laws and community attitudes. This is central to creating an environment in which HIV prevention and treatment work.

For practical purposes, this paper has separate sections on prevention and treatment – but in reality HIV treatment and prevention must now be inextricably linked: well integrated treatment and prevention programs are critical to a successful HIV response, be it in Australia or anywhere else.

The aim of this paper is unequivocal and ambitious:

- to dramatically drive down rates of new HIV infections in Australia; and
- to maximise the health prospects for Australians living with HIV,

so as to achieve virtual elimination of HIV and AIDS in Australia and to sustain that achievement indefinitely.

This is the goal envisioned by the 2011 UN Declaration on HIV/AIDS - and it is a goal that Australia is well placed to achieve.

### **2. UNITED NATIONS DECLARATION ON HIV/AIDS – IMPLICATIONS FOR AUSTRALIA'S HIV RESPONSE**

#### **2.1 Overview**

In June 2011, the United Nations agreed to a new Declaration to fight AIDS, building on earlier Declarations adopted in 2001 and 2006.

The centrepiece of the 2011 Declaration is bold new HIV prevention and treatment targets for the global community to reach by 2015. These global targets include reducing sexual transmission of HIV by 50%; reducing HIV transmissions through injecting drug use by 50%; and eliminating mother to child HIV transmissions – all by 2015. The Declaration also sets a target of having 15 million people living with HIV in low- and middle-income countries on antiretroviral treatment by 2015.

So how will these targets be achieved under the UN Declaration? Firstly, by dramatically scaling up prevention programs and targeting them at populations at higher risk; by widely promoting HIV testing; by expanding HIV education and ensuring wide availability of condoms and sterile injecting equipment; by implementing harm reduction approaches; by promoting male circumcision in certain contexts; and by mobilizing communities,

particularly through exploiting new technologies for communication and connecting people – such as social media, mobile phones and the internet.

Finally, the Declaration calls for countries to act on new scientific evidence that has emerged about the health benefits of earlier HIV treatment for HIV positive people – and the additional prevention benefits that treatment can deliver. So just as HIV treatment was revolutionized 15 years ago by combining different drugs – termed “combination treatment” – the Declaration heralds an era of “combination prevention”, where proven prevention programs and communication innovations are combined with wide availability of HIV treatment to drive down new HIV infections.

## 2.2 Funding the global HIV response

The UN Declaration recognizes the added costs associated with fully implementing the UN Declaration, but also recognizes that investing now will pay great dividends in the future.

Figure 1 depicts the financing needed to fully roll out a new investment framework for 2011–20 in low-income

and middle-income countries, as proposed by Schwartländer et al<sup>2</sup> and endorsed by UNAIDS. In this model, resource needs increase from present rates of about US\$16 billion to peak at US\$22 billion in 2015.

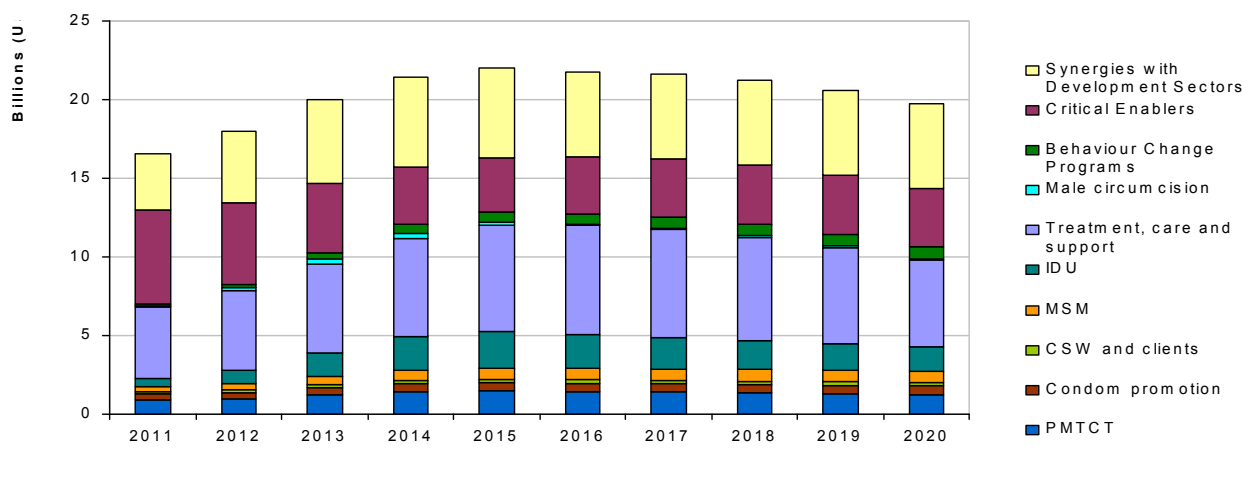
However, by investing now to comprehensively scale up HIV programs, Schwartländer and colleagues predict that by 2016 HIV funding levels will plateau and then start to fall as infection rates decline, along with treatment and care costs.

Failure to act now will inevitably result in far greater costs in the future, both health care costs and the economic and societal impact on millions of individuals and their communities around the world.

*“The world cannot live up to the targets and spirit of the UN Declaration on HIV/AIDS unless countries and donors commit to using the tools available, focusing them on the most effective programmes and investing accordingly.”*

*Michel Sidibé, UNAIDS Executive Director*

Figure 1 – Estimated cost of investment framework 2011-2020<sup>2</sup>.



## 2.3 Australia’s leadership role

Australia played a pivotal role in negotiating the 2011 UN Declaration on HIV/AIDS and obtaining agreement of all UN Member States to adopt it.<sup>3</sup> Consequently, we will be expected to show leadership in implementing the Declaration’s commitments domestically and championing its implementation internationally.

Australia should now systematically update our domestic and international HIV strategies and policies to align them with the UN Declaration’s commitments, in consultation with key stakeholders.

## 3. NEW DEVELOPMENTS IN HIV TREATMENT

The past five years have seen significant advances in scientific understanding of HIV and its treatment and prevention. These advances have exciting implications for HIV policy and strategy and suggest that we are entering a new chapter in the fight against AIDS, where HIV disease progression can be halted and HIV

transmissions dramatically reversed - and in some areas eliminated.

### 3.1 Early treatment of HIV – for individual benefit

The impact of HIV antiretroviral (ARV) treatment in preventing disease progression and prolonging life has been demonstrated all over the world.

While the benefits of ARV treatment are uncontested, the question of exactly when to start taking treatment (“how early should early ARV treatment be?”) has not been answered definitively, and therefore is a focus of continuing research and debate.<sup>4</sup>

Three large observational cohort studies<sup>5 6 7</sup> have suggested clinical benefit in starting ARV treatment above 350 CD4 cells, but the magnitude and thresholds for benefit were quite different. The CASCADE<sup>8</sup> observational cohort study found clinical benefit in starting treatment at less than 500 CD4 cells, but not in the 500 to 800 CD4 cell range.

Expert opinion on “When to Start” at higher CD4 counts is often divided, but opinion does seem to favour earlier treatment, including because studies such as CASCADE have not shown any harm in this approach and because of the additional prevention benefit that being on treatment can deliver (see section 4).

Recommendations on when to start treatment made in the *US DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*<sup>9</sup>, which is the main guideline reference used in Australia<sup>10</sup>, have attracted some controversy. These guidelines recommend HIV treatment for all people with CD4 counts of 500, raising the treatment threshold from a CD4 count of 350 or less. For people with higher CD4 counts (500 or above), the guidelines authors are divided between recommending these patients start treatment immediately or that treatment should be optional and considered on a case-by-case basis.

These recommendations are based on findings that HIV related sickness and death is not only caused by immune deficiency, but also by the direct effects of HIV on specific body organs - and the indirect effect of HIV-associated inflammation on these organs. Other arguments used in the US DHHS guidelines to support their early treatment recommendations include that:

- Untreated HIV infection may have detrimental effects at all stages of infection.
- Treatment is beneficial even when initiated later in HIV infection. However, later treatment may not repair damage associated with viral replication and immune activation during early stages of infection.
- Earlier treatment may prevent the damage associated with HIV replication during early stages of infection.
- Earlier treatment may also reduce the added risk associated with HIV infection of developing health problems like cardiovascular disease, cancers, osteopenia/osteoporosis and neurologic complications<sup>11</sup>.

Some disagree with the US DDHS guideline's recommendations, arguing that more research is need about the optimum point to start HIV treatment. Other concerns about starting treatment earlier include the cost of the medication, the possibility of developing long-term treatment related side-effects and toxicities; the possibility of developing early resistance to HIV treatments; and the fact that treatment is a life-long commitment which some patients may not be ready to make.

### 3.2 The START (Strategic Timing of Antiretroviral Treatment) Study

The START<sup>12</sup> study is designed to address the question of when is the best time to start treatment in HIV positive people with CD4 counts above 500 who have not taken treatment before.

This multi-centre randomized clinical trial is taking place at about 90 sites in nearly 30 countries, including Australia. Participants are randomised to either receive antiretroviral treatment immediately or to defer treatment until their first CD4 count is less than 350 cells or they have clinical signs of advanced HIV disease. The plan is for START to recruit 4000 people and to conclude around 2015.

There are concerns that this trial may be overtaken by other research on early treatment and/or a shift in clinical practice to much earlier treatment. Some have commented that the trial is already in difficulty and will never be completed.

NAPWA<sup>13</sup> strongly supports the START study and has been involved in its planning at the local and international level.

It is NAPWA's view (and that of this author) that START is viable and that many people with HIV will be interested in participating in it. At the same time, it is important that all people with HIV are able to start treatment if they and their doctor agree this is the best course for them, based on currently available information.

It may be that consensus on when to start treatment emerges before the conclusion of the START study. However, the study will none the less be of value, not only in answering (or confirming the answer to) an important scientific question, but also because of several innovative sub-studies designed to explore other issues about the impact and treatment of HIV infection.

### 3.3 Discussion

The arguments in favour of starting HIV treatment earlier at higher CD4 counts are increasingly compelling. Indeed, few if any disadvantages have been shown to starting treatment early with the potent and well tolerated ARV drugs that are now available. It is true that some studies looking at when to treat have found no clinical advantage in starting ARV treatment with a CD4 count above 500 - but none have found any harm either.

Given that ARV treatment needs to be life-long, then deferring treatment for months or years is unlikely to save significant time on ARV treatment and may incur additional health risks.

*"If you are going to be on HIV medications for years, sparing a few months on the front end (and perhaps risking additional complications) doesn't seem like a good investment."*  
Assoc. Professor Ben Young  
MD. [www.thebody.com](http://www.thebody.com)

Ultimately, starting treatment is a decision for HIV positive people to make, in partnership with their doctors. To support this, HIV positive Australians should be kept up to date with the latest developments. It is some years since major HIV awareness programs have been conducted in Australia: many HIV positive people are probably unaware of new scientific information about HIV and its impacts, including about when to start HIV treatment and the role of treatment in helping prevent HIV transmission.

### 4. NEW DEVELOPMENTS IN HIV PREVENTION

As mentioned earlier, the 2011 United Nations Declaration on HIV/AIDS recognizes that there are additional means and important new scientific evidence available to reverse the global HIV epidemic and avert millions of HIV infections and AIDS related deaths.

An area of great promise is the role of HIV treatment in helping prevent HIV transmission – “treatment as prevention” is now the focus of worldwide interest.

As noted by UNAIDS<sup>14</sup> Executive Director Michel Sidibé, we can now think about the role of HIV treatment in a new way, not just to save lives of those infected, but

to prevent infection in the first place – making the step from averting illness in individuals to dramatically slowing the epidemic in populations<sup>15</sup>.

#### 4.1 Impact of ARV treatment on HIV transmission

Various observational and cohort studies have shown the impact of HIV treatment on HIV transmission<sup>16</sup>. The impact of ARV treatment for HIV prevention has also been the subject of mathematical modelling studies.

Of particular interest is a recent study<sup>17</sup> which modelled the impact of expanded ARV treatment to all HIV-infected adults in care in San Francisco. This study predicts decreases in new HIV infections from expanded ARV treatment at five years of between 59% and 76% among MSM.

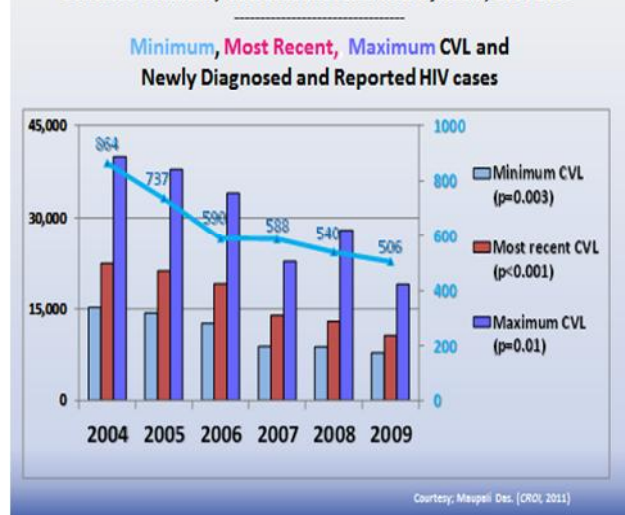
In response, our Australian colleagues Wilson et al<sup>18</sup>, argue that this modelling may be "overly optimistic", based on differences in the effect of ARV on HIV transmission in anal versus vaginal intercourse. They also note that despite wide availability of ARV treatment in Australia, HIV infection rates are now similar to those in the pre-modern ARV treatment era<sup>19</sup>.

This comment raises an interesting point. However, the San Francisco modelling may be realistic not only for that city, but for other comparable Australian cities (e.g. Sydney, Melbourne, Brisbane), particularly if PrEP and early ARV treatment is accessible and where new scientific evidence supporting the benefit of earlier treatment to the individual - as well as its added prevention benefit - is widely promoted among gay men and health care providers.

However, the right targeting is essential: wide testing and treatment availability does not necessarily equal uptake among subgroups of the HIV positive population most relevant to transmission of infection. For example, Murray et al<sup>20</sup> observe that HIV positive MSM not taking ARV treatment could be the source of the increases in HIV infections in Australian MSM - especially in younger MSM. Consequently, greater HIV treatment uptake should decrease HIV incidence, especially in younger MSM.

The success of San Francisco's "Test and Treat" program is also encouraging for the Australian context. A recent study<sup>21</sup> of this program found impressive individual

Success of Test & Treat in San Francisco? Reduced Time to Virologic Suppression, Decreased Community Viral Load and Fewer New Infections, 2004-2009



and population-level successes in prioritizing prevention to diagnosing, providing treatment and care, and preventing transmission.

Adding to this are results from two ground-breaking clinical studies (HPTN 052 and iPrEx), discussed below, which provide further evidence of the preventive effectiveness of ARV treatment.

Whatever the exact impact, it is likely that expanded ARV treatment together with targeted promotion of HIV testing and awareness campaigns would have a significant impact on HIV transmission rates, especially in the setting of the cohesive gay communities in Australia.

#### 4.2 HIV Prevention Trials Network (HPTN) 052 Study

The HPTN 052<sup>22</sup> study looked at transmission of HIV in 1763 HIV-discordant<sup>23</sup> heterosexual couples in Africa, Asia and North and South America.

Couples were randomized to one of two study arms: 1) immediate ARV treatment for the HIV infected partner, or 2) delayed ARV treatment for the HIV infected partner until the CD4 count fell below 250 or an AIDS defining illness developed.

All couples received counselling, risk reduction counselling, free condoms and STI testing and treatment. The HIV positive partner received primary HIV health care.

The study found that immediate provision of ARV treatment to the HIV positive partner led to a 96% decrease in new HIV infections, a 41% reduction in disease progression/death and an 80% reduction in TB. Study results also support the therapeutic benefit in starting ART early (HIV positive partners in HPTN 053 had CD4 counts of between 350 and 550 CD4 cells).

This study is the first randomized clinical study to show that treating HIV infected individuals with ARV can reduce the risk of sexual transmission of HIV to their uninfected partners. The study authors conclude that these results support the use of ARV treatment as a part of a public health strategy to reduce the spread of HIV infection.

#### 4.3 iPrEx Study of Pre-exposure Prophylaxis for MSM

The iPrEx study<sup>24 25</sup>, first reported in November 2010, is the first clinical trial to show the safety and efficacy of using antiretroviral drugs for HIV prevention in HIV negative people. This randomized study, conducted in North and South America, Asia and Africa, is one of the largest HIV prevention multisite studies of MSM ever conducted.

The study found that daily PrEP with the HIV drugs FTC/TDF reduced HIV infections by an average of 44% in men and transgender women who have sex with men. PrEP efficacy was 73% among individuals who reported using the drug more consistently (drug level testing found little or nil drug in the blood of a number of participants).

Of particular relevance to Australia are the iPrEx study results from the San Francisco sites. Like major Australian capital cities, San Francisco has a significant MSM population, significant HIV prevalence, and a cohesive and well organised gay community with a long

history of successful HIV awareness information campaigns.

A further iPrEx analysis underway is showing that results were significantly more impressive in San Francisco than other study sites, with around 95% of those on the treatment arm having detectable ARV drug levels and no HIV infections among those who took the drug.

Of interest is that condom use rates for receptive intercourse remained steady. The number of sexual partners also remained steady over the course of the study.

Further research from this study<sup>19</sup>, released in July 2011, found that the impact of PrEP was durable throughout the iPrEx study, across participant sub-groups, with no evidence of HIV drug resistance among those infected with HIV after starting PrEP.

The iPrEx study is ongoing, with the current phase providing drug to all participants. The study will look at whether participants are able to use PrEP more consistently now that its benefits have been demonstrated and all participants know they are receiving active drug (rather than the possibility of being in the placebo study group). The study will also look at drug levels and examine the differences between participants who took the drugs consistently every day and those who took drugs intermittently. The study will also look at possible dosage options, which may also lessen costs.

The iPrEx study authors propose that the iPrEx study addresses an important unmet need in public health – particularly as HIV prevalence is higher among MSM than in other groups in almost all countries – by showing that individuals with a high risk of exposure to HIV can be mobilized to participate in prevention initiatives and that pre-exposure prophylaxis is effective for slowing the spread of HIV in this population.

#### **4.4 Implications of HPTN 052 and iPrEx studies for Australia**

The HPTN 052 study is clearly translatable to heterosexual HIV transmission in Australia. It would be unthinkable that sero-discordant heterosexual couples would not be offered treatment, irrespective of the CD4 count of the HIV positive partner.

Inevitably, there will be discussion (and possibly contention) among some about the translatability of the HPTN 052 study results to MSM, given we don't have results from a similar randomized clinical trial among MSM sero-discordant couples.

In terms of MSM HIV transmission, there is little prospect of a randomized study like HPTN 052 among MSM sero-discordant couples, which many would regard as unethical. However, observational studies are feasible and are likely underway.

In the meantime, there are compelling arguments for sero-discordant MSM couples in Australia and elsewhere to be offered ARV treatment, irrespective of CD4 count, as for heterosexual sero-discordant couples.

Clearly, the iPrEx study means PrEP has arrived and will become an essential part of “combination prevention”. Surveys of gay men in the United Kingdom and USA find that although awareness of PrEP remains low among MSM, once information is provided there is a high level of

acceptability of PrEP. A recent survey of Australian HIV negative gay men found similar PrEP acceptability<sup>26</sup>.

Gilead Pharmaceuticals, the manufacturer of Truvada (FTC/TDF), is moving ahead with plans to submit data in 2012 to seek US FDA approval of Truvada for use in HIV negative people to prevent HIV infection. HIV organizations have urged both Gilead and the FDA to fast track consideration of Truvada for PrEP<sup>27</sup>.

The challenge for Australia is not whether we should implement PrEP – the arguments in favour are overwhelming – but how we should make it available in a targeted and cost effective way for maximum effect as part of “combination prevention”.

## **5. GLOBAL REACTION TO NEW DEVELOPMENTS IN HIV TREATMENT & PREVENTION**

Over the past two years there has been a flurry of activity at local, national and global levels as scientific knowledge about HIV increases; more potent and better tolerated ARV treatments become available; as evidence emerges to support starting treatment earlier; and as studies show the potential for using HIV treatment as prevention, as part of a “combination prevention” policy and program approach.

These responses include:

### **5.1 2011 United Nations Declaration on HIV/AIDS**

The outcome of the 2011 Declaration<sup>2</sup> was significantly informed by new scientific information about HIV and by new findings on early treatment and treatment as prevention. UNAIDS gave briefings to Member States on these developments and the UN Secretary-General called for ambitious new HIV treatment and prevention targets to be set<sup>28</sup>.

### **5.2 PEPFAR – US President's Emergency Plan for AIDS Relief**

The US PEPFAR program is the largest by any nation to combat a single disease internationally<sup>29</sup>. The PEPFAR scientific advisory board is producing recommendations to guide PEPFAR's response to growing scientific evidence supporting treatment as prevention, in particular the impact of the HPTN 052 study of HIV transmission among sero-discordant couples. Among the measures believed to be under consideration is offering treatment to all pregnant women for life – regardless of CD4 count; and offering treatment to all sero-discordant couples – regardless of CD4 count.

### **5.3 African plans to treat HIV discordant couples**

HIV-positive Rwandans in sero-discordant relationships will be offered antiretroviral treatment regardless of CD4 count (and as soon as they test HIV positive) as part of a new national plan to boost national HIV prevention and treatment efforts (Rwanda has a successful ARV treatment programme, with 93% coverage of people eligible for ARV treatment under WHO treatment guidelines). Other countries are believed to be considering following Rwanda's lead.<sup>30</sup>

#### **5.4 “Test and Treat” program, San Francisco, Department of Public Health**

As referred to earlier, there have been impressive individual and population-level successes resulting from San Francisco’s “Test and Treat” policy, where all HIV positive people are offered HIV treatment, irrespective of CD4 count<sup>31</sup>. “Test and Treat” reflects accumulating evidence about the individual and public health benefits of earlier treatment and combination treatment (including treatment as prevention).

The San Francisco experience has particular relevance for HIV in Australia. Like major Australian capital cities, San Francisco has a significant MSM population, significant HIV prevalence, and a cohesive and well organised gay community with a long history of successful HIV awareness information campaigns.

#### **5.5 “Test and Treat” Programs, US Centres for Disease Control (CDC) New York, Washington DC**

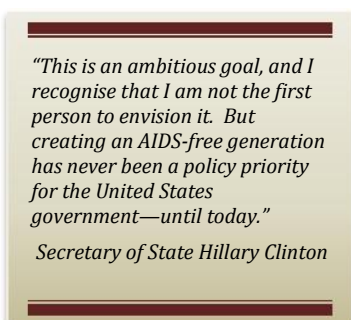
Extensive “test and treat” programs for prevention and treatment are now being rolled out in New York City and Washington DC.

#### **5.6 New USA National HIV/AIDS Strategy**

In July 2010, President Obama released a new national HIV/AIDS strategy<sup>32</sup> for the USA. This impressive plan contains ambitious goals and timelines for HIV prevention for 2010-2015, including to lower the annual number of new infections by 25%; increase from 79% to 90% the percentage of people living with HIV who know of their infection; reduce the HIV transmission rate by 30%; increase the percentage of newly diagnosed people linked to care within 3 months from 65% to 85%; and to increase the proportion of HIV-diagnosed gay and bisexual men, African Americans and Latinos with undetectable viral load by 20%. Some of these targets could be revised as the National Strategy was finalized before new research findings about HIV treatment as prevention became available.

#### **5.7 US commits to treatment as prevention policy to achieve a global “AIDS-free generation”**

In November 2011, US Secretary of State Hillary Clinton announced that the US is now committed to a policy of creating the first AIDS-free generation by using antiretroviral treatment as the central tool in a strategy to radically reduce new HIV infections.



#### **5.8 CDC’s High-Impact HIV Prevention Strategic Plan for Reducing HIV Infections in the USA (2011)**

CDC is the government agency with primary responsibility for HIV prevention in the USA. This new strategic plan<sup>33</sup>, with a proposed \$USD394 million budget, calls for a multifaceted approach to HIV prevention

incorporating HIV testing, ARV treatment as prevention, improved access to condoms and sterile syringes, prevention program for HIV positive people and their partners, special focus on populations at higher risk, treatment for substance abuse, and screening and treatment for other sexually transmitted infections.

This plan complements the prevention goals and targets set in the new US National HIV Strategy

#### **5.9 CDC Statement on PrEP for prevention of HIV infection in MSM**

Based on the results of the iPrEX pre-exposure prophylaxis study referred to earlier, CDC and other U.S. Public Health Service (PHS) agencies are developing PHS guidelines on the use of PrEP for MSM at high risk for HIV acquisition in the United States, as part of a comprehensive set of HIV prevention services. Until these more detailed PHS guidelines become available, CDC has provided interim recommendations<sup>34</sup> to help guide use of PrEP in clinical practice.

#### **5.10 Updated US DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents**

These guidelines<sup>35</sup> are the main HIV treatment guidelines used in Australia. A major update of these guidelines is expected to be released by the DHHS in April 2012. It is probable that developments in early treatment and treatment as prevention will be the subject of expanded discussion in the next edition of the DHHS guidelines.

### **6. AUSTRALIAN REACTION TO NEW SCIENCE & NEW THINKING ON EARLY TREATMENT & COMBINATION PREVENTION**

The potential impact in Australia of the 2011 UN Declaration on HIV/AIDS and its targets and timelines, together with the advent of new scientific information about early HIV treatment and treatment as prevention, has started to be discussed by community based organizations and Commonwealth and State/Territory health officials.

Logically, these new developments would best be addressed through updated Commonwealth and State/Territory HIV strategic plans or adjuncts to current plans.

#### **6.1 National HIV/AIDS Strategy and State/Territory HIV Strategic Plans**

Australia’s current 6th National HIV strategy (2010-2013)<sup>36</sup> is fine on principles, but scant on concrete actions and enhanced funding – and its implementation has been slow and frustrating. Also, the current Strategy does not reflect the new scientific developments in HIV treatment and combination prevention discussed in this paper, most of which came after the Strategy was written.

Unfortunately, the 6th National HIV strategy and most State/Territory strategies continue the lamentable drift of previous strategies away from using ambitious, time-bound targets: these are essential to drive momentum and monitor progress. Australia’s reluctance to set bold targets contradicts what Australia has committed to do under the 2011 UN Declaration on HIV/AIDS. Other

countries, notably the USA, are now moving to use ambitious goals and targets for their domestic responses.

The fact that we have reached the mid-term time point of our current National Strategy, plus the fact that a number of State/Territory HIV strategies have expired, provides an opportunity to revitalize these strategies, including by adopting bold treatment and prevention targets based on those in the 2011 UN Declaration on HIV/AIDS.

## **6.2 HIV community based organisations response**

There is growing interest in new scientific information about early HIV treatment and treatment as prevention in the Australian HIV community sector. There have been briefings and discussions on these topics at the recent annual general meetings of AFAO<sup>37</sup>, ACON<sup>38</sup> and NAPWA<sup>13</sup>.

The community sector is currently discussing how best to respond to the developments highlighted in this paper. Naturally, there is interest in knowing how the Commonwealth and State/Territory governments propose to react.

## **7. ELIMINATING HIV TRANSMISSION AND AIDS – A NEW GOAL FOR AUSTRALIA**

### **7.1 Building on our success - Australia's unique opportunity**

Over the past ten years the level of HIV related illness and AIDS related deaths in Australia has plummeted and many HIV positive people are living full lives and enjoying good health. Even people with very advanced HIV disease have seen improvements to their health and wellbeing as a result of HIV treatment, care and support.

On the other hand, HIV remains a very serious disease. HIV treatment is not a cure - the health consequences of having HIV infection remain with HIV positive people for life. As well as the higher risks for HIV positive people of developing problems like cardiovascular disease, cancers, kidney disease and neurological problems, HIV also appears to increase frailty and accelerate aging in significant numbers of people. At least we are fortunate that Australia is at the forefront of research in this area and HIV positive people experiencing these health challenges are able to access high quality health care and support services.

On prevention, our harm reduction approaches and pragmatic policies and programs have helped Australia maintain very low rates of HIV transmission from injecting drug use and among sex workers – we have achieved virtual elimination of HIV transmission in these populations. While there are concerning risk factors for HIV infection among indigenous Australians, rates of HIV infection remain low and comparable with those in the general population. So at present, Australia's HIV epidemic remains largely contained to the population in which HIV first emerged - men who have sex with men (MSM).

However, we should not take the relative stability of Australia's HIV epidemic for granted. Firstly, we have not been successful in maintaining a downward trend in HIV infection rates over the past several years, with rises in HIV infection rates in a number of settings. Indeed, the

rate of new HIV diagnoses is currently at 1000 plus annually.

There are other disturbing trends that may lead to further rises in HIV infection, including a decrease in HIV testing rates and an increase in unprotected anal intercourse among MSM.

So while we will continue to benefit from our 30 years of investment in HIV prevention, treatment and research, there are worrying signs. However, if we deploy HIV prevention and treatment to greatest effect, we have an opportunity not only to address areas of difficulty in our HIV response, but to achieve much more.

We have many advantages in our favour, including:

- an excellent health system.
- experienced health professionals.
- good access to HIV antiretroviral treatments.
- a proven record in delivering innovative and effective HIV prevention programs.
- support for harm reduction approaches to injecting drug use.
- a strong community based response to HIV.
- an impressive record in HIV research and a strong research infrastructure.
- a mostly sound policy and regulatory framework for HIV at Commonwealth and State/Territory levels.
- Improving community attitudes to HIV and to those living with and at high risk of HIV infection.

Indeed, Australia is uniquely placed to be the first country to achieve virtual elimination of HIV transmission and new AIDS diagnoses and in doing so to lead the world by example.

### **7.2 Investing in Australia's HIV response**

In terms of costs associated with HIV in Australia, the current rate of around 1000 new HIV diagnoses annually is adding further substantial health care costs and other economic impacts, perhaps as much as \$1billion for each 1000 new diagnoses.

Cost estimates will vary depending on which factors are taken into account. The first would be the cost of HIV antiretroviral drugs and drugs related to HIV infection, as well as the cost of health services. Lifetime cost estimates for this vary from \$450,000 to \$600,000<sup>39 40</sup>.

Additional health care costs can reasonably be included based on findings that people with HIV have a higher risk of developing cardiovascular disease, some cancers, bone disorders, kidney and liver problems, neurological problems and mental health impacts. Other cost impacts that may be included are likely higher rates of sick leave and productivity impacts among people with HIV due to HIV related health problems.

These costs must be compared with the substantial return from investing in HIV prevention and treatment demonstrated by many studies – this return has been particularly well demonstrated in Australia's HIV response<sup>41</sup>.

This is a critical time for Australia to increase our domestic investment in HIV prevention and treatment to fully capitalize on the new scientific advances outlined in this paper. By doing so, we can gain substantial individual, societal and financial benefits in the years ahead as we work to eliminate HIV transmission and new AIDS diagnoses.

### 7.3 A new overarching goal for Australia's HIV response

Drawing on the advances and opportunities discussed earlier in this paper, Australia should set a new overarching goal for our HIV response.

- A new overarching goal for Australia's HIV response -

**Achieve virtual elimination of HIV transmission and AIDS diagnoses in Australia by 2018 and sustain that achievement indefinitely.**

Through this goal, HIV transmission would be reduced to the level of virtual elimination and no person living with HIV in Australia would progress to an AIDS diagnosis.

## 8. STEPS TO REVOLUTIONIZE HIV PREVENTION AND TREATMENT IN AUSTRALIA

### 8.1 Set bold time-bound targets

To support achieving this aspirational goal, a series of bold, time-bound targets should be set for Australia and agreement reached on a set of actions to realize them.

The following targets are proposed as a basis for discussion among stakeholders. They are based on those set under the 2011 UN Declaration on HIV/AIDS, but aim to reflect the pattern of Australia's HIV epidemic:

#### Proposed Australian Targets for HIV Prevention:

- **Reducing sexual transmission of HIV among MSM by 80% by 2015.**
- **Sustaining virtual elimination of HIV transmission from injecting drug use.**
- **Sustaining virtual elimination of HIV transmission among sex workers and clients**
- **Sustaining virtual elimination of mother to child transmission of HIV.**

#### Proposed Australian Target for HIV Treatment:

- **Having 90% of people with HIV on antiretroviral treatment by 2013.**

If these targets were reached, Australia should come close to the elimination of HIV transmission and new AIDS diagnoses by 2015, and fully realize that goal by 2018.

The need for additional targets, including for other at risk populations in Australia, should be discussed – and

should be consistent with the approach of prioritising efforts to target higher risk populations endorsed under the 2011 Declaration on HIV/AIDS<sup>42</sup>.

### 8.2 Policy, strategy and program actions

To reach the targets proposed in section 8.1, complementary policy and program actions will be necessary at national, State/Territory and community levels. These should include the following:

#### 8.2.1 Deliver new awareness campaigns targeting people with HIV

Many people with HIV are unlikely to be fully aware of the new advances discussed in this paper and the possible implications for them.

New awareness campaigns, which are community based and peer driven, should be rolled out as soon as possible to inform people with HIV of growing evidence about the health benefits associated with starting HIV treatment early (including above 500 CD4 counts) and the additional impact that taking treatment has on preventing HIV transmission.

These campaigns should include use of public space advertising, social media and the internet.

It is likely that these awareness campaigns will result in an increase in the proportion of HIV positive people on HIV treatment in Australia, from the current figure of around 70%<sup>43</sup> to around 90%.

#### 8.2.2 Deliver new awareness campaigns targeting MSM

MSM continue to comprise the majority of new HIV infections in Australia and are the population most impacted by HIV. However, it is likely that many MSM are not aware of new scientific information about HIV and its prevention and treatment. Adding to this are trends among MSM indicating a decrease in HIV testing rates and increased unprotected anal intercourse.

New community based and peer driven awareness campaigns are needed to update MSM on new scientific information about HIV; and explain what is meant by new buzzwords like "test and treat", "treatment as prevention", "combination prevention" and "prevention + treatment".

With treatment and prevention becoming inextricably linked, information campaigns will have elements and messages which can resonate with both HIV positive people and HIV negative people at higher risk (like MSM).

#### 8.2.3 Update health promotion programs about "combination prevention" of HIV

All health promotion programs where HIV is relevant should be updated, including those targeting injecting drug users, sex workers and other special populations at higher risk<sup>44</sup>, to explain the concept of "combination HIV prevention" (i.e. where successful strategies like correct and consistent condom use, safe injecting practices and harm reduction are used to prevent HIV transmission and where the added HIV prevention benefit associated with HIV treatment uptake is recognized).

#### 8.2.4 Promote HIV testing & Make rapid HIV testing available

Globally, almost 60% of all people living with HIV do not know their HIV status<sup>45</sup>. To change this, UNAIDS has called for HIV testing to become as simple and as ubiquitous as home-based pregnancy test kits. UNAIDS

argues that this will drive down the high costs of maintaining dedicated HIV testing and counselling centres as well as empowering individuals to access HIV treatment and care services in a timely and confidential manner.

In Australia, there are concerns that the rate of regular testing among gay men is declining<sup>46</sup>, so further campaigns are needed to encourage regular HIV testing by MSM and others at high risk.

This observation is supported by a recent Australian pilot of oral fluid testing conducted in community settings which found that a significant minority of HIV-positive MSM are currently unaware of their positive sero-status<sup>47</sup>. Also of concern is another Australian study which found that onward transmission of HIV in MSM who are in the process of sero-conversion is significant<sup>48</sup>.

Lack of availability of rapid testing services is seen as a major barrier to regular testing for some and the availability of rapid testing has been called for by Australian HIV/AIDS organisations. Indeed, Australia is probably the only developed country not to have rapid HIV testing in place.

Demonstration pilots of HIV rapid testing should be rolled out as soon as possible as an interim measure until rapid tests are Medicare listed. HIV testing campaigns linked to strategies like wider health provider initiated HIV testing and rapid testing in community based organization settings should be implemented as soon as possible.

#### 8.2.5 Make PrEP (pre-exposure prophylaxis) available

Pending FDA approval of use of antiretroviral drugs for PrEP and TGA consideration in Australia, demonstration pilots of PrEP should be set up to provide access to PrEP selectively in HIV negative people at high risk of becoming HIV infected.

#### 8.2.6 Remove arbitrary restrictions on HIV treatments

Complex and out-dated prescribing criteria for antiretroviral treatments must be simplified so that doctors can prescribe ARVs for their patients who wish to take up early treatment. This must include removal of the arbitrary prescribing restriction for HIV positive people with CD4 counts above 500.

#### 8.2.7 Inform sero-discordant couples

The HPTN 052 study referred to earlier has clear implications for people in sero-discordant relationships and it is important that HIV positive and HIV negative partners are encouraged to discuss this study with their doctors. Obviously, those in heterosexual sero-discordant relationships need to be informed about HPTN 052 and its implications for disease progression, treatment and prevention. MSM in sero-discordant relationships should also be encouraged to discuss the relevance of the HPTN 052 study both for clinical management and prevention.

#### 8.2.8 Sustain virtual elimination of HIV transmission from injecting drug use and sex work

Australia's achievement in reaching virtual elimination of HIV transmission through injecting drug use and in the sex industry is remarkable. However, this achievement will only be sustained if programs like needle exchange, peer education and support for community based organisations of people who use drugs and sex workers are continued and enhanced, and that a supportive legal and policy framework is in place.

#### 8.2.9 Address disincentives to HIV treatment uptake

To increase the percentage of HIV positive Australians on HIV treatment it will be essential to address disincentives to treatment uptake. These include reforming the byzantine system for dispensing HIV treatments to allow the option of community pharmacy dispensing.

Another barrier to be addressed is the considerable financial burden of pharmacy item co-payments and dispensing fees for HIV and related medicines.

#### 8.2.10 Mobilize gay community and other key communities

Community mobilization will be essential to achieving the targets proposed in this paper.

Fortuitously, there has been a long history of engagement and mobilization of affected communities since the beginning of the HIV epidemic, particularly the gay and lesbian community. This has included community mobilization resulting in adoption of safe sex as a community norm among gay men in the 1980s; changes to Australia's drug approval and funding systems (early 1990s); reform of our clinical trial approval system (early 1990s); and accelerating access to new drugs and viral load testing with the advent of modern antiretroviral treatment (circa 1995).

It is time for the community to mobilize again.

## 9. CONCLUSION

Australia has shown great leadership and innovation in HIV prevention, treatment and care over the past 30 years. It is time for us to do so again.

We must not miss this opportunity to capitalise on new scientific advances to drive down Australia's rate of new HIV infections and minimize the health impacts of living with HIV. We need community mobilization and political will to succeed - but our strong record of showing this should give encouragement.

By revolutionizing our HIV response in prevention and treatment through decisive program and policy actions and bold targets for achieving them, we will encourage other countries to do the same.

This paper ends with the thoughts of Desmond Tutu, writing in the Washington Post, where he notes that after 30 long years of AIDS, the world finally possesses affordable tools and scientific knowledge that could stop HIV in its tracks.

However, Archbishop Tutu warns that just as the end of AIDS has finally come within reach, we are witnessing an unprecedented drop in financial and political support for HIV.

Desmond Tutu is right - things are finely balanced - if we give in to inaction and defeatism and fail to carry out the pledges made in the UN Declaration on HIV/AIDS - the price will be very high. We must seize the opportunity to re-vitalize the global fight against HIV that adoption of the UN Declaration provides - and there is hope that we will.

1 December 2011

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<sup>1</sup> Full text of 2011 United Nations Declaration on HIV/AIDS available at <http://www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2011highlevelmeetingonaids/>

<sup>2</sup> Schwartländer B et al. Towards an improved investment approach for an effective response to HIV/AIDS. *Lancet* 2011; 377: 2031–41

<sup>3</sup> Australia's UN Ambassador, Gary Quinlan, and Botswana's UN Ambassador, Charles Ntwaagae, co-facilitated the 2011 United Nations General Assembly's Special Session on HIV/AIDS and negotiated agreement to the Declaration by all Member States.

<sup>4</sup> Kuritzkes DR; HAART for HIV-1 Infection – Zeroing In on When to Start. *Arch Intern Med.* 2011;171(17):1569-1570.

<sup>5</sup> Kitahata MM, Gange SJ, Abraham AG, et al; NA-ACCORD Investigators. Effect of early versus deferred antiretroviral therapy for HIV on survival. *N Engl J Med.* 2009;360(18):1815-1826.

<sup>6</sup> Sterne JA, May M, Costagliola D, et al; When To Start Consortium. Timing of initiation of antiretroviral therapy in AIDS-free HIV-1-infected patients: a collaborative analysis of 18 HIV cohort studies. *Lancet.* 2009;373(9672):1352-1363.

<sup>7</sup> Cain LE, Logan R, Robins JM, et al; HIV-CAUSAL Collaboration. When to initiate combined antiretroviral therapy to reduce mortality and AIDS-defining illnesses in HIV-infected persons in developed countries. *Ann Intern Med.* 2011;154(8):509-515.

<sup>8</sup> Writing Committee for the CASCADE Collaboration. Timing of HAART initiation and clinical outcomes in human immunodeficiency virus type 1 seroconverters. *Arch Intern Med.* 2011;171(17):1560-1569.

<sup>9</sup> Available at <http://www.aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7> (Released 14 October 2011)

<sup>10</sup> In 2005, the Australian Health Minister's Advisory Committee on HIV and STIs endorsed the *USA Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*, for use in Australia and requested that an Australian guidelines panel provide a commentary on the DHHS guidelines relevant to Australia. ASHM hosts the work of the commentary panel. The DHHS Guidelines plus Australian commentary is available at <http://ashm.org.au/projects/arvguidelines/>.

<sup>11</sup> Discussed in *DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, October 2011, p29. <http://www.aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7>

<sup>12</sup> For START study details see <http://insight.ccbcr.umn.edu/start/> and [www.napwa.org.au/start](http://www.napwa.org.au/start)

<sup>13</sup> National Association of People Living with HIV/AIDS (NAPWA), Australia. [www.napwa.org.au](http://www.napwa.org.au)

<sup>14</sup> United Nations Joint Program on HIV/AIDS. [www.unaids.org.au](http://www.unaids.org.au)

<sup>15</sup> Sidibè, M. Antiretrovirals for Prevention: Realizing the Potential. *Current HIV Research* 2011,9,470-472.

<sup>16</sup> For a detailed discussion of studies supporting HIV treatment as prevention and other scientific evidence see Granich R, et al.

Harnessing the Prevention Benefits of Antiretroviral Therapy to Address HIV and TB. *Current HIV Research* 2011,9,358-359.

<sup>17</sup> Charlebois ED et al. The Effect of Expanded Antiretroviral Treatment Strategies on the HIV Epidemic among Men who have Sex with Men. *Clinical Infectious Diseases* 2011;52(8):1046-1049.

<sup>18</sup> Wilson DL et al. Correspondence – Overly Optimistic Forecasts for the Impact of Treatment of HIV prevention for Men who have Sex with Men. *Clinical Infectious Diseases* 2011;53(6), p611-612 (15 September 2011)

<sup>19</sup> Note: The Opposites Attract Study is being conducted by the Kirby Institute. This is a five-year cohort study exploring viral load, HIV treatment and HIV transmission in sero-discordant male homosexual couples.

<sup>20</sup> Murray J et al. Increasing HIV diagnoses in Australia among men who have sex with men correlated with the growing number not taking antiretroviral therapy. *Sexual Health*, 2011, 8, 304–310.

<sup>21</sup> Moupali Das et al. Success of Test and Treat in San Francisco: Reduced Time to Virologic Suppression, Decreased Community Viral Load, and Fewer New HIV Infections, 2004 to 2009. Presented at 2011 CROI (Paper # 1022).

<sup>22</sup> Cohen MS, Chen YQ et al, for the HPTN 052 Study Team. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011. Available at: [www.nejm.org/doi/full/10.1056/NEJMoa1105243](http://www.nejm.org/doi/full/10.1056/NEJMoa1105243).

<sup>23</sup> Definition of HIV discordant (also known as "sero-discordant or sero-positive): where one partner is HIV infected and the other is HIV negative.

<sup>24</sup> Grant RM, Lama JR et al, for the iPrEx Study Team. Pre-exposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. *N Engl J Med* 2010; 363:2587-2599 (December 30, 2010).

<sup>25</sup> Grant RM et al. Completed observation of the randomized placebo-controlled phase of iPrEx: daily oral FTC/TDF pre-exposure HIV prophylaxis among men and trans women who have sex with men. Sixth IAS Conference, Rome, July 2011, abstract WELBC04.

<sup>26</sup> PrEP Project: PrEPARE survey of over 1500 gay men in Australia. National Centre in HIV Social Research, 2011.

<sup>27</sup> *Don't Delay HIV Prevention for Gay and Bi-sexual Men and Transgender Women*. Letter online at [www.avac.org/pressreleases/fda-gilead](http://www.avac.org/pressreleases/fda-gilead) 18 October 2011.

<sup>28</sup> Report of the UN Secretary-General: Uniting for universal access: towards zero new HIV infections, zero discrimination and zero AIDS-related deaths (March 2011). Available at <http://www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2011highlevelmeetingonaids/>

<sup>29</sup> US President's Emergency Plan for HIV Relief (PEPFAR). See <http://www.pepfar.gov/>

<sup>30</sup> Reported in <http://www.irinnews.org/printreport.aspx?reportid=93706> 12 September 2011.

<sup>31</sup> Guidelines for San Francisco's Test and Treat program are available at <http://php.ucsf.edu/downloads/ARTInitGuide.pdf>

<sup>32</sup> National HIV/AIDS Strategy for the USA (July 2010). Available at [www.cdc.gov/HIV/strategy/](http://www.cdc.gov/HIV/strategy/)

<sup>33</sup> High-Impact HIV Prevention - CDC's Approach to Reducing HIV Infections in the United States. Centers for Disease Control and Prevention (August 2011). Available at [www.cdc.gov/HIV/strategy/](http://www.cdc.gov/HIV/strategy/)

<sup>34</sup> CDC PrEP interim guidelines *MMWR* 2011;60(03);65-68. Available at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm#box>

<sup>35</sup> Available at <http://www.aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7> (Released 14 October 2011)

<sup>36</sup> 6<sup>th</sup> National HIV/AIDS Strategy (2010-2013). Available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-national-strategies-2010-hiv>

<sup>37</sup> Australian Federation of HIV/AIDS Organisations (AFAO). See [www.afao.org.au](http://www.afao.org.au)

<sup>38</sup> ACON Health, the principal community HIV organisation in New South Wales. See [www.acon.org.au](http://www.acon.org.au)

<sup>39</sup> Australian Federation of AIDS Organisations (2006) 'Cost-benefit Analysis: Lifetime Costs Per Infection' Sydney, AFAO

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<sup>40</sup> Schackman et al. The Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States. *Med Care* 2006;44: 990–997.

<sup>41</sup> Returns on investment in public health: An epidemiological and economic analysis prepared for the Australian Department of Health and Ageing (2002) *Access Economics*.

<sup>42</sup> See paras 29, 60 and 61 of 2011 United Nations Declaration on HIV/AIDS. Available at <http://www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2011highlevelmeetingonaids/>

<sup>43</sup> We do not have accurate information on the proportion of people with HIV currently on HIV treatment in Australia. A figure of around 70% is generally used. The Gay Community Periodic Survey (GCPS) shows around two-thirds of HIV-positive gay men in that survey reported being on antiretroviral treatment in 2010.

<sup>44</sup> These special populations would include, depending on each country's epidemic, women and girls, young people, orphans and vulnerable children, migrants and people affected by humanitarian emergencies, prisoners, indigenous people and people with disabilities. See para 60 of 2011 United Nations Declaration on HIV/AIDS. Available at <http://www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2011highlevelmeetingonaids/>

<sup>45</sup> UNAIDS World AIDS Day Report 2011, p31. Available at [www.unaids.org.au](http://www.unaids.org.au)

<sup>46</sup> HIV/AIDS, Hepatitis and Sexually Transmissible Infections in Australia - Annual Report on Trends in Australia 2011. National Centre in HIV Social Research (UNSW) p15-16.

<sup>47</sup> Birrell F et al. Pilot of non-invasive (oral fluid) testing for HIV within a community setting. *Sex Health*. 2010 Mar;7(1):11-6.

<sup>48</sup> Chibo et al. HIV transmissions during seroconversion contribute significantly to new HIV infections in MSM in Australia. *AIDS Research and Human Retroviruses* 2011;27(0).