

# HERE FOR HEALTH

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## Ending HIV Advocacy Plan

2015



## 1. Introduction and Background

ACON has a long heritage in HIV advocacy from the very beginning of the epidemic, and the organisation's inception in 1985. This advocacy work has focussed on a broad range of issues as they impact on both the prevention of HIV and other STIs, as well as care and support for people living with HIV.

### Environment, Context and Key Principles

In scaling up efforts in prevention, testing and treatment commensurate with the NSW HIV Strategy 2012 – 2015 and 7<sup>th</sup> National HIV Strategy's bold goals and targets, ACON is committed to scaling up advocacy efforts. In making this commitment, ACON remains conscious of the roles of our partner organisations, the responsibilities of State and Federal Governments, the funding environment, the pace of change and demand for evolution.

Advocacy is a quasi-political process, where policy opportunities will present themselves, or be created through a deep understanding of the context, the environment and systems.

As such, ACON will undertake activities in this plan with the following contexts and principles in mind:

- Human rights and legal reform are central to our efforts; advocating for easy access to proven prevention, testing and treatment technologies, appropriate service delivery models and peer driven responses.
- The policy relevance of research, scientific and social developments are harnessed to meet the goals under the NSW HIV Strategy and the 7<sup>th</sup> National HIV Strategy.
- The federated nature of responsibilities between Federal and State Governments are acknowledged as a key influence in the advocacy environment.
- The Federal Government has broad responsibilities in terms of health funding at a macro level, regulatory responsibilities, universal health care responsibilities under Medicare and the Pharmaceutical Benefits Scheme, primary health care, and key responsibilities for our international responsibilities as a donor and with regard to our human rights obligations.
- The NSW Government has responsibilities that more directly relate to health service provision other than primary care, such as awareness raising, population health responsibilities, public health system, direct service provision in terms of HIV prevention, testing and treatment. Both State and Federal Governments fund HIV related research.
- ACON needs to continue to build expertise about how these responsibilities interact, intersect and can be manipulated to extract maximum policy change and progress.
- Recognition that Treatment as Prevention (TasP) is a relatively new approach and we have particular expertise in translating our experience in embracing a TasP approach with our

community since 2012, and this experience is critical to continued advancement toward our aim to virtually eliminate HIV transmissions by the end of this decade.

- Goals set in the NSW HIV Strategy and the 7th Australian HIV Strategy recognise the opportunities presented by the science, and goals have been set on the basis of a completely supportive and enabling environment where all the tools are in place –policy and regulatory leadership to create this supportive, enabling environment is required at the State and Federal level.
- ACON has an opportunity with an engaged NSW Government who are driving and facilitating change in the HIV sector – workarounds that prevent our progress being stymied by Federal inaction are a key focus over the next three years.
- Regulatory road blocks and slow process is noted particularly, and ACON will continue to keep pushing for progress over the longer term, while in the short term, seeking to develop workarounds to provide our community with access to new technologies, even if that requires bold action.
- At this point in time, our advocacy efforts are focussed on increased and improved access to PrEP; to rapid, home and dried blood spot testing; and to HIV treatments. It is believed that focussing on these issues will deliver the greatest public health benefits for our community in relation to reducing HIV transmissions by 2020.
- ACON will play a leading advocacy role in the NSW context, and will be a highly active participant in national advocacy efforts – particularly with key policy actors, ASHM, AFAO, NAPWA and with other partners such as our national research centres, the Australian Human Rights Commission, the Global Fund, International Societies, and where appropriate, the pharmaceutical industry.

Further to this summary of the environment, context and principles, this document seeks to outline clear actions, roles, and responsibilities for the work ahead. ACON acknowledges success requires harnessing the collective strengths of a range of partners – including the community – in the effort to end HIV.

## **Partnership**

Partnership has been the cornerstone of the response to HIV in Australia, and applies to our work in advocacy.

Our work will be undertaken with multiple partners from across the HIV partnership including with the community, whom our close connections with, have helped us identify emerging issues and to create dialogue around these issues with policy makers and researchers.

ACON is a member of the Australian Federation of AIDS Organisations (AFAO) which is the peak body established to represent HIV NGO interests at a federal level.

Despite the national role of AFAO, ACON has been highly engaged with federal advocacy work, particularly over the last four years. This work has been done often in partnership with AFAO, or as standalone representations. ACON works similarly at the national level in partnership with ASHM.

ACON is the largest HIV community NGO in Australia and has the most experience in implementing a partnership approach. ACON's policy brand recognition has been developed by virtue of the fact we are a trusted and respected source of advice.

### **Partners to this plan**

We need to work with a range of partners to achieve the goals outlined in the NSW and Australian HIV Strategies. Primarily this will include:

- The NSW Ministry of Health
- The NSW Minister for Health and their office
- NSW blood borne virus NGOs
- AFAO and NAPWHA
- Industry players in the pharmaceutical and bio-technology sectors
- Community, including gay men, other LGBTI organisations, media and business

## **2. Our Focus**

Our work must be focussed on:

- areas which will have the most impact on the fight to end HIV.
- policy goals and targets in the NSW and National HIV Strategies.
- addressing priority areas and the clear rationale for change from an individual, community, population health and health system perspective.
- making PrEP available to gay men who want to access to this prevention method. This will be critical to ensure access to this game changing biomedical intervention.
- securing access to a wider variety of HIV testing services, especially HIV self-testing and rapid HIV testing.

### 3. Pre-Exposure Prophylaxis – PrEP

#### Summary to date

ACON has supported a balanced perspective on PrEP that avoids polarising opinion along moral grounds, as it has in the USA and some other jurisdictions.

We are a member of the steering committee NSW PrEP Demonstration Project (PRELUDE) – currently under way in NSW.

At the end of May 2015, ACON understands that the maximum number of 300 people will be registered to access PrEP under the trial in NSW. ACON has supported the trial through the development of education resources for participants.

It is hoped the demonstration projects will provide useful information to use in advocacy and implementation work, as well as creating a constituency for change.

Recent research findings reinforce the efficacy of PrEP as an additional HIV prevention tool. The United Kingdom PROUD study demonstrated the effectiveness for the daily use of Truvada as PrEP was 86%. The results from the French and Canadian study Ipergay also demonstrated effectiveness of 86%.

Combined with the evidence for condom use in NSW among gay men, these results provide compelling evidence that PrEP is one of the most effective tools to drive down HIV infection rates.

These results have increased sector confidence in the viability of PrEP and diminished concerns. Given that primary infection is a key driver of new infections among gay men in the NSW epidemic, the potential impact of PrEP on new infections is substantial.

PrEP has been available to individuals who can directly import or purchase the drug online, with a valid script, for some time. Following a review of regulatory issues, potential legal issues and with partners (ASHM and Positive Life NSW), ACON produced a guide informing individuals how they can legally obtain PrEP until such a time when it is approved for use by the Australian Therapeutic Goods Administration (TGA).

In this education material, we have stressed the need to consult with a sexual health physician to obtain a prescription in order to take advantage of the self-importation scheme available under Australian law. Over the past 12 months, ACON advocated to the drug's manufacturer (Gilead Sciences) to apply for TGA approval of a new indication for the drug, which is already approved in Australia for use as HIV treatment. An application was lodged in late 2014.

It should be noted that in the USA, it was the Food and Drug Administration who approached Gilead to put in a submission for licensing Truvada as PrEP, rather than Gilead leading on this process.

While Australia is the only developed country regulatory system that does not have a mechanism for speeding up process/fast tracking for important new drugs, Australia is the first country outside

the USA that Gilead has lodged a marketing submission to government regulators. Apparently this is seen as a test-case by Gilead with regard to marketing the drug outside the USA for PrEP.

## Opportunities

The NSW Government has provided funds to establish the NSW demonstration trial of PrEP, run through the Kirby Institute. Through the PRELUDE trial, 300 people in NSW will access this critical prevention technology.

Recent research from the Centre for Social Research in Health (CSRH) at UNSW shows that interest in using PrEP among sexually active gay men is around 23%, and the majority of those men meet criteria as having characteristics likely to make them ‘successful candidates’ for PrEP.

In the context of the likely long wait for PrEP approval from the TGA (and further, listing on the PBS), ACON will continue to work to ensure that more men can safely access PrEP.

ACON has established a NSW PrEP Advocacy Working Group, which includes representation from ASHM, Positive Life NSW and private practice GPs. This group meets every 3 weeks and is focussed on work that would allow PrEP access to be taken to the scale needed to meet demand for PrEP in NSW. Most recently, the group has worked on the development of an advertising/information campaign regarding online access to PrEP.

## Actions

Activities	Target Audience	External Partners	Timeframe
<b>3.1 Research</b>			
3.1.1 - Actively participate in PrEP related research activities, including PRELUDE, BRISE and HIV Prevention Revolution Pillars Project	Researchers and Policy Makers	Kirby Institute, CSRH, AFAO	Ongoing
3.1.2 - Advocate for – and participate in - research and modelling examining the demand estimate for PrEP, likely uptake, and the cost effectiveness.	Politicians and Policy Makers	ASHM, Positive Life NSW, Kirby Institute, Gilead	Short term
3.1.3 - Work with partners to encourage Gilead Sciences to provide extra drug for expanded spaces in PRELUDE and other PrEP demonstration projects	Pharmaceutical Companies	ASHM, AFAO, Kirby Institute	Medium term
3.1.4 - Promote outcomes of the PRELUDE study and other PrEP demonstration projects	Community, Policy Makers	ASHM, Kirby Institute, IAS, CROI	Long term and ongoing

<b>3.2 Community education and engagement</b>			
3.2.1 - Provide information to our communities on the benefits and potential risks of PrEP use	Community	ASHM, Positive Life NSW, AFAO	Ongoing
3.2.2 - Assess further options to promote PrEP access (i.e. print resource development and distribution, advertising, etc.) and assess the associated risks.	Community	AFAO	Immediate
3.2.3 - Support high profile speakers on PrEP, as part of our advocacy and community education activities.	Community, Politicians and Policy Makers	ASHM	Medium term
3.2.4 - Undertake ongoing community forums to address PrEP access and stigma regarding PrEP use	Community	ASHM, Positive Life NSW	Medium term
3.2.5 - Collaborate with partners to promote PrEP guidelines to GP's	Community	ASHM, GPs	Short term
3.2.6 - Examine the possibility of developing PrEP friendly GP list for publication	Community	ASHM, Positive Life NSW	Medium term
3.2.7 - Work with media outlets to generate supportive and accurate media stories on PrEP	Community	AFAO	Medium term
<b>3.3 Political and policy engagement</b>			
3.3.1 - Lead and participate in the NSW PrEP Advocacy Working Group	Partners	ASHM, Positive Life NSW, GPs	Immediate and ongoing
3.3.2 - Work with partners to develop a PrEP access model, after looking at existing models in Australia and overseas, and assess them for appropriateness in the NSW context	Partners	ASHM, Positive Life NSW	Immediate
3.3.3 - Work with partners to establish the eligibility criteria and parameters for a PrEP access scheme	Partners	ASHM, Positive Life NSW,	Immediate
3.3.4 - Seek NSW Ministry of Health support for a NSW PrEP access scheme, or seek alternative sources of funding for an access model	Politicians and Policy Makers	ASHM	Immediate
3.3.5 - Host a forum in NSW Parliament House	Politicians	Kirby Institute;	Immediate

to engage MPs with the latest information on Ending HIV, including a focus on PrEP		ASHM & Bob Grant	
3.3.6 - Obtain up to date legal advice on, and communicate with, the TGA about limitations for public communication, including restricted and prohibited representations under the Therapeutic Goods Act 1989	Politicians and Policy Makers	AFAO, TGA	Short term
3.3.7 - Research the ability of the Ministry of Health and/or Health Minister to approve public health campaigns that would otherwise be a restricted or prohibited representation under the Therapeutic Goods Act 1989.	Politicians and Policy Makers	AFAO	Short to medium term
3.3.8 - Develop a fact sheet on PrEP for politicians or journalists	Politicians, Media	ASHM, Positive Life NSW	Medium term



## 4. HIV Testing

### Summary to date

Globally, there has been widespread uptake of rapid point-of-care (PoCT) technologies in addition to high quality laboratory diagnostic technologies, with high levels of accuracy and an ability to recognise early HIV infection. Until very recently, PoCT technology was not available in Australia.

ACON, and our partners, have undertaken advocacy efforts to remove regulatory prohibitions on rapid and self-testing. We have focused on the need to increase rates of testing, to reduce the undiagnosed 'pool' of infection, which is strongly supported by the NSW HIV Strategy.

We have consistently advocated for the use of peers in the delivery of community based POCT services; and for trained peers with broad clinical oversight to be recognised as appropriate to deliver these services in national and state clinical policy documents. We have done this because it is essential to removing the barriers to testing.

Despite recent access to rapid HIV testing in limited locations, gay men in Australia still face access issues relating to a broad range of testing devices that can be used in a variety of settings and undertaken by a wider variety of people.

In April 2014, ACON welcomed the announcement of the removal of regulatory restrictions on self-testing. This was an important step in the move towards greater testing options.

Strong advocacy steps have been taken in response to decisions by the TGA not to licence new testing devices. Letters and other representations contributed to a TGA decision to review performance requirements and risk mitigation strategies for rapid and self-testing devices.

In 2015, the Review findings were published, incorporating many of the advocacy points ACON and others raised. This is a very welcome and sensible outcome which establishes a transparent and reasonable standard for assessing rapid and self-testing devices.

ACON applied to the TGA for approval of an advertisement regarding self-testing, under the restricted representations regulation in the Act. ACON ran the ad, on the basis that the text provided didn't constitute a restricted representation. However, the advertisements were very text heavy and cautionary in tone, due to parameters sets by the TGA.

A review of TGA regulations and processes in relation to medicines and medical devices was instigated in late 2014, and ACON made a submission and met with the review panel. We largely focused on importance of accepting assessments from overseas jurisdictions with comparable regulatory systems. The outcome of this review is due in late 2015.

### Opportunities

With most policy barriers to the approval and use of rapid and self-testing devices cleared, the focus must be on ensuring manufacturers put forward applications for devices to be approved for use in Australia.

ACON will inform manufacturers of the changes in the policy environment and encourage them to put forward applications for approval and subsidy of their products. ACON will also encourage reconsideration of the OraSure OraQuick, which was rejected under the old framework, under the new policy. We will also continue to work with Atomo, an Australian manufacturer.

Subsidisation remains a significant issue. There is no rapid test listed on the Medicare Benefits Scheme. Alere, manufacturer of the Determine Combo Test submitted an application in May 2014, to which various community organisations provided letters of support. The Medical Services Advisory Committee (MSAC) sought further information from Alere in December and the process of review means we are unlikely to see a rapid test listed until the end of 2015.

It should be noted that internationally, self-testing devices have been approved for use and available for purchase in the USA, France and the UK. These tests can be bought via the personal importation scheme and ACON will look at re-running advertisements on how to access HIV self-testing kits.

## Actions

Activities	Target Audience	External Partners	Timeframe
<b>4.1 Research</b>			
4.1.1 - Promote the outcomes of the FORTH study and other HST and rapid testing demonstration projects.	Community, Policy Makers and Politicians	ASHM, Kirby Institute	Long term
<b>4.2 Community education and engagement</b>			
4.2.1 - Re-run our current self-testing advertisement in its current form.	Community		Immediate
4.2.2 - Run our advertisement on self-testing with amended wording (reduced caution) and more specific information on where self-tests can be obtained.	Community		Short term
4.2.3 - Promote the availability and use of HIV self-testing devices to community, including benefits, how to access support and limitations	Community	AFAO	Medium term
<b>4.3 Political and policy engagement</b>			
4.3.1 - Communicate with the TGA to clarify any limitations to our proposed public communication about HST, including those related to restricted and prohibited representations under the Therapeutic Goods Act 1989.	Policy Makers	AFAO	Immediate
4.3.2 - Advocate for a review of the	Politicians and	ASHM, AFAO	Short term

decisions for a range of devices (new or previously rejected) in light of revisions to standards for assessing rapid and self-testing devices.	Policy Makers		
4.3.3 - Work with national partners to ensure rapid testing is listed as a Medicare item subsidised by the Australian government through the MBS.	Politicians and Policy Makers	AFAO, ASHM	Short term
4.3.4 - Advocate federally for the MBS listing of rapid test kits as a 'class', therefore removing the need to make the case for each individual device, as long as they meet approval criteria.	Politicians and Policy Makers	AFAO, ASHM	Medium term
4.3.5 - Request the TGA approve at least one self-testing device to mitigate the risks of personal importation.	Politicians and Policy Makers	AFAO, ASHM	Medium term
4.3.6 - Work with industry to see high quality rapid and HST devices listed on the Australian Register of Therapeutic Goods.	Policy Makers and Politicians	AFAO	Medium term
4.3.7 - Advocate for greater access to rapid testing across all parts of NSW.	Politicians and Policy Makers	ASHM	Medium term
4.3.8 - Advocate for access to HIV home based/self-testing outside of research trials.	Politicians and Policy Makers	AFAO, VAC	Short term
4.3.9 - Participate in and promote the development of a pilot of a NSW based Dried Blood Spot home HIV testing service.	Policy Makers Community	Kirby Institute, NSW MoH	Short term
4.3.10 - Advocate publically for greater flexibility regarding communication strategies about self-testing.	Policy Makers and Politicians	AFAO	Medium term

## 5. Other Advocacy Efforts

Across prevention, testing, and treatment lie an important set of actions that enable, support and contribute to the goals of the NSW and National HIV Strategies. ACON will actively work with partners to ensure our efforts continue to reflect a comprehensive approach to HIV prevention, in the community interest.

Such actions include:

- Providing feedback to the community about progress being made under the NSW HIV Strategy to 2015.

- Work with AFAO to produce a “report card” style progress update for the Federal Government against the 7<sup>th</sup> National Strategy goals and targets, including what more can be done to achieve these goals and targets.
- Work with Positive Life NSW and the NSW Ministry of Health to develop and improve contact tracing strategies in NSW, involving community based organisations where appropriate.
- Strengthen relationships across the political spectrum, and engage our community partners (including sport, business and other community sector partners) to reinforce support for advocacy asks on behalf of the LGBTI community.
- Use our expertise and reach to ensure media stories support the need for further developments at a policy, funding and system level to help end HIV by 2020.