



HIV testing among gay men and other men who have sex with men

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This discussion paper provides information and analysis on issues concerning HIV testing in Australia as they relate to gay men and other men who have sex with men (MSM). The paper is designed to generate discussion within the community HIV sector about possible approaches and responses to these matters. While there are many areas for discussion regarding HIV testing for key affected populations other than these men, they are not generally within the scope of this paper. However, there is some discussion of other populations, settings and issues (particularly where they intersect with or affect gay men and other MSM) later in this paper.

GAY MEN AND OTHER MEN WHO HAVE SEX WITH MEN

Strategic context

Increasing the rates of voluntary HIV testing is supported across a number of strategic documents addressing HIV.

Section 7.2 of the *Seventh National HIV Strategy 2014–2017* highlights the priority action in HIV testing to:

“Increase access to and uptake of voluntary and appropriate HIV testing among people from priority populations, particularly gay men and other men who have sex with men.”¹

Increasing voluntary HIV Testing is also a key action area in the *United Nations Political Declaration on HIV and AIDS 2011*:

“59 (f) Significantly expanding and promoting voluntary and confidential HIV testing and counselling and provider-initiated HIV testing and counselling.”²

Issues to be addressed in increasing voluntary testing accessibility in Australia are examined in the AFAO discussion paper, *Implementing the United Nations Political Declaration on HIV/AIDS in Australia's Domestic HIV Response: Turning Political Will into Action*.³

The *Melbourne Declaration* highlights the need for increasing voluntary HIV testing:

“Action Area 1: Substantially increase access to and uptake of voluntary HIV testing in Australia”,

and specifically notes the need to make HIV rapid tests available (including investigating options for home use) as a key action area.⁴

The importance of HIV testing

Undiagnosed HIV and primary HIV infection

A significant percentage of HIV sexual transmissions are from people who do not know they are HIV-positive. An estimated 31% of new HIV infections are transmitted from the approximately 9% of men who have sex with men (MSM) with undiagnosed HIV.⁵ Rates of undiagnosed HIV among MSM have also been estimated to be even higher, between 10% and 20%^{6,7,8} and even as high as 31% in some jurisdictions.⁹ With an assumed 25% rate of undiagnosed HIV, it has been estimated that over 48% of infections would come from this group.¹⁰

At the time of writing, the Count Study, a national study that will estimate the prevalence of HIV and undiagnosed HIV infection, was currently recruiting men around the country.¹¹

A significant percentage of HIV sexual transmissions are from people in primary HIV infection – the initial period (weeks) after a person becomes infected with HIV and when their viral load reaches its highest point. An estimated 19% of all new HIV infections are transmitted from the approximately 3% of Australian MSM who are in primary HIV infection.^{12,13}

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Although risk is not limited to people with undiagnosed infection, increasing testing rates among gay men and other MSM will increase the number of these men aware of their HIV status, minimise the time between infection and diagnosis, and reduce onward transmission.

Late diagnoses

In Australia, the average time between a person becoming infected with HIV and being diagnosed is estimated at approximately four years.¹⁴ This is based on median CD4 count at diagnosis for all people diagnosed with HIV. Mathematical modelling data from the Netherlands and Switzerland estimates the time to diagnosis for MSM to be approximately 2.5 years.^{15,16} It has been argued that with similar situations in these countries, Australia may have a similar time to diagnosis for MSM, though this is debated. Having accurate data in this area is important for more robust analysis of Australia's epidemic.

Recent analysis has estimated the median time to diagnosis for MSM in Australia for 2012 at 1.36 years. However, the analysis also approximates the distribution of the time between infection and diagnosis for these men, with 25% of these men diagnosed up to 0.54 years after infection, 25% diagnosed between 0.54 and 1.36 years after infection, 25% diagnosed between 1.36 and 4.62 years after infection, and 25% diagnosed 4.62 years or more after infection. The *mean* time is quite long in comparison to the median, at 3.37 years, because the number of people who progress to AIDS before diagnosis skew the mean significantly, leaving the above median time and distribution of time as the better measure.¹⁷

Previously, late diagnosis in Australia was defined as a diagnosis with a CD4 count of less than 200 at diagnosis. Since 2012, Australia, like many comparable countries, now defines a late diagnosis as a diagnosis with a CD4 count of less than 350, and a diagnosis with a CD4 count of less than 200 as advanced HIV disease. Between 2008 and 2012, 15.1% of people diagnosed with HIV in Australia had advanced HIV disease with a CD4 count of less than 200. This is a decrease from 23.1% of people diagnosed with HIV between 2003 and 2007 who had advanced HIV disease. However, the proportion with late diagnosis, defined by a CD4 count of less than 350 has increased slightly from 38.6% in 2003–2007 to 39.3% in 2008–2012.¹⁸

Although late diagnoses are a high proportion of total diagnoses among heterosexuals and people from high HIV prevalence countries, more than half of all late diagnoses continue to be among MSM.¹⁹ It should also be noted that men who have sex with both men and women have much higher rates of delayed diagnosis (both late diagnosis and diagnosis of

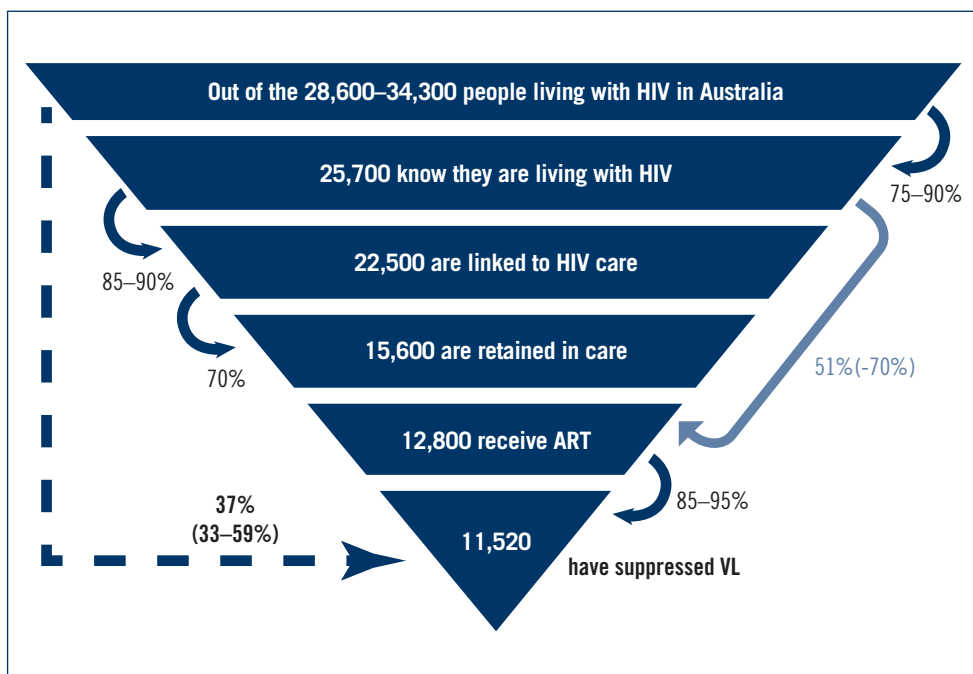


Figure 1 Source: Wilson/Kirby Institute

advanced disease) than men who only have sex with men.²⁰

There are serious health issues associated with progressed or advanced HIV disease. Increased testing and more people knowing their HIV status will improve health outcomes for people with HIV and reduce health impacts of late diagnosis.

Testing and linkage to care and treatment

In Australia, mathematical modelling shows that approximately 51–70% of the people who know they are HIV-positive are receiving antiretroviral treatment. Of these people, approximately 85–95% have suppressed (undetectable) viral load. Based on 10–25% of the total number of people with HIV in Australia not knowing they are HIV-positive (i.e., they are as yet undiagnosed), this means only 37% of all people with HIV in Australia have an undetectable viral load (Figure 1).²¹ This model may be a somewhat conservative estimate.

Recent research has shown large reductions in HIV transmissions from people on HIV treatment, with a 96% reduction among serodiscordant heterosexual couples (couples where one partner is HIV-positive and the other partner is HIV-negative).²² Currently there is not definitive data on the preventative effects of treatment for gay men and other MSM, however it is widely thought that there would be similarly substantial reductions in transmission risk.

In March 2014, the PARTNER Study, a study that enrolled both heterosexual and homosexual couples to examine the risk of HIV transmission from individuals taking effective HIV treatment, released

preliminary results. It reported that in the first two years of the study there were no cases of transmission within couples where the HIV-positive partner was on treatment and had an undetectable viral load (less than 200 copies/ml). At that time, 1,110 couples had been involved in the study, 40% of whom were gay men. Based on the study's estimates of reliability, the investigators predicted a maximum 5% chance that over a ten-year period, one in ten HIV-negative partners in a gay couple who had unprotected anal sex might acquire HIV. They believed it was more likely that chance of acquiring HIV from their partner was nearer to zero, and in fact could actually be zero. However, definitive results will not be known until 2017.²³ The Opposites Attract study, which is recruiting at the time of writing, looks to also provide data on the effectiveness of this "treatment as prevention" in gay male serodiscordant couples.²⁴

Delayed initiation of HIV treatments at a population level also means that community viral load increases, which in turn increases the likelihood of new HIV transmissions. It is clear that the more people there are who know their HIV status (from being tested), the larger the proportion of people with HIV who can be linked to care, and treatment if they choose, there will be. This will lead to an increase in the proportion of people with HIV accessing treatment early and a reduction in transmissions due to lower infectivity.

Test and Treat models

Reductions in community viral load have been linked to substantial reductions in new HIV infections. In San Francisco for example, between 2004 and 2008, a concerted effort to increase HIV testing rates and linkage to care

of people diagnosed HIV-positive (leading to reduced time to virological suppression), was associated with a reduction in new HIV infections of over 40%.²⁵

However, test and treat models can be seen as a top-down or population health model, instead of a community-based bottom-up model. The effectiveness of applying the San Francisco model to Australia has also been debated, given the varied epidemiology of HIV between the two. For example, it has been argued that with the disproportionately high number of infections at the time in San Francisco compared to the whole of Australia, there would be a much greater impact with any intervention. The particularly low levels of linkage to care were also one of the key reasons for the decision for this model in San Francisco. The geographical spread of a large country like Australia as opposed to a single city has been argued as a potential impediment to the application of the San Francisco model. It has also been noted that this test and treat model was part of a much broader city plan for HIV which also included a major reorientation of all HIV services based on risk factors, issues and priorities specific to San Francisco.

What gay men want

In the latter part of 2012, AFAO commissioned a substantial market research project with gay men, entitled “Exploring HIV Prevention and Testing”.

Some key findings from this market research identified what Australian gay men want in terms of HIV testing services. The research makes it clear that to increase testing frequency the HIV testing process needs to be more convenient and more comfortable for the individual. A sense of control is a key driver to getting tested and an important feature of the testing experience.

Three key themes emerged in relation to gay men’s ideal testing experience:

- **Comfort: feeling looked after, respected, no judgement and minimal anxiety.** This can mean different things to different people but includes things like anonymity and a more personalised experience. It also includes things such as the ability to complete screening questions online prior to arriving at the testing site or while waiting to see a clinician. The research indicated that providing such an environment also gave men a greater sense of control and would greatly reduce anxiety.
- **Control: feeling confident, informed and in charge.** This included things such as knowing what’s involved in the testing process and understanding that they are able to make decisions on certain aspects of the testing process. Self-collection of

samples and deciding on how to receive results (such as via electronic formats such as email and SMS) are key examples of this. Having a regular doctor or clinic also provides a sense of control with a continuity of care and all medical records always to hand so that nothing would be missed.

- **Connection: feeling secure, safe and having proximity to exactly what is needed.** ‘Connection’ is ultimately about comprehensive, integrated health care and feeling part of a community. Men feel connected when they are in an environment with like-minded people who understand the complexity of life and understand what they may be going through. Men feel connected when they trust their health care professional and know they are an expert in gay men’s health/sexual health/HIV and are informed about the latest advances in terms of treatment and testing.

Gay men have high expectations; they want testing to be as easy as possible – simpler, more immediate and more accessible. This includes concepts such as harnessing mobile phone technology (e.g. GPS technology to locate testing sites, and actual appointment waiting times), testing sites that come to them (such as at festivals, saunas and gyms), and longer and more convenient opening hours such as evenings and weekends.²⁶

Comprehensive sexual health testing

Other sexually transmissible infections (STIs) can play a significant role in the transmission and acquisition of HIV, in that their presence may increase the risk of acquiring or passing on HIV, even when there are no symptoms, as is often the case. Many STIs continue to be diagnosed at high rates among Australian gay men and other MSM, and there have been resurgent epidemics among MSM of several STIs including syphilis, gonorrhoea and chlamydia (including new strains such as LGV). It is for these reasons it is argued that HIV testing should be part of comprehensive sexual health testing. This is supported by the *Australian STI & HIV Testing Guidelines for Asymptomatic Men Who Have Sex With Men*, which advise that sexually active gay men and other MSM be offered tests for HIV and other STIs together, at the frequency recommended given sexual behaviours and activities.²⁷

Recent research indicates a significant improvement in the reach of comprehensive STI testing between 2003 and 2012, though rates are still relatively low. Among HIV-negative and unknown status men comprehensive STI and HIV testing increased substantially from 13% in 2003 to 34% in 2012. During the same period, comprehensive STI testing (excluding HIV testing) increased from 24% to 57% among HIV-positive men.



However, opportunities are still being missed to test for STIs, with the proportion of men reporting comprehensive testing significantly trailing those who have had any STI or HIV test in the previous year. Where STI testing is occurring, anal and throat swabs are less likely to be collected than other types of specimens; this notwithstanding there has been a significant relative increase in the last 10 years of anal and throat swabs, relative to other STI tests.²⁸

Any advocacy for or implementation of activities to increase HIV testing would need to be considered in the context of enhancing access to comprehensive sexual health testing. Considerations for comprehensive sexual health testing as they specifically relate to HIV rapid testing are discussed later in this paper.

Increasing access to and frequency of testing

The current guidelines for STI testing for MSM recommend that these men should be tested for HIV and other STIs at least once a year, or up to four times a year for men who have had episodes of unprotected anal sex, have had more than 10 partners in the previous six months, participate in group sex and/or use recreational drugs during sex.²⁹

When considering increasing rates of HIV testing, it is important to distinguish between increasing coverage (reducing the number of men who have never tested for HIV), and increasing testing frequency. There has been a gradual downward trend in the proportion of gay men and other MSM that have ever been tested for HIV, down to 86.4% nationally in 2012 (Figure 2). Of these men, the proportion that is testing at least once a year has been decreasing in recent years to 60.5% in 2012 (Figure 3).³⁰ It is also possible that this annual testing rate is an overestimation as they are based on self-reported data. Clinical data suggests that only about 20% of men who should be testing every three to six months, as outlined in the guidelines, are testing that frequently.³¹

Modelling suggests that with every 10% increase in the number of MSM testing annually for HIV, there will be a decrease of approximately 13 HIV diagnoses each year, and importantly a decrease of approximately 22–27 HIV infections each year (though these benefits would not be observed immediately).³²

Increasing the frequency of testing to multiple times per year, especially for MSM at higher risk of HIV acquisition, will enhance these benefits and reduce infections further. This increase in frequency would also be important for detecting people in primary HIV infection. If testing rates were higher, and many of the people who were found to be HIV-positive were offered and received risk reduction counselling and treatment, there would be a further reduction in infections.³³

Barriers to testing

There are many barriers to HIV testing that people encounter or experience. These barriers are broadly classed as structural (or logistical), psychological (or emotional) or psychosocial (psychological and cultural) barriers. Addressing and overcoming these barriers are important and necessary steps in increasing access to and frequency of testing. Psychological and psychosocial barriers are very different, and need to be distinguished between when addressing them or developing messages.

A literature review of psychosocial factors influencing HIV testing found limited research identifying barriers and facilitators of HIV testing, but that important psychosocial barriers such as perceived risk and HIV stigma remain. The researchers argue that what has been lacking has been research using methods other than those exploring the association with a provided set of factors³⁴, meaning that some issues may not be raised through some research but could still be important. It has also been argued that some research may overestimate the importance of making testing more convenient, because it: concentrates on the reasons for not testing as opposed to comparing the barriers and facilitators between different groups (such as testers and non-testers); has a focus on behavioural rather than psychosocial factors; and asks questions about what they want, like or prefer which may not translate into action.

Study on understanding patterns and determinants of sexual health testing

A recent research study was conducted to assess patterns and determinants of testing for HIV and STIs among gay men and other MSM in NSW. This research identified four main groups of testers: non-testers, non-routine testers, testers with moderate routines, and testers with strong routines. Participants reporting moderate or strong testing routines

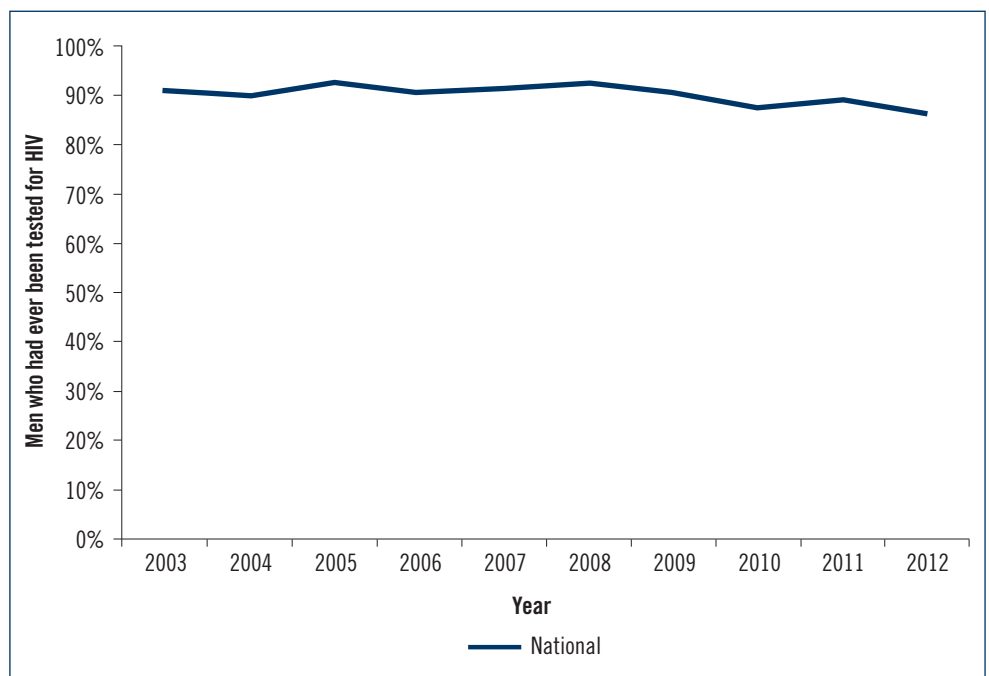


Figure 2 Men who had ever been tested for HIV: *Gay Community Periodic Survey, 2003–2012.*

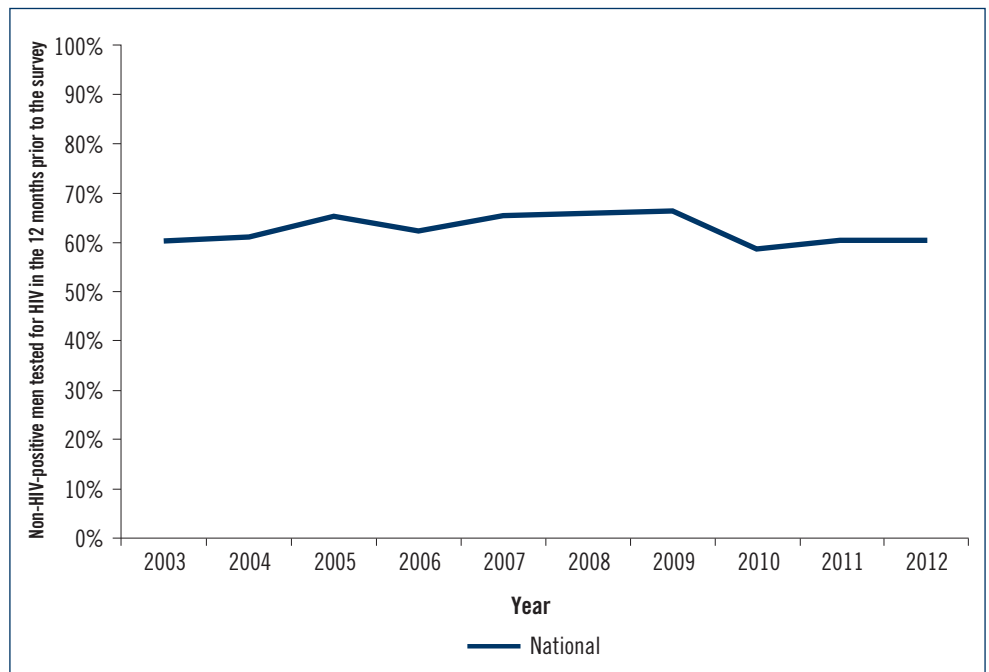


Figure 3 Non-HIV-positive men tested for HIV in the 12 months prior to the survey: *Gay Community Periodic Survey, 2003–2012.*

represented around half of the sample. The research assessed the contribution of a large range of potential barriers and facilitators to testing for either HIV or other STIs, including psychosocial factors.

In analysing all of these potential barriers and facilitators together, participants' routines of sexual health testing were found to be independently associated with knowledge of HIV or STIs, attitudes towards testing, perceived benefits (or pros) of testing and fears and worries regarding STI testing. The most important perceived pros of testing for HIV that were found to influence these men's decision to test were that testing gives peace of mind, helps to put a new relationship on the

right track, makes you feel more responsible for your own health and is beneficial because you receive information and advice at the same time. Fears and worries regarding testing for STIs mostly relate to fears of medical procedures, and fears of partners' and parents' reactions. In addition to the above mentioned psychosocial barriers, routines of HIV testing were also found to be associated with perceived HIV stigma, while routines of STI testing were found to be associated with subjective norms regarding testing for STIs.

The findings suggest that psychosocial barriers and facilitators play an important role in explaining these men's routines of testing (they explain a large proportion of the variance in

testing behaviours) and that these psychosocial barriers should be addressed by sexual health promotion programs.

Based on the findings of their research, the authors suggest the following directions for campaigns and interventions aimed at promoting sexual health testing among these men:

- Further increasing knowledge, especially knowledge of STIs, which was found to be lower than knowledge of HIV
- Promoting positive attitudes towards testing for HIV and STIs
- Addressing men's evaluation of the pros and cons of testing, and promotion of the specific pros that were found to influence decisions to test
- Reducing the (perceived) stigma attached to HIV, especially in HIV testers with no routine
- Addressing specific fears and worries regarding testing for STIs in some men
- Strengthening positive norms around STI testing.

The first three barriers: knowledge, positive attitudes towards testing and lack of perception of pros of testing, operate across all subgroups and can be addressed in campaigns aimed at all gay men/MSM. Complementary, tailored interventions would be also required to address specific barriers to testing such as stigma, subjective norms, and fears and worries, especially in some specific groups of gay men such as non-routine testers and non-testers.

It has also been recommended that campaigns or interventions should not focus on only one barrier, or look at stigma as a separate issue to behavioural norms. Instead it has been recommended that programs need to target four to five barriers.³⁵

Exploring HIV Prevention and Testing market research

In the market research on HIV testing commissioned by AFAO, barriers to testing were categorised as emotional and logistical.

Emotional barriers include screening and risk assessment questions, the perceived judgmental attitudes of clinic staff, and the wait time for results. Being asked so many questions can be confronting and emotionally difficult for many gay men. There is still significant stigma associated with HIV and HIV testing: the HIV testing experience can leave men feeling judged, exposed and vulnerable. It also means confronting the possibility of the worst case scenario – a positive test result.

The logistics of testing are also a key barrier. Having to find a place to get tested, booking the appointment, getting to the testing site, waiting to see the health care professional

and making a second appointment to receive results, all make the testing experience time-consuming and inconvenient – especially for the younger men who expect the testing experience to be easier and more immediate. Financial costs, including the need to take time off work, and other considerations, were also identified as significant barriers.

As discussed earlier in this paper, there were three key areas that emerged from this research in terms of what gay men want from testing: comfort, control and connection. It was also noted that men want testing to be as easy as possible: simpler, more immediate and more accessible. Addressing these requirements will help address emotional and logistical barriers.

Anxiety relating to HIV testing reduces with experience and familiarity with the testing process. First time testers (particularly younger men) reported that their initial HIV/STI testing experience was stressful and frightening, and suggested that a good first test experience could assist them in forming strong, long-term testing routines. In fact, generally, making sure men are able to access suitable places to be tested is critical to forming appropriate HIV and STI testing routines. Men who live outside of metropolitan areas, and/or live at home with their parents or family, also find it difficult to find appropriate testing services, highlighting a need for specialist, discrete services in key locations to sustain regular testing. For men that do not test frequently, having their friends talk to them about testing and locating a good clinic is seen as important. Establishing a cohesive network of gay/MSM friendly clinics/health care professionals (with some kind of cohesive branding) was offered as a possible way to reduce barriers to testing.

The key factors identified that would support routine testing were:

- a trusted and respected clinic or health care professional (gay/MSM friendly, sexual health experts, caring, observant, taking the time to explain things and sharing new information, professional and personable)
- convenient location (close to home or work, close to public transport or free parking)
- free (especially with younger men)
- comprehensive testing (all STIs covered in the test)
- reminders for testing (e.g. from sexual health clinic).³⁶

PASH Study

The Pleasure and Sexual Health (PASH) Study found a number of reasons (both structural and psychological) for gay men and other MSM *never* testing for HIV. These included: thinking they were at low risk; being

unsure where to go to get tested; difficulties getting an appointment; not wanting to be seen at a sexual health centre; not wanting family or other people to know; preferring not to know the result; being concerned about stigma; the doctor not bulk billing; not trusting the doctor's confidentiality; and believing that testing costs too much.

Among participants who had never tested, the reported incentives to increase the likelihood of testing included: being able to obtain results in a few minutes; being able to perform HIV tests at home (home testing); greater convenience; not needing to see a doctor; being able to trust the doctor's confidentiality; and availability of testing at gay venues. Similar responses were reported about the incentives for testing more frequently for men who *had* tested previously.³⁷

Survey exploring reasons for avoiding and delaying testing for HIV

In a New South Wales report (*NSW HIV Modelling & Acceptability Report*) on a national study of gay men, the impediments for being tested were similar to those identified in the PASH study. It also reported other impediments including: having to return for the results; not having enough time; not having symptoms that cause concern; being too much hassle; not liking needles; fear of finding out they have HIV; fear of being tested; perception that no need to test if not changing partners; not wanting to tell partners if they were HIV-positive; embarrassment about discussing their sex life with a doctor/nurse; the doctor not suggesting a test; and feeling they are being asked to test too often.

Some similar responses to the PASH study were also reported in the New South Wales study, regarding what would encourage men to test more frequently. The NSW study also reported interest in new test methods such as saliva-based and finger prick testing, non-clinic based testing facilities (including community organisations, and sending their own saliva or finger prick specimen directly to a laboratory), and simplified procedures for receiving test results (such as by email, phone or SMS, as well as being able to return for results the next day or within a few days).³⁸

A key finding from this study was that among men who had engaged in unprotected anal intercourse with casual partners (UAIC), those who had not tested recently (in the previous six months) tended to be older and felt they had not experienced any symptoms of illness, suggesting that there is a real lack of understanding among these men about seroconversion (including the probability of seroconversion illness), and about the benefits of early diagnosis and treatment.³⁹

The Three-Test Rule

A further structural barrier to testing is what is often referred to as the 'three-test rule' or the 'three-test pathology testing rule'. This rule effectively places an upper limit on the number of pathology tests ordered by a general practitioner (for a non-hospitalised patient) that would be covered by Medicare. This is outlined in Rule 18 of the Pathology Services section of the *Medicare Benefits Schedule Book*. Here it is described as an 'episode cone', stating that for a set of pathology tests ordered in one patient's appointment (or episode), the Medicare benefits payable will be equivalent to the sum of the benefits for the three tests with the highest fees.⁴⁰

In the context of the importance of offering HIV testing to gay men and other MSM as part of comprehensive sexual testing, this rule provides potential barriers and disincentives to testing for clinicians and/or these men (and other people seeking to test frequently for HIV and other STIs). According to this rule, if more than three tests are ordered (which would be the case in any comprehensive sexual health check), the clinician may need to absorb the cost of those additional tests or pass the cost on to the patient. Or alternatively, this could mean not all of the tests would be done leaving these men's testing needs unmet.

The three-test rule can also impact HIV-positive patients who have their monitoring tests (e.g. CD4 and viral load) ordered at the same time as their STI tests.

It is understood that many general practice clinics with a high case-load of gay men and other MSM have arrangements with the laboratories they partner with so that these costs are not incurred by the clinician or patient as a result of the high quantity of tests put through the laboratory. Alternatively, clinicians could bill separately to avoid the three-test rule. However, these could be seen as workarounds to the problem and may not be consistent in all areas. Arrangements with laboratories would also most likely not be available for clinics that do not have a high case-load of gay men and other MSM. This could be especially problematic for people in rural, regional and remote areas.

To address this issue in a more systematic way, an exemption from this rule for the screening of STIs could be investigated with MSAC (Medical Services Advisory Committee).

Improving traditional (non-rapid) HIV testing

Traditional HIV testing here refers to testing done in clinical settings, where a blood sample is taken with a venous blood draw and sent to a laboratory for analysis and awaiting results, which can be up to a week or more. HIV rapid tests provide results 'while you wait' (usually within 30 minutes) and are designed to be



able to be performed in both clinical and non-clinical settings. HIV rapid tests are discussed in more detail later in this paper.

Making HIV rapid testing available for gay men and other MSM goes some way to reducing the barriers to regular testing. However, there are numerous other ways to improve the speed and/or convenience of traditional (non-rapid) HIV testing. It should be noted that each of these options will not be suitable for all men for a range of reasons (including access and location). However, asking gay men what they need and including various viable options will provide a range of testing choices to help meet the varying needs of men in different settings.

Alternative methods for receiving results

The *National HIV Testing Policy* was reviewed and updated in 2011. One of the key changes was allowing for negative HIV test results to be given in other ways than in person (e.g. by phone, SMS, etc.), based on clinical judgement by the person responsible for conveying the test results.⁴¹ Although the *National HIV Testing Policy* allows for this, it is unclear how systematically initiatives such as giving negative test results by phone are being taken up by clinics and GPs around Australia. Providing negative results in other ways in as many testing services as possible, and communicating this option to gay men and other MSM, would help address the structural barriers to testing associated with having to book (and potentially pay) and return for a second appointment to receive results. At the time of writing, the *National HIV Testing Policy* was being reviewed again to incorporate the possibility of allowing all results to be given by other methods based on clinical judgement, noting it is preferable that a positive HIV test result be given in person.

One of the ways the changes in the policy would be communicated to clinicians is through the work of the Australasian Society for HIV Medicine (ASHM), through their usual communication mechanisms to their members and training provided (including introductory training and updates and refresher courses for existing clinicians). The utilisation of other organisations and colleges for communication of these changes could also be investigated. This could include the Australasian Chapter of Sexual Health Medicine/Royal Australasian College of Physicians, the Royal Australian College of General Practitioners, the Australian College of Rural & Remote Medicine, and the Australasian Society for Infectious Diseases, amongst others. Training for clinicians run by other organisations in different jurisdictions, such as courses on HIV medicine, would also need to be considered. At a jurisdictional level, agencies could help facilitate this and advocate for this in their jurisdictions. This could include utilising Medicare Locals or similar bodies.

Alternative service models

Other options for improving testing include different service models. "Express" testing services at clinics is one model that could improve gay men's experience of HIV and STI testing and encourage them to test more frequently. Express clinics are typically run alongside routine clinics and offered to existing patients who have tested before. They often offer things such as a computer assisted self-completed interviews, self-collected samples (e.g. swabs) and staffing including nurses. The Sydney Sexual Health Centre trialled an express service from December 2010, and found it improved the patient journey, with reduced waiting times and length of stay (both in the express service and the clinic overall). It also allowed more

patients to be seen overall in the clinic with minimal additional costs.⁴²

The Chelsea and Westminster Hospital NHS Foundation Trust operates the Dean Street Express Clinic in Soho, central London (Soho is one of London's main gay neighbourhoods). It offers a walk-in service for asymptomatic clients, with touch screen check-in, self-collected swabs and urine samples, as well as blood tests and HIV rapid tests. Swabs and urine samples are sent from the self-screening suites to an onsite lab using a vacuum chute. The HIV rapid test result is provided during the consult (about 60 seconds for result), and all other results are provided via SMS within six hours.⁴³

The use of clinical staff other than doctors, such as nurses, could expand the clinical capacity for testing and make getting tested easier and more accessible.

Another alternative service model is providing pre-filled pathology forms to patients (most likely existing patients who are regular testers). These forms could be mailed to the patient for them to take to a collection point to provide samples. An extension of this concept, a 'virtual' STI clinic, is soon to be trialled in NSW. Patients will be able to download the appropriate pathology forms (based on their online risk assessment) and take them to a pathology provider for samples to be taken.

Unsupervised testing centres are another alternative that could be considered, where all samples are self-collected by the patient (including finger-prick HIV rapid testing), and the clinic operating the centre managing the results by phone.

Laboratory testing

Currently, it can take up to a week (or longer in some areas where capacity or distance from services are issues) after the blood sample is taken for results to be conveyed to clinicians. Reducing this time and providing a faster turn-around of results – and communicating this to gay men and other MSM – would help address the psychological barriers to testing associated with having to wait for results. One way this could be done would be investigating if prioritising tests from populations such as MSM would be possible. However, with confirmatory testing required for any initially reactive results, shorter time frames may not be possible outside of existing relationships and agreements between individual clinics/clinicians and laboratories. Also, in the context of offering comprehensive sexual health testing, shorter time frames for results for HIV may not be desirable. The time it can take for tests of other STIs to show results could mean not all results would be given at once. It is also worth noting for rural and remote areas, that shorter time frames for getting results will not be possible with already limited pathology facilities in the area.

Self-collected samples

Other methods of collecting samples should also be considered, such as dried blood spot testing, where blood from a finger prick is blotted and dried on filter paper and sent to laboratories for analysis. Dried blood spot testing would address issues regarding convenience and intrusiveness that act as barriers for some people to test. It could also be an effective option for expanding testing services in remote or resource-poor settings. The quality of dried blood spot testing has improved but is most likely to only be available in public hospitals and large laboratories. The capacity of laboratories to do this kind of testing would need to be investigated for its optimal implementation; however, this may not allow for testing of other STIs as part of a comprehensive approach to sexual health testing (as discussed earlier in this paper). The Terrence Higgins Trust (THT) in the United Kingdom has recently offered this technology in some locations, and through a study in which participants ordered self-collection kits online, posted the dried blood spot specimen to the laboratory and received their results by text message. At the time of writing, ACON, Sydney Sexual Health Centre and the Kirby Institute were investigating a similar trial for New South Wales.

A similar model is currently being piloted in Queensland for chlamydia, where selected pharmacies will sell subsidised chlamydia self-test kits that people can use at home and post in to have the results sent to them by SMS.⁴⁴

Posting swabs and containers to clients for pre-paid post returns has been utilised as a model previously, but has been noted that this is not always cost-effective and the samples are not always returned.

Queensland Positive People are also currently trialling posting HIV testing kits to regional and remote areas for people to self-collect oral fluid samples and post to a sexual health clinic to process and provide results.

National HIV Testing Day/Week

A national HIV testing day or week could help promote the importance of testing and help increase testing rates. Advising gay men about the availability of various service models and types of testing, as well as other recent changes in testing (such as other methods to receive results) could be included in its promotion. This would not only raise the awareness of the importance of testing, but to also help encourage men to seek testing. The importance of comprehensive sexual health testing could also be incorporated in the event's promotions.

Testing in community settings

Offering a mix of service models of HIV testing, and providing testing a variety of settings including community settings, would offer men more choices and assist

in addressing numerous structural and psychological barriers to testing.

A recent study found that gay men had a higher preference for testing services in community settings than traditional clinical settings.⁴⁵ The AFAO-commissioned market research found that men would like to have more control over the kind of testing service and experience they can access, with testing service design needing to reflect the different needs men have at different times. For example, some men may need their testing service to be anonymous and efficient, while others may need theirs to be personable and reassuring, and others may prefer mobile and spontaneous services.⁴⁶

The Seroconversion Study is a study to collect information from people who have recently been diagnosed with HIV about their experiences with HIV, both before and after they were diagnosed. It has found that access to peer-based services appears to be key to ensuring that individuals are encouraged to test, and to test earlier. It found that peer-based community services were able to provide a more supportive and understanding perspective, and enabled the discussion of topics that might otherwise be too embarrassing. The integration of a testing service that is directly linked to support services was also found to be beneficial.⁴⁷

Clinics in community settings

HIV testing clinics have been set up in community settings in several jurisdictions across the country. In November 2012, the Queensland AIDS Council (QuAC), formerly Queensland Association for Healthy Communities, set up an after-hours testing clinic called Testing Point. This was initially for HIV and syphilis, but now offers all HIV and STI testing. It is run by volunteer nurses and GPs in QuAC's Brisbane premises. This started as a six-month trial but is now an ongoing service. This was also initially offered as a site for the HIV rapid testing trial in Brisbane discussed later in this paper, but in March 2014 Testing Point was removed from this trial. Testing Point continues to operate, including offering HIV rapid testing. At the time of writing, the QuAC was investigating funding and expansion options for Testing Point.

In New South Wales, after-hours sexual health testing services called a[TEST] operate out of dedicated spaces at both the ACON Surry Hills and AFAO Newtown offices in Sydney, and more recently out of an existing clinic in Kings Cross. The ACON office site has been operating since June 2013, the AFAO office site started in November 2013, and the Kings Cross site began in May 2014. There have also been pop-up testing sites, including caravans in Sydney and Lismore and a pop-up shop front in Sydney. These

sites operate in partnership with sexual health clinics, and utilise ACON peer workers to service the clients, including performing HIV rapid tests and giving the results. A nurse is also on site and performs venous blood draws. All sites offer HIV rapid testing as part of the New South Wales trials discussed later in this paper.

In Victoria, a shop-front community clinic called PRONTO! has been operating since August 2013. This is a partnership between the Victorian AIDS Council/Gay Men's Health Centre and the Burnet Institute. It utilises peer workers to service the clients, including performing HIV rapid tests and giving the results (venous blood draws for confirmatory testing on a reactive rapid test result only), and has nursing staff on site. The service is initially only offering HIV rapid testing, but all STI tests are planned to be offered in the near future. HIV rapid testing is currently offered through a trial, as discussed later in the paper.

The Western Australian AIDS Council (WAAC) has operated a number of gay men's sexual health clinics in community settings since 1988, including at sex-on-premises venues and the WAAC offices. WAAC currently operates two testing clinics for gay men and other MSM. Initially established as a testing service run out of the WAAC premises, the M Clinic now operates as a stand-alone clinic and is run by peer workers. They also offer a testing service at a Perth sauna (sex-on-premises venue).

Monitoring and evaluation reports have shown the M Clinic service to be a very successful model in a jurisdiction that otherwise experiences a significant gap in sexual health service. In May 2012, WAAC reported that since its establishment in July 2010, the M Clinic had seen over 1300 clients and has had the highest number of HIV notifications among MSM from any single clinic in Western Australia; and since November 2011, the M Clinic had diagnosed 50% of new HIV diagnoses among MSM in Western Australia.

The M Clinic peer-based model has addressed numerous barriers to testing, with people preferring to talk to a peer about risk behaviour and providing more convenient opening hours. This service model was reported to be particularly attractive to men under 30, raising the likelihood that the M Clinic may be diagnosing people that have not previously been tested for HIV.⁴⁸ At the time of writing, M Clinic was one of two Western Australian sites planning to offer HIV rapid testing through an expansion on the study currently being conducted in New South Wales by the Kirby Institute. These trials are discussed later in this paper.

In the ACT, there are outreach clinics (called STRIP clinics) several times a year for four to five weeks at a time, operating out of AIDS Action Council of the ACT's offices for all of the LGBTI community, and at a sex on premise venue for men only.

Clinics in community settings overseas

Magnet is a shop-front style clinic located in the Castro district of San Francisco and run by staff and volunteers as a drop-in service, though appointments can be booked online for existing clients. In addition to their clinical services, Magnet is also an art gallery, lounge and internet café, offering a place where gay men can connect in addition to getting tested. The inviting location in the gay district was designed to encourage men to think and talk about sexual health. Magnet has proven to be successful in attracting gay men to their service, with 4,600 clients in 2007.^{49,50} Currently however, Magnet is unable to keep up with demand, limited by both physical size and human resource capacity. In 2012, they estimated having 9,500 clients with 14,473 clinical visits.⁵¹

BCN Checkpoint is another overseas example of a clinic in a community setting. It is a community-based testing service of HIV and other STIs for gay men and other MSM, located in Barcelona's gay neighbourhood. The centre was set up in 2006 by Projecte dels NOMS-Hispanosida association, and is the first of its kind in Spain. It offers HIV and syphilis rapid testing, traditional HIV testing, and vaccination for hepatitis A and B. It also offers complete STI screening for MSM (within a study) for HIV, syphilis, chlamydia, gonorrhoea, hepatitis A, hepatitis B, hepatitis C, and human papillomavirus (HPV) including anal cytology.^{52,53}

Outreach testing

Offering testing in outreach settings has been considered in several locations around the world. Outreach settings include community organisation premises, events, bars, sex-on-premises venues (such as the testing service at the sauna in Perth and the planned expansion of the HIV rapid testing trial in Queensland discussed later in this paper), and mobile testing services such as vans. Many of these settings meet the need for opportunistic testing, and are not necessarily intended as an option for ongoing regular or routine testing. However, these outreach settings could potentially target people not accessing HIV testing services elsewhere. So, depending on the setting and population, outreach testing could often result in a relatively low number of people being tested, but a high yield of infections detected due to reaching people engaged in high risk activities. It can come with substantial costs however.⁵⁴ They could also provide information on and referrals

to other testing services. It should be kept in mind that such settings may not always allow for testing of other STIs as part of a comprehensive approach to sexual health testing.

Community settings: issues for consideration

Working with clinical partners

There are numerous issues to consider for setting up a testing clinic in a community setting. Understanding the requirements of clinical governance is an important consideration to ensure appropriate processes and procedures are being followed. It is essential that the role of community organisation peer educators, as distinct from clinical staff, is well defined; and a doctor would need to be available for consultations if seeing symptomatic clients – including for prescribing of treatments for STIs and referrals. The potential issues of storing drugs and specialist medical equipment may need to be considered. Patient privacy and confidentiality and the security of health information would also need to be managed and maintained.

Use of peer educators

There are specific considerations regarding peer educators at clinics, depending on the roles and functions of peer educators. Currently, peer educators may only be involved in greeting the clients as they arrive and/or performing the risk assessment and obtaining informed consent for participation in a HIV rapid testing trial. The peer educators currently performing HIV rapid tests and giving results in community-based clinics are doing so as part of trials. Subject to Therapeutic Good Administration (TGA) approval, non-clinical staff such as peer educators should in the future be able to operate HIV rapid test kits and give results, with clinical staff performing venepunctures for blood samples.

Utilising peer educators in testing services can be very beneficial and address some of the barriers to testing – many men feel more comfortable with a peer and feeling less judged or anxious when speaking about their sexual history and risk. If men feel more comfortable, this could also facilitate improved partner notification with men providing more or all of their partners' names in a peer setting. However, there are also some important issues to consider when considering the use of peer educators.

Many community organisations utilise volunteers in their peer education services. The use of volunteers in supporting HIV testing services could be an attractive prospect, both for the organisation and the volunteer; however, it should be kept in mind that both

paid staff and volunteers (peers) will need to have shifts at sufficient frequency to maintain skills at an appropriate or adequate level.

There are also ethical issues that need careful consideration when establishing community based testing services utilising peer educators. This could involve things such as the peer educator knowing clients attending the service (e.g. as previous sexual partners, friends, sexual partners of friends, etc.), ensuring confidentiality, and retaining a professional relationship with the clients when interaction could occur in other places in the community. There may also be legal issues to consider, with what clients may disclose to the peer educator during the testing process.

Appropriate and adequate training and accreditation is required for peer educators. This includes such things as gaining informed consent, maintaining confidentiality, and in the event that TGA approvals allow, specific training of how to operate and interpret particular HIV rapid test kits, and deliver results. Peer educators also must have sufficient HIV (and STI) knowledge to ask and answer questions regarding risk, prevention, transmission and treatments.

Other logistical issues

When setting up a new testing clinic, either within the existing premises of a community organisation or at a different site, organisations will need to consider risk assessments and a range of issues related to starting clinical work. These include issues such as quality assurance, quality control, and external quality assessment schemes, as well as accreditation and a relationship with a laboratory (this also includes the process with the laboratory for confirmatory testing of reactive HIV rapid test results). Other issues such as professional indemnity insurance requirements for community testing would also need to be considered. There will also be jurisdictional requirements or guidelines to be taken into account.

Clinical workload issues

Increasing the number of gay men and other MSM testing for HIV (and other STIs) and increasing their testing frequency will put a larger demand on clinical services providing these tests.

Some existing clinical services (both sexual health clinics and GPs) are already at or close to full capacity. There is a need to examine models to expand capacity at these services, including whether to utilise clinicians other than doctors for HIV and sexual health testing (e.g. practice nurses) in GP clinics. Offering other methods to receive results, such as by phone or SMS, would also create capacity by removing the need to return for a second appointment.

Setting up new testing services (e.g. in community settings, or express services in existing clinics) could substantially increase the overall service capacity for HIV and STI testing, as well as provide different options for men to access testing services.

Window periods of traditional HIV tests

The window period refers to the period of time between the time of infection and when the HIV test can detect the infection. The length of the window period depends on the type of test used. Older generation tests take up to three months to detect infection; however, newer generation tests can detect infection much earlier in the infection.

The window period of the latest generation tests have anecdotally been noted to be approximately six weeks or even a much shorter timeframe. The window period of each of the particular types or generations of tests is not always known.

As the *National HIV Testing Policy* states, “More advanced HIV tests can detect infection sooner than others; however not all jurisdictions laboratories currently use the more advanced technology. It is important that a practitioner delivering a test result is aware of what test is being used and how soon after infection it can detect infection. If he or she does not have that information then a window period of three months should be used.”⁵⁵

Some gay men may have a more accurate understanding and knowledge of window periods than other men or the broader population. However, due to the differences in the use of testing technology between clinics, there is not a standard time frame that is understood by the communities being tested or by the HIV community sector. It is therefore difficult to communicate this information to gay men and other MSM.

This lack of consistent understanding across gay men and other MSM is demonstrated in a recent study. When asked “how long after getting infected with HIV would you need to wait before the virus (or its antibodies) could be detected in an HIV test?”, participants in the study gave a broad range of time frames: It would show up immediately (0.8%); Within a few hours (1.7%); A few days (6.7%); Two weeks (9.2%); Six weeks (25.1%); Three months (41.6%); Six months (4.9%). Also, 9.9% of men didn't know how long they needed to wait.⁵⁶

This lack of understanding can mean men are going to be tested too early if they think the test can detect infection in a shorter period than possible. This would then mean they would need to be tested again a short period afterwards, which may prove problematic given the barriers to testing. Conversely, some

men may be testing later than they need to because they think the test wouldn't be able to detect a possible infection in a shorter time, which could have consequences both for their own health but also in terms of possible onward transmission.

A similar lack of consistent understanding was also found in this study with respect to the window period of HIV rapid tests. This and other issues relating HIV rapid testing are further discussed later in this paper.

Furthermore, it is unclear if clinicians not regularly testing patients for HIV understand the different window periods associated with different laboratory tests.

It has been argued that there is a need for laboratories to provide clear guidance to clinicians on the exact window periods for the tests they use. This information should then be communicated to the patient for a more consistent understanding for the tests they are having. Another option is to advocate for all laboratories to upgrade to the latest generation tests, to ensure a consistent message about the window period of laboratory tests can be provided.

Detecting recent HIV infection

In Australia, there has been national reporting for over 15 years on recent (or newly acquired) HIV infection as defined as a HIV seroconversion after a recent prior negative test, or the diagnosis of a characteristic illness associated with seroconversion. Recently, the definition has been expanded to include the detection of HIV prior to the appearance of HIV antibodies. However, over the past ten years, tests have been developed to distinguish recently acquired HIV infection (individuals infected within the previous three months) from established infections.

These incidence tests could provide a valuable surveillance mechanism for recent infection, such as for population incidence estimates, to better inform the development and assessment of prevention interventions (including those about testing), and help identify high risk groups and target resources.

These incidence tests are currently only performed in two laboratories in Australia (one in Sydney and one in Melbourne), with some referrals sent from other laboratories (including in other jurisdictions). A systematic and national testing of samples from people once they are diagnosed with HIV would be a useful surveillance and monitoring tool.

HIV rapid testing

HIV rapid tests provide results ‘while you wait’ (usually within 30 minutes) and are designed to be able to be performed in both clinical and non-clinical settings, rather than



the traditional practice of testing in clinical settings, where a blood sample is taken with a venous blood draw and sent to a laboratory for analysis and results (which can be up to over a week).

As noted earlier in this paper, HIV rapid testing is considered to be one tool to help overcome some men's barriers to testing. A recent study found that gay men had a higher preference for HIV rapid testing than traditional testing.⁵⁷ In addition to the acceptability of HIV rapid testing⁵⁸ discussed later in this section, the AFAO-commissioned market research identified that any means to reduce the waiting time for results, including via HIV rapid testing, was regarded by respondents as a means of reducing the associated anxiety. Rapid tests were perceived to have the added benefits of not having to return for a second appointment to collect test results, and as an opportunity to re-engage these men with new information and technology.⁵⁹

The World Health Organization developed a set of criteria for an ideal rapid test. According to the ASSURED criteria, rapid tests should be Affordable, Sensitive, Specific, User-friendly (simple to perform in a few steps with minimal training), Robust and rapid (results available in less than 30 min), Equipment-free, and Deliverable to those who need them.⁶⁰

In other places, HIV rapid testing is sometimes used interchangeably with the term point of care testing. However, it is important to note the difference between the type of test being performed (in this case, HIV rapid tests), and the setting in which they can

be used. These can include clinical settings (including where there is a point of care), and non-clinical settings such in community-based services, outreach or self-administered testing. In this paper, HIV rapid testing is referred to as a type of HIV test, and it addresses various settings where the different types of HIV tests (including HIV rapid tests) can be performed.

The *National HIV Testing Policy* was revised in 2011. Some significant changes were incorporated, including the provision of a framework for HIV rapid testing in clinical as well as non-clinical and community settings.⁶¹

HIV rapid tests are designed as screening tests, rather than diagnostic tests, and will provide one of three results:

- Indeterminate (error with the test kit), which will require a another test to be performed
- Non-reactive (considered negative, noting the window period)
- Reactive (all reactive results require a venous blood draw for confirmatory testing before a diagnosis is given).

Considerations of HIV rapid testing

There are limitations of HIV rapid tests that need to be understood when considering offering HIV rapid testing. One is that they have slightly longer periods of time to be able to detect infection (window periods), which would need to be managed by offering traditional (venous blood draw) tests to those who have had recent risk events (such as unprotected anal intercourse). The window period differs from one type (brand/product)

of kit to another. The other issue is that HIV rapid tests can give a slightly higher number of false reactive (false positive) results. The *National Testing Policy* and the Therapeutic Goods Administration (TGA) conditions require that a person with a reactive test result also have a confirmatory laboratory test before confirming an HIV-positive diagnosis.⁶²

This higher number of false reactive results, even among high prevalence populations, means that HIV rapid testing is not appropriate for use in populations with low prevalence of HIV. For example, this means that rapid testing would not be appropriate among people in remote areas, unless they are gay men or other MSM. Rapid testing should never be targeted towards sex workers, including gay and MSM sex workers. This is because there will be an even higher number of false reactive results for people among these low prevalence populations.

When used in low prevalence populations, such as among sex workers, HIV rapid tests would produce many more false positives than true positives. For example, in an analysis of the low HIV prevalence of female sex workers, the TGA approved Alere Determine HIV Combo test would give 15 false positives for every one true positive result.⁶³

Regulatory context and issues

On 12 December 2012, Australia's first HIV rapid testing kit was approved for use by the TGA – the Alere Determine HIV Combo test. The TGA approval is subject to certain conditions including who can perform the test, and training and accreditation requirements to perform HIV rapid tests.⁶⁴ There is currently some uncertainty relating to the interpretation of the conditions of this test. At the time of writing, the *National HIV Testing Policy* was being reviewed again and will incorporate changes, including clarification on who can perform the test (including trained peer workers) and recognition of prior learning to meet accreditation requirements for existing clinics that routinely perform HIV testing (e.g. sexual health clinic, GPs with high case loads of gay men and other MSM). In February 2014, the Department of Health sought input on potential changes to the conditions of the Determine test to clarify these issues to enable the better implementation of HIV rapid testing. At the time of writing, a decision had not yet been made on these changes. If clarity on these conditions is not attained before the HIV rapid testing trials discussed later in this paper conclude, this could have significant impacts in terms of being able to provide access to HIV rapid testing for gay men in those jurisdictions.

Laboratory accreditation requirements were originally designed for traditional testing. A system that would waive the laboratory accreditation requirements and instead use

a separate and more appropriate framework for HIV rapid tests (such as the CLIA waiver system in the United States⁶⁵) is one option to help overcome some of the issues currently experienced in the approval and implementation of HIV rapid tests.

The Alere test kit took over two years to be assessed and approved by the TGA. Currently, there are a number of other test kits either being assessed by the TGA or soon to be submitted. It is important that there are a range of HIV rapid tests to choose from. Each type (brand/product) of kit varies in the time it takes to give a result, and different clinics or GPs will prefer different time frames to suit the clinic's work flow. Some men being tested may also have a preference for tests with particular time frames for results. Having multiple HIV rapid test kits available can also have other benefits. For example, Magnet (the shop-front clinic in San Francisco) uses an algorithm of multiple HIV rapid tests to mitigate the limitations of specific tests regarding false negative and false reactive results.

In addition to the protracted timeframe for the TGA approval process, the cost of application can also be seen as a barrier for manufacturers to submit their test kits for approval. There are potential options for streamlining and reducing these costs. One option is for manufacturers of HIV rapid test kits being given a fee reduction or waiver, on the basis of a public health interest. The other option that could be investigated is for the streamlining of the approval process for kits that have been approved by comparable regulatory bodies in other jurisdictions (such as in European countries, United Kingdom, USA, Canada or New Zealand).

A further barrier to the uptake of HIV rapid testing, particularly through General Practice, may be failure to ascribe a Medicare rebate for HIV rapid testing. A recent survey in Victoria on HIV rapid testing completed by GPs and sexual health practitioners with a special interest in HIV, found that 15% of respondents would not offer HIV rapid tests unless they were covered by Medicare; the remaining 85% of respondents would offer rapid testing but would charge a fee to the patient.⁶⁶

The manufacturer of a TGA approved kit is required to make a submission for their inclusion on the Medicare Benefits Scheme (MBS) for this rebate. This should only need to be done by one manufacturer of a TGA approved test, and if granted should then apply to all approved HIV rapid tests from that point on.

In May 2014, Alere, the manufacturer of the Determine HIV Combo test, applied to the Medical Services Advisory Committee (MSAC) for a rebate for HIV rapid testing, though requesting it be limited to antibody/

antigen combination rapid tests (Alere is currently the only manufacturer that uses this technology). AFAO has supplied a letter of support to MSAC for the MBS listing of HIV rapid testing, for the inclusion of any TGA registered HIV rapid tests. Other organisations also supplied letters of support to MSAC in response to Alere's application. At the time of writing, no decision had yet been made by MSAC.

Initial implementation of HIV rapid testing outside of trials

Although the requirements in terms of training and accreditation have not yet been finalised, a number of clinics and GPs have started offering HIV rapid testing using the Alere Determine HIV Combo test. Prahran Market Clinic (PMC) in Melbourne was the first and started this in their clinic in March 2013.⁶⁷ In discussions with PMC, AFAO learned that they have received the specific training to use the Alere Determine HIV Combo test, and have formed partnerships with the Royal College of Pathologists for their quality assurance and VIDRL (laboratory) to oversee the testing (VIDRL also required that the first 100 tests also have accompanying blood draw samples for comparison). The specific test training, quality assurance and relationship with an accredited medical testing laboratory are all conditions of the TGA approval.⁶⁸ A small number of other testing services are now also offering HIV rapid testing using the Alere test, including a GP clinic in Melbourne. Some of the private clinics are passing on the cost of the kit to their patients.

In June 2013, Queensland Health began offering HIV rapid testing through many of their public sexual health clinics throughout the state, using the Alere Determine HIV Combo test. They are also currently investigating other options to expand this, including through s100 prescribers (clinicians that can prescribe HIV medications) and the option of offering rapid testing in hospital Accident and Emergency departments.

Late in 2013, the Interchange General Practice in Canberra started offering HIV rapid testing using the Alere Determine HIV Combo test. They are passing on the cost of the test (\$20) to their patients.

There have also been a small number of other GP clinics in other jurisdictions that have started offering HIV rapid testing.

Although there still may be greater clarity needed in terms of the accreditation required to perform HIV rapid tests, the conditions of the TGA approval are written such that the onus is on the manufacturer of the kits to ensure that the device is only supplied with the conditions met. So in supplying to these services, the manufacturer must be satisfied

that these conditions are being met – possibly due to the fact that they are existing services that specialise in HIV and sexual health testing, and accreditation requirements are met by their existing skills and experience coupled with the specific training for the kit.

HIV rapid testing trials

There have been and continue to be several HIV rapid testing trials operating in Australia to date, in Sydney, other parts of NSW, Melbourne and Brisbane.

The clinical trial of HIV rapid testing in four Sydney sexual health clinics found nearly all men were satisfied with HIV rapid test pre-test discussion (97%), result delivery (97%), and the process overall (98%). Most men (92%) would recommend rapid testing to someone else, and 80% wanted a rapid test for their next HIV test.⁶⁹ Data on the acceptability of clinical staff conducting the testing was also collected, and was found to increase with time and experience of rapid testing.⁷⁰ This trial has now been extended and is operating at numerous additional sites throughout New South Wales, including a small number of GPs. The extension has also incorporated other changes including providing data on acceptability, cost, feasibility and impact in a range of settings and uses the Trinity Biotech Uni-Gold HIV test (one of the tests currently being assessed by the TGA). Another trial is also operating in Sydney using the Orasure Oraquick Rapid Test (another test to be assessed by the TGA). Some sites in Sydney are offering the choice of both the Trinity and Orasure tests. This will guide the wider roll out of HIV rapid testing and describe a framework for evaluation of HIV rapid testing demonstration projects in NSW. It will also facilitate a coordinated approach to issues regarding importation, quality assurance, training and evaluation, as well as the regular monitoring of the performance of the tests. This trial, conducted by the Kirby Institute, is due to finish at the end of 2014.

The Kirby Institute study utilising the Trinity test, is also expanding into Western Australia. In May 2014, the Western Australian AIDS Council's M Clinic began offering HIV rapid testing through the study. The second site in Western Australia will be the Sexual Health Clinic at Royal Perth Hospital. At the time of writing, the Royal Perth Hospital site had not yet begun as part of the trial but was expected to start later in 2014. Each of these sites will initially operate for 12 months from their commencement as part of the trial.

The randomised control trial at the Melbourne Sexual Health Clinic found that over an 18-month period, men who could access HIV rapid testing re-presented for HIV testing earlier and tested more often overall than men who could only access traditional HIV testing.⁷¹ This trial has not been extended.

A trial of HIV rapid testing is currently being run through the PRONTO! community-based clinic discussed earlier in the paper. This trial is due to finish in August 2015.

The Brisbane trial, which looks at performance and acceptability of clients and staff, has not yet produced results, but continues to operate. With Queensland Health's roll out of the TGA approved Alere Determine HIV Combo test to their public sexual health clinics throughout the state, there are currently plans to expand the trial, including a peer-based clinic (through Queensland Positive People) to be operated out of the Brisbane Sexual Health Clinic (Biala) building, as well as outreach testing at sex-on-premises venues. Initial discussions have also been had to investigate the option of offering HIV rapid testing in some pharmacies as part of this trial. This plan would utilise trained pharmacists to perform the tests under some set conditions, including having a separate private room and being part of or nearby a medical centre with links to a pathology laboratory to offer confirmatory testing in the case of any reactive results on the HIV rapid tests. Testing Point, the clinic operating out of the Queensland AIDS Council's office (discussed earlier in this paper) was removed from this trial.

If any other kits are to be offered for use prior to approval by the TGA, those kits can only be offered through clinical trials.

Acceptability by General Practitioners

A recent survey in Victoria on HIV rapid testing completed by GPs and sexual health doctors, found that all respondent GPs thought that HIV rapid testing should be available in primary care clinics. More than three quarters (77%) of respondents also thought HIV rapid testing should be available in community organisations – provided by appropriately trained staff. 85% of respondents said they would consider a partnership project with a community based organisation to offer rapid testing with trained peer educators.⁷²

Window periods of HIV rapid tests

As discussed earlier in this paper, there is not a standard time frame that is understood by gay men and other MSM for the window period of traditional HIV testing, as demonstrated in a recent study. This same study also found there is a similar lack of understanding for the window period of HIV rapid testing specifically. When asked “how long after getting infected with HIV would you need to wait before the virus could be detected in a rapid HIV test?”, participants in the study gave a broad range of time frames: immediately (2.4%); a few days (9.6%); two weeks (8.9%); six weeks (18.9%); three months (22.2%); six months (2.1%). Also, 36% of men said they didn't know anything about these

tests.⁷³ As discussed earlier in this section, HIV rapid tests have slightly longer window periods than traditional testing, and also vary from one type of kit to another.

Understanding of what ‘rapid’ means

In addition to (and potentially linked to) the lack of consistent understanding about the window period for HIV rapid tests, another issue to be considered in the implementation of HIV rapid tests is what gay men and other MSM understand ‘rapid’ to mean in this context. Anecdotally, there have been reports that some men thought that rapid meant that the test could detect HIV very shortly after someone becomes infected. Some media reports may have contributed to this misapprehension.

Other rapid STI tests

In the context of offering HIV testing as part of comprehensive sexual health testing for gay men and other MSM, there are some additional considerations relating to HIV rapid testing. For example, if HIV testing is done using a rapid test, blood would still need to be drawn for STIs such as syphilis (for all men), hepatitis A and B (for those not yet immunised) and hepatitis C (for some men). Although offering HIV rapid testing offers benefits to the men being tested, this may provide some challenges to clinicians, such as managing work flow if blood needs to be drawn to test for these other STIs anyway. Options to alleviate this issue would be offering rapid tests for other STIs, particularly those tested through blood. The New Zealand AIDS Foundation (NZAF) for example, offers rapid testing for HIV, syphilis and hepatitis C. New Zealand however, does not have the same regulatory requirements as Australia does through the TGA.

There is currently no rapid test for hepatitis C approved for use in Australia by the TGA. A rapid hepatitis C test has however been submitted to the TGA for assessment, but at the time of writing a decision had not yet been made.

There is a syphilis rapid test approved by the TGA, the Alere Determine Syphilis TP. There is also another syphilis rapid test, the SD BIOLINE Syphilis 3.0, which is currently not required to be approved by the TGA as it qualified for a transition period until mid-2014 and potentially later. These do not appear to be used widely however. This may be because most syphilis rapid tests (including these two) are not able to differentiate between past and current infections. There have been several trials for rapid testing for different STIs, including for gonorrhoea and chlamydia, and for differentiating between past and current syphilis infection, however none have yet passed the trial stage or been approved by the TGA.

Other settings and populations

There could be other settings in which HIV rapid testing could be seen to have benefits for its use. However, as previously discussed, populations with low HIV prevalence would not be appropriate for HIV rapid testing due to the higher number of false reactive results that would be given. For example, remote settings (where access to testing and testing facilities can be limited) could be seen as a potentially beneficial setting to offer HIV rapid testing. However, in addition to the issue of false reactivities, it may be even harder to manage in remote areas if there is difficulty in getting the patient back or contacting them for the results of the confirmatory test.⁷⁴ Facilities to draw blood for a confirmatory test are also required in offering HIV rapid testing, which may not be possible in some settings.

Self-administered HIV rapid testing

Home-based testing

Self-testing (also known as home-based testing) is defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* as a process where HIV testing is conducted:

- in the home or similar environment by a lay person; or
- where a sample is collected by a lay person and, if the sample is tested by another person, the results are returned directly to the person from whom the sample was taken without the direct supervision of a doctor or another health professional who has training in a discipline to which the self-testing relates.⁷⁵

Self-testing for HIV in Australia is currently not supported by the *National HIV Testing Policy*. It states “HIV testing in Australia should always be performed in a clinically supervised context, where there is an appropriate level of interaction between the individual being tested and a suitably qualified health professional.”⁷⁶ At the time of writing the *National HIV Testing Policy* was being reviewed again to incorporate changes to this part of the policy, noting the support of the evaluation of new or novel approaches to testing and/or the introduction of testing strategies that have proved effective at increasing the diagnosis rate of HIV infection in other environments. The review has also included the continued support of the regulatory framework with the TGA approving test kits for sale and distribution, including potentially placing specific conditions on devices for self-testing in an attempt to mitigate some of the concerns held about self-testing (noted later in this section).

Further to this, the *Therapeutic Goods (Excluded Purposes) Specification 2010* and section 41BEA of the *Therapeutic Goods Act 1989* prohibit the inclusion of self-testing

in-vitro diagnostic devices (IVDs) for HIV in the *Australian Register of Therapeutic Goods* (ARTG).⁷⁷

So, for home-based testing to be possible, the *National HIV Testing Policy* would need to be amended as outlined in the current review, and its exclusion would need to be removed from the therapeutic good regulations outlined above. In April 2014, the TGA and the Commonwealth Department of Health requested the views of numerous organisations in the HIV sector (including AFAO and its members) on a proposal to allow the registration and sale of HIV self-testing kits. AFAO and other organisations supplied submissions supporting this proposal and the change to the legislative instrument precluding the TGA from evaluating HIV self-tests for inclusion on the ARTG. In July 2014, at the launch of the 2014–2017 National Strategies for blood-borne viruses and STIs, the federal government announced the lifting of the restrictions on self-testing for HIV. Once these changes are achieved, a testing kit manufacturer would then need to apply to the TGA (as with any testing kit) for their kit to be approved for that use.

Some concerns have been raised with regard to home-based testing. These relate to issues such as the lack of counselling outside of a clinical setting, a possible lack of support at home if the result is reactive, and potentially less formal linkages to testing services for confirmatory diagnoses and into care. Other concerns relate specifically to the capacity of non-clinical people to interpret and understand test results. These include not having received training to use the test, interpreting the result given, understanding the false negative and false reactive rates, and understanding what the window period is for the test. Potentially, people could be making decisions about risk based on these interpretations and possible misunderstandings. However, many of these concerns could be mitigated by placing conditions on the approval of self-testing kits, such as consumer support centres, and instructions for home use. These have been placed on the HIV test approved for home use in the United States (discussed later in this section).

Another consideration is the possibility of people testing their sexual partners and what each partner's understanding of the test's window period and the result would be, and the decisions they make about risk based on that understanding.

As home-based testing is simply a setting in which HIV rapid tests can be used in, the same issues regarding the use of HIV rapid tests by low prevalence populations discussed earlier in this paper are still of concern. Consideration would also need to be given to context and cultural issues if

home-based testing was made available. This would include issues relating to remote communities including isolation and support and care linkages.

Further to these issues, home-based testing could also mean that testing for other STIs would not happen as frequently as if all the tests were done together.

However, as discussed earlier in this paper, home-based testing has been raised as a potential option that gay men and other MSM would use to increase their frequency of testing, or to test if they hadn't tested before, if it were available. This could be seen to overcome several barriers to testing such as not wanting to discuss risk or sexual behaviours with a clinician, as well as many logistical barriers related to testing in a clinical setting. Specifically, it has been argued that home-testing would be expected to reach people who are currently not being tested otherwise, which, in turn, could lead to earlier treatment and reduce the transmission rate of the virus.

In addition to overcoming several barriers to testing, a recent study reviewed the evidence on supervised (self-testing and counselling aided by a health care professional) and unsupervised (performed by self-tester with access to phone/internet counselling) self-testing strategies. Although they noted the quality of the studies varied and they found only one randomised controlled study, they found that self-testing kits were found to be highly acceptable (up to 84% in non-monogamous US urban gay men). They were also found to generally provide accurate results, though the rates of false-positive results varied (with one study in the US as high as 7%). It also found that self-testing to be feasible with 95% of US urban gay men reporting that unsupervised testing kits were "very easy to use". A small number of individuals reported difficulty interpreting the testing device or were unable to read or interpret a faint or weakly positive test line on the testing device. There was no evidence that a positive test would lead to a major adverse event such as suicide. However, the investigators noted that the potential to optimise linkages to care remains unproven, with only one study identified (on unsupervised testing) that looked at linkage to care following a positive result using self-testing. This study found the rate was high, with 96% of individuals testing HIV-positive stating they would seek post-test counselling. They also conclude that more data from diverse settings are needed to inform scale-up and policy recommendations for HIV self-tests.⁷⁸

It could also be argued that if men who are at low risk of HIV but nonetheless want to be tested, for whatever reason, then giving them



the capacity to self-test potentially frees up resources (e.g. capacity at clinics and GPs) for those who are at greater risk.

There is now a HIV rapid test approved for home use in the USA, the OraQuick In-Home HIV Test, which tests for HIV antibodies in oral fluid. It is available on-line and through a range of retail pharmacies. The U.S. Food and Drug Administration (FDA), the USA's regulatory body, approved its use with a number of conditions, including the setting up of consumer support centre with a 24 hour information phone line, and the kit including instructions for home use.

France has also approved HIV rapid tests for use at home, and will commercially available in 2014.⁷⁹ In the United Kingdom in 2011, a House of Lords select committee recommended that the ban on home testing should be repealed along with recommendations about quality control and licensing.⁸⁰ This recommendation was accepted and from April 2014, the selling and advertising of self-testing kits in the United Kingdom will become legal.⁸¹

An Australian study to trial home-based testing has been funded and at the time of writing is recruiting men. It aims to explore gay men's views of home HIV testing and if having access to home HIV tests results in more frequent testing. The study is being conducted by The Kirby Institute, in collaboration with Melbourne Sexual Health Centre, Sydney Sexual Health Centre, University of Melbourne, Victorian AIDS Council/ Gay Men's Health Centre and ACON.⁸²

Use in other settings

There are concerns that there is a potential for misuse of self-administered tests in other settings for non-voluntary testing, for example, sex workers being required to use the test in

order to be able to work, and for testing of Aboriginal and Torres Strait Islander people in remote areas. Also, in situations in which there are power imbalances, there is also a concern about people being coerced into testing.⁸³ It is essential that all HIV testing be voluntary as stated in the *National HIV Testing Policy*.⁸⁴

Information for people purchasing tests over the internet

Although no HIV rapid tests have yet been evaluated or approved for home use in Australia, it is possible for people to purchase tests over the internet or over the counter at some outlets. Given that people in Australia are able to buy their own tests over the internet or from known outlets for home use, options should be considered that may reduce the risks associated with doing so. Choosing a safe and credible test from the variety of tests that may be advertised is very important as the quality of the tests can vary substantially, and claims made by some sellers may not be correct. Tests that are approved by relevant authorities in comparable countries may be more likely to meet the quality requirements for Australia, and those approved specifically for home use in will also have instructions included for home use (rather than instructions for a clinician which may not be understood).

There has been a concern that providing this kind of information could be an offence under the *Therapeutic Goods Act 1989*, as a type of ‘advertising’ for a product that is not on the Australian Register of Therapeutic Goods (ARTG). In April 2014, ACON made an application to the TGA for “approval to use a restricted representation in advertising” in order to provide this kind of information. However, the TGA advised that it did not require approval, as the information would be about a class of products and not a specific therapeutic product, and would therefore not be classed as an ‘advertisement’. In further correspondence with ACON, the TGA did advise that any generic information needed to be compliant with the *General Principles of the Therapeutic Goods Advertising Code*.⁸⁵

Impact on national surveillance

If home-based testing were approved, there is a concern it could affect Australia’s national HIV surveillance data. It could be even more difficult to determine the total number of tests being done in the country. Further, there is a potential that people who receive a reactive result using their home test do not go to a clinician for confirmatory testing and linkage to care. This would mean delays in confirmatory diagnoses – with people whose test produced a false positive potentially believing that they are HIV-positive; and people who have in fact acquired HIV unduly delaying seeking a confirmatory test, due to

fear or other concerns. As previously discussed, there is very limited data on linkages to care following a positive result from a self-test kit. However, it has been argued that many of the people that would utilise home testing would not be getting tested regularly or at all otherwise, and therefore would not be captured in the surveillance anyway. Further to this, it has also been argued that options for increasing testing rates should be prioritised above the need for accurate surveillance data.

The role of health promotion

Health promotion plays a key role in educating and informing gay men and other MSM about HIV and STI testing, and to help ensure comprehensive sexual health checks remain the norm for these men. It is important that a consistent message about the importance of both HIV and other STI testing is delivered by the HIV community sector through all health promotion channels (e.g. social marketing, peer education, counselling, etc.), to enhance community understanding of this issue. These messages need to relate to the tests that are being offered to these men, so it is important clinicians are aware of both the STI testing guidelines for MSM and the health promotion messages that are being delivered to these communities.

Internally, within community HIV organisations, it is important that consistent information is being given through all health promotion channels (e.g. social marketing, peer education, counselling, etc.). Organisational structures and processes need to be in place to ensure an agreed upon position is shared through these different channels for communication to their communities. Working with the clinical sector is also important to minimise inconsistencies between the health promotion messages being delivered and the testing being offered by clinicians.

Reaching gay men

With social marketing specifically, there have been some key conclusions made in the “Reaching gay men” report, which was commissioned by AFAO and based on external evaluations of its campaigns. These conclusions included having a comprehensive advertising strategy, particularly including online advertising, and not relying on advertising in gay newspapers and magazines alone. In terms of print-based advertising, the report concludes that each advertisement should appear multiple times in the same publication in an attempt to reach as much of the potential audience as possible. For online advertising, it notes the importance of messaging (including paid advertising) across a range of social media channels, particularly Facebook, and a high frequency of messaging,

particularly on platforms such as Twitter. It highlights the importance of paid advertising on sexual networking sites or mobile apps as part of a broad advertising strategy, noting the targeting of sub-populations of gay men (such as HIV-positive gay men) to particular sites that have higher usage among these men. Finally, it notes that although promotion in venues such as bars, clubs and sex on premise venue is important, these strategies should only be used as a to complement comprehensive advertising strategies.⁸⁶

Exploring HIV Prevention and Testing market research

In the market research on HIV testing commissioned by AFAO, several recommendations about messaging for testing were made. It was recommended that messages about testing should focus on the benefits of taking care of your sexual health such as feeling in control (as in the HIV testing message in the Drama Downunder campaign) and better sex, rather than the consequences of risk taking. It also noted humour is appreciated in the context of sexual health (using the Drama Downunder campaign as the example) and suggested that this could continue to work as a framework for future communications on testing.

The research report also noted that messaging can vary, adapting to different contexts. For example, for routine testers it is about control, peace of mind and knowing their status. For those men ‘who want to have fun’, for whom pleasure is paramount, messages like ‘more fucks, more tests’ resonate. It’s direct, clear and a call to action. (However it could be noted that using terms such as ‘more’ is a relative term that could sometimes cause at risk men to self-select out of these messages.)

Any messaging needs to convince men that testing has been made easier, that it’s more flexible, more modern, tech enabled and comfortable. Testing being non-judgmental is often assumed but men want to be reassured this is actually the case.

Messaging needs to provide a call to action, such as to book in or drop in and get tested. Other examples of a call to action that were suggested were a testing week/month, and offering incentives as a way to help men motivate each other.

The market research report further indicated that men are using lots of different media to stay connected and get connected, so a broad media mix would be a consideration for the promotion of any testing messages, and a cohesive national campaign is required to trigger men to test – that gets men to talk about testing, to ask partners when they were last tested and to talk about where they get tested. As part of such a campaign, non-testers would need to be welcomed and encouraged

to get tested, and ideally they would be rewarded in some way and directed to specific clinics that can manage the anxiety of a first test.⁸⁷ At the time of writing, a national HIV testing campaign was about to be launched by AFAO.

Measuring and evaluating increases in testing

As, stated in the discussion paper, *Implementing the United Nations Political Declaration on HIV/AIDS in Australia's Domestic HIV Response: Turning Political Will into Action*, the Australian HIV response has benefited from a strong surveillance and research base, but there are a number of areas in which monitoring and evaluation could be improved in relation to testing. These include an increased understanding of testing uptake among priority population groups, and patterns and population characteristics of people accessing voluntary HIV testing. It also states that all surveillance, monitoring and evaluation is to be developed with community input to ensure affected communities are not further marginalised by perceiving themselves to be 'under surveillance'.⁸⁸

Currently, national testing data is difficult to collate as it is held in different jurisdictions and with a mix of public and private testing services. Engaging with GPs and other private services in providing this data is important, however trying to collate these around the country may continue to be difficult and incomplete. A national baseline of testing rates would be useful to measure the changes to testing rates against. An option to consider for improving this kind of data is setting up a national sentinel surveillance system. Some jurisdictions in Australia have a sentinel surveillance system for improved data. A national system could coordinate improved data collection across the country.

It will also be helpful to collect not just the total number of tests being performed, but also changes in testing patterns in particular populations (e.g. the number of people testing who had never tested before).

Specifically relating to HIV rapid tests (both for clinical and home-based testing), one way to improve the monitoring and surveillance of these tests would be to investigate if the TGA could make it a condition of approval of tests that the manufacturer (and its distributors) advise how many test kits were sold across the country (and in each jurisdiction).

Although there are some improvements that could be made to the monitoring of testing that should be pursued, it has also been argued that the limitations of some areas of data should not prevent programs being developed while these improvements are explored.

Undiagnosed HIV and primary HIV infection

Significant percentages of HIV sexual transmissions are from:

- ◆ people who do not know they are HIV-positive
- ◆ people in primary HIV infection – the initial period (weeks) after a person becomes infected with HIV and when their viral load reaches its highest point.

Increasing testing rates among gay men and other MSM will increase the number of these men aware of their HIV status, minimise the time between infection and diagnosis, and reduce onward transmission.

Late diagnoses

The time between infection and diagnosis is significant for many gay men and other MSM.

Although there has been a decrease in the proportion of people diagnosed with advanced HIV disease (CD4 count of less than 200), there has been a slight increase in the proportion diagnosed with late diagnosis (CD4 count of less than 350).

More than half of all late diagnoses continue to be among MSM. Men who have sex with both men and women have much higher rates of delayed diagnosis (both late diagnosis and advanced disease) than men who only have sex with men.

Testing and linkage to care and treatment

Mathematical modelling shows that in Australia there could be a considerable proportion of people diagnosed with HIV not receiving antiretroviral treatment. It also shows there could be only a relatively small proportion of all people living with HIV (including those that are undiagnosed) with an undetectable viral load.

The more people there are who know their HIV status (from being tested), the larger the proportion of people with HIV who can be linked to care, and treatment if they choose, there will be. This will lead to an increase in the proportion of people with HIV accessing treatment early and a reduction in transmissions due to lower infectivity.

What gay men want

Three key themes emerged in relation to gay men's ideal testing experience:

- ◆ Comfort: feeling looked after, respected, no judgement and minimal anxiety
- ◆ Control: feeling confident, informed and in charge
- ◆ Connection: feeling secure, safe and having proximity to exactly what is needed.

Gay men want testing to be as easy as possible – simpler, more immediate and more accessible.

Comprehensive sexual health testing

Other STIs can play a significant role in the transmission and acquisition of HIV. Many STIs continue to be diagnosed at high rates among Australian gay men and other MSM, and there have been resurgent epidemics among MSM of several STIs. It is for these reasons it is argued that HIV testing should be part of comprehensive sexual health testing.

Increasing access to and frequency of testing

There has been a gradual downward trend in the proportion of gay men and other MSM that have *ever* been tested for HIV, and in recent years a decrease in the proportion of these men that are testing at least once a year. Clinical data suggests that only a minority of men who should be testing every three to six months, as outlined in the guidelines, are testing that frequently.

Modelling suggests increasing the number of gay men and other MSM testing annually for HIV would lead to a considerable decrease in HIV infections each year. Increasing the frequency of testing to multiple times per year, especially for MSM at higher risk of HIV acquisition, will reduce infections further.

Barriers to testing

There are many barriers to HIV testing that people encounter or experience. Addressing and overcoming these barriers are important and necessary steps in increasing access to and frequency of testing. These barriers are broadly classed as:

- ◆ structural (or logistical) – e.g. getting to a testing service, needing to make a second appointment and cost
- ◆ psychological (or emotional) – e.g. discussing behaviour and risk, perceived judgement and waiting for results, or
- ◆ psychosocial (psychological and cultural) – e.g. knowledge and perceived risk, fear of reactions from others and perceived HIV stigma.

Some barriers could be addressed in programs aimed at all gay men and other MSM. However, more tailored programs would also be needed for particular groups of men in order to address some other barriers.

Improving traditional (non-rapid) HIV testing

Making HIV rapid testing available for gay men and other MSM goes some way to reducing the barriers to regular testing. However, there are numerous other ways that could improve the speed and/or convenience of traditional (non-rapid) HIV testing:

- ◆ Alternative methods for receiving results – e.g. phone, SMS, email
- ◆ Alternative service models – e.g. express clinics, other clinic models
- ◆ Laboratory testing timeframes
- ◆ Self-collected samples – e.g. dried blood spot testing, other test kits posted to receive results
- ◆ National HIV Testing Day/Week.

Testing in community settings

Offering a mix of service models of HIV testing, and providing testing in a variety of settings, including community settings, would offer men more choices and assist in addressing many structural and psychological barriers to testing.

Gay men have shown a preference for testing services in community settings over traditional clinical settings. These men would like to have more control over the kind of testing service and experience they can access.

Access to peer-based services appears to be key to ensuring that individuals are encouraged to test, and to test earlier. Peer-based community services have been found to provide a more supportive and understanding perspective, and enable the discussion of topics that might otherwise be too embarrassing.

There are a number of issues to consider when setting up a testing clinic in a community setting, including those related to working with clinical partners, use of peer educators, and other logistical issues such as quality assurance and accreditation.

Clinical workload issues

Increasing the number of gay men and other MSM testing for HIV (and other STIs) and increasing their testing frequency will put a larger demand on clinical services providing these tests. Other models and procedures should be investigated to expand capacity for these services.

Window periods of traditional HIV tests

Some gay men may have a more accurate understanding and knowledge of window periods than other men or the broader population. However, due to the differences in the use of testing technology between clinics, there is not a standard time frame that is understood by the communities being tested or by the HIV community sector. It is therefore difficult to communicate this information to gay men and other MSM.

Laboratories need to provide clear guidance to clinicians on the exact window periods for the tests they use. Advocating for all laboratories to use the latest generation tests could lead to a consistent message about the window period of laboratory tests being provided and help enable gay men to seek testing at the most appropriate times.

Detecting recent HIV infection

Tests have been developed to distinguish recently acquired HIV infection (individuals infected within the previous three months) from established infections. These incidence tests could provide a valuable surveillance mechanism for recent infection, such as for population incidence estimates, to better inform the development and assessment of prevention interventions (including those about testing), and help identify high risk groups and target resources. They are currently only performed in two laboratories in Australia. A systematic and national testing of samples from people once they are diagnosed with HIV would be a useful surveillance and monitoring tool.

HIV rapid testing

HIV rapid testing is one tool to help overcome some men's barriers to testing. HIV rapid tests have been found to be very acceptable to gay men and general practitioners, with a higher preference for HIV rapid testing than traditional testing amongst gay men.

HIV rapid tests are designed as screening tests, rather than diagnostic tests, with all reactive results requiring confirmatory testing (via traditional testing) before a diagnosis is given.

There are limitations of HIV rapid tests that need to be understood when considering offering HIV rapid testing. HIV rapid tests:

- ◆ have slightly longer periods of time to be able to detect infection (window periods), so are not appropriate for someone with a recent risk event, and
- ◆ can give a slightly higher number of false reactive (false positive) results, so are not appropriate for populations with low prevalence of HIV.

There are some regulatory issues for HIV rapid testing that need to be considered.

- ◆ Clarity is required on the TGA conditions placed on the HIV rapid tests. In February 2014, the Commonwealth Department of Health sought input on potential changes to the conditions of the Alere Determine HIV Combo test (currently the only TGA approved test) to help clarify these issues.
- ◆ Laboratory accreditation requirements were originally designed for traditional testing. A system that would waive the laboratory accreditation requirements and instead use a separate and more appropriate framework for HIV rapid tests could help overcome some of the issues currently experienced in the approval and implementation of HIV rapid tests.
- ◆ Time and cost of TGA applications can be a barrier for test kit manufacturers. A fee reduction or waiver on the basis of a public health interest, and a streamlining of the approval process for kits that have been approved by comparable regulatory bodies in other jurisdictions are options that can be investigated.
- ◆ There is currently no Medicare funding of HIV rapid testing through a MBS listing. In May 2014, Alere submitted an application to MSAC for a listing.

Other issues relating to HIV rapid testing include:

- ◆ a lack of understanding of the window periods of HIV rapid tests
- ◆ a potential misunderstanding by some men of what 'rapid' means, and
- ◆ limited access to and/or use of rapid tests for other STIs.

There has been limited implementation of the Alere Determine HIV Combo test in most jurisdictions. There are a number of HIV rapid testing trials operating in various states which currently help gay men and other MSM access rapid testing.

Self-administered HIV rapid testing

Self-testing (or home-based testing) for HIV in Australia is currently not supported by the *National HIV Testing Policy*. The policy is currently being reviewed and incorporates changes to this part of the policy.

A legislative instrument currently prohibits the approval of HIV tests for self-testing by the TGA. In April 2014, the TGA and the Commonwealth Department of Health requested input on a proposal to remove this exclusion and allow the registration and sale of HIV self-testing kits. In July 2014, the federal government announced the lifting of the restrictions on self-testing for HIV.

Home-based testing is one tool that gay men and other MSM could use to increase their frequency of testing, or to test if they hadn't tested before. It could overcome several barriers to testing such as not wanting to discuss risk or sexual behaviours with a clinician, as well as many logistical barriers related to testing in a clinical setting. Home-based testing could reach people who are currently not otherwise testing.

Some concerns have been raised with regard to home-based testing, including:

- ◆ a lack of counselling outside of a clinical setting
- ◆ a possible lack of support at home if the result is reactive
- ◆ less formal linkages to testing services for confirmatory diagnoses and into care, and
- ◆ the capacity of non-clinical people to interpret and understand test results, and the decisions made based on potential misinterpretations.

However, many of these concerns could be mitigated by placing conditions on the approval of self-testing kits.

Other concerns related to home-based testing include:

- ◆ less frequent testing for other STIs
- ◆ the potential use by populations with low prevalence of HIV
- ◆ the potential misuse of the tests in other settings, and
- ◆ the potential impact on national testing surveillance.

While no HIV rapid tests have yet been evaluated or approved for use in Australia, given that people are able to buy their own tests over the internet or from other outlets, options should be considered that may reduce the risks associated with doing so. These include choosing a test that is safe and credible, approved by relevant authorities in comparable countries, and approved specifically for home use.

The role of health promotion

Health promotion plays a key role in educating and informing gay men and other MSM about HIV and STI testing, and to help ensure comprehensive sexual health checks remain the norm.

Messages about the importance of both HIV and other STI testing delivered by the HIV community sector should be consistent through all health promotion channels to enhance community understanding of this issue. It is important clinicians are aware of both the STI testing guidelines for MSM and the health promotion messages that are being delivered to these communities.

Messages about testing:

- ◆ should focus on the benefits of taking care of your sexual health such as feeling in control and better sex, rather than the consequences of risk taking
- ◆ can vary, adapting to different contexts and the testing routine of different men
- ◆ needs to convince men that testing has been made easier, that it's more flexible, more modern, tech enabled and comfortable (reassured of being non-judgmental)
- ◆ need to provide a call to action, such as to book or drop in and get tested (another example of a call to action is a testing week/month).

Gay men are using lots of different media to stay connected and get connected, so a broad media mix should be a consideration for the promotion of any testing messages.

Measuring and evaluating increases in testing

Currently, national testing data is difficult to collate. A national baseline of testing rates would be useful to measure the changes to testing rates against. Setting up a national sentinel surveillance system is an option to consider for improving this kind of data. It will also be helpful to collect not just the total number of tests being performed, but also changes in testing patterns in particular populations (e.g. the number of people testing who had never tested before).

One way to improve the monitoring and surveillance of HIV rapid tests is investigating if the TGA could to make it a condition of approval of tests that the manufacturer (and its distributors) advise how many test kits were sold across the country (and in each jurisdiction).

Issues related to specific populations

There are particular testing issues for a range of sub-populations, and gay men and other men who have sex with men (MSM) form part of these populations. This section of the paper outlines some of the key issues for gay men and other MSM within these sub-groups/communities that may impact upon HIV testing rates and sexual practices.

Gay men and MSM among CALD communities

People from culturally and linguistically diverse (CALD) communities can experience significant and particular barriers to accessing HIV testing, care and support. Among some communities, this can be in part due to HIV-related stigma and a belief that HIV is something that doesn't exist in Australia – unlike in their home country. This can lead to a reluctance to test. For gay men and other MSM of CALD background, the compounding issue of homophobia prevalent in some communities can be an additional deterrent to testing.

In this context, it can be a challenge to ensure that gay-themed health promotion messages reach these gay men and other MSM, as they may not be exposed to or identify with/relate to such health-promotion. At the same time, articulating MSM specific health promotion messages within a CALD community environment can sometimes face stiff community resistance, as it may be perceived as culturally unacceptable.

Impact of migration policies

Screening for HIV is compulsory for all people applying for permanent residence in Australia. Generally, applicants for permanent visas must satisfy the migration Health Requirement, under which anticipated future costs associated with any health condition or disability must be taken into account. As the future cost of providing antiretrovirals to an HIV-positive person under the Pharmaceutical Benefits Scheme (PBS) inevitably exceeds the threshold for passing the cost test of the Health Requirement, prospective migrants and refugees with HIV inevitably fail and are refused a visa. Some prospective migrants may ultimately be able to gain entry if they have the Health Requirement waived. These waivers apply to a special sub-set of visas where the applicants meet certain other legal requirements.

Thus, being allowed to remain/stay in Australia can be associated with being HIV negative. There is anecdotal evidence that this association may discourage people among culturally and linguistically diverse (CALD) communities from testing. There are reports that individuals who may have

entered Australia on a temporary visa – a s457 working visa for example – avoid testing while here, under the belief that a positive result may result in them being sent back to their home country.

The policy rationale for the Health Requirement applying to people with HIV is economic, relating to the significant cost of providing health care and medications, but this is not generally understood. The perception of prospective migrants – and of migrant communities in Australia – is that Australia screens prospective migrants for HIV due to a desire “keep them out” and that waiver processes represent hoops to be jumped through. This perception fuels HIV-related stigma and creates a psychosocial barrier potentially undermining prevention programs targeting CALD communities. Addressing the legal and regulatory settings may help reduce stigma and increase rates of testing.

There is little research regarding gay men and other MSM among many CALD communities in Australia. It is difficult, therefore, to speculate about how the migration and stigma dynamic affects their testing patterns.

Fly-In-Fly-Out and Drive-In-Drive-Out Workers

Fly-In-Fly-Out (FIFO) and Drive-In-Drive-Out (DIDO) workers face particular issues relating to HIV testing. Often they are migrant workers on temporary long-stay visas, such as s457 visas, who are not generally required to test for HIV when applying for their visas. Thus, there is a proportion of FIFO and DIDO workers who do not know their sero-status after arrival in Australia. It has also been noted that, testing facilities/resources/locations are limited in many areas where FIFO and DIDO work, such as remote mines. Improving access to testing for gay men and other MSM among the FIFO and DIDO populations is crucial. Many FIFO workers also travel to countries with high HIV prevalence when on leave. So if these workers are participating in risk behaviours, they could be at higher risk of exposure to HIV and would need to consider increasing their frequency of HIV testing. Education for these workers is needed.

Aboriginal and Torres Strait Islander peoples

Aboriginal and Torres Strait Islander populations generally have low HIV prevalence, and have a notification rate of newly diagnosed HIV similar to that of the non-Indigenous population.⁹³ However, Aboriginal and Torres Strait Islander populations can have increased vulnerability to HIV, with a higher proportion acquiring HIV through injecting drug use⁹⁰, increased sexual risk behaviours for anal sex⁹¹ and elevated rates

of incarceration. An effective response requires ongoing and strengthened engagement with these communities.

The largest proportion of new HIV notifications among Aboriginal and Torres Strait Islander people between 2008 and 2012 was MSM (56%).⁹² Aboriginal and Torres Strait Islander gay men, MSM and sistergirls are likely to/have higher prevalence rates than the general Aboriginal and Torres Strait Islander population. Aboriginal and Torres Strait Islander gay men and MSM (no data available for sistergirls) have been found to have as high a HIV prevalence rate as non-Indigenous gay men and MSM.⁹³ This high prevalence is exacerbated by a tendency for high rates of both late diagnosis and diagnosis with advanced disease.⁹⁴ Although there is no difference in HIV or STI testing rates between Aboriginal and Torres Strait Islander and non-Indigenous gay men and MSM, Aboriginal and Torres Strait Islander gay men and MSM have higher rates of unprotected anal intercourse and injecting drug use.⁹⁵ Therefore it is essential to increase testing rates in these communities due to these increased risk factors.

People with Disabilities

It is important that HIV sector organisations understand key issues for people with disabilities when accessing sexual health services.

People with mental and intellectual disabilities can experience significant issues in terms of their capacity to negotiate their sexual health and consent to sexual health testing and treatment. For example, there are concerns that people in care facilities may experience coercion to be tested. There are also concerns that people with mental and intellectual disabilities may not be offered the appropriate tests, particularly if their carers (e.g. their parents) are not aware of their sexuality. There are also potential issues related to privacy and access to medical information.

Many issues involve people's capacity to make a medical decision. The *HIV Testing Policy* (2011) provides guidance on informed consent for testing for “patients without capacity to make medical decisions or where informed consent cannot be obtained from the person being tested”. It states:

Clinical judgement should be exercised in determining whether a person has capacity to make a medical decision or not. In cases where the patient has an appointed guardian, consent must be obtained from that person. Where no formal appointment has been made, consent should be sought from another person/agency legally authorised to

make such decisions on behalf of the patient, usually their partner (provided there continues to be a relationship), carer or close relative or friend. If you have concerns about seeking consent from an informal guardian, you can make an application to the appropriate authority in your state or territory for a formal guardian to be appointed.

Rarely, circumstances will arise that are not adequately covered by existing laws and policies. In these circumstances, practitioners should seek any clinical or legal support necessary to exercise their clinical judgement.

On the rare occasions when informed consent cannot be obtained, pre-test discussions and the provision of appropriate information to the patient should still take place, where appropriate.⁹⁶

For people with physical disabilities, HIV testing services need to consider whether they provide an accessible service. This may include ensuring that there is lift access for anyone with mobility issues. It may also include ensuring imagery promoting the service is inclusive. Outreach testing could be an alternative model to help overcome some accessibility issues.

Sex workers

The prevalence and incidence of HIV among Australian sex workers is low due to the success of advocacy, community led health promotion, peer education and the normalisation of safer sex practices. Mandatory HIV and STI testing for sex workers is contrary to best-practice models of voluntary testing as outlined in the *National HIV Testing Guidelines* and the National Strategies, and is not justified by current epidemiology in Australia.⁹⁷ It has proven to be a barrier to otherwise successful HIV and STI peer education, prevention and free and anonymous testing and treatment. The outcomes of mandatory testing are counterproductive to reducing HIV and STI rates, do not reach the intended target group, are costly and inefficient, and mandatory testing has proven to be a very difficult policy to repeal once in place.⁹⁸

Rapid tests should not be targeted towards sex workers as rapid testing is not recommended for low prevalence populations. As a low prevalence population, sex workers will face much higher rates of false positives than high prevalence populations. Rapid testing should not be targeted towards sex workers in jurisdictions in which sex workers working with HIV/STIs are criminalised, as rapid testing can mean instant criminalisation and potential incarceration. In those jurisdictions, rapid testing may put sex workers' confidentiality, careers, lives and income at risk. Rapid tests

should never be used as part of mandatory HIV/STI testing and should never be used in sex work workplaces, where sex workers receive results during a shift whilst sharing space with colleagues, employers and clients. Rapid testing in workplaces may result in privacy breaches, particularly because sex workers are more likely to receive false positive results and will be excluded from work within 30 minutes of receiving a reactive result. Workers who decline testing may be treated with suspicion, having rapid testing in sex work workplaces will create an environment where rapid testing may become a condition of employment.

Rapid testing must always be voluntary and should not replace conventional testing: sex workers, including male sex workers that have sex with men, should have choice over the frequency and kinds of tests they access. Rapid testing should never be combined with contact tracing, which has resulted in sex workers living with HIV being publicly vilified and their privacy and confidentiality breached. New HIV testing technologies should not be used as a substitute for peer education, safer sex provision, or community led health promotion. Rapid testing should also not be an alternative to human rights and an enabling legal environment. At the time of writing, Scarlet Alliance, Australian Sex Workers Association was finalising a position paper on sex workers and HIV rapid testing.

People who inject drugs

HIV transmission among people who inject drugs has been effectively minimised particularly through the success of peer led and harm reduction based work by and for people who inject drugs, such as needle and syringe programs (NSPs) and peer education.⁹⁹ However, they may be vulnerable to HIV transmission where there is inadequate access to safe injecting. Gay men and other MSM who do inject safely may still be at risk of HIV acquisition due to unsafe sexual practices. Furthermore, there are groups of gay men and other MSM who use drugs for the purpose of having, and/or enhancing their sexual experiences, sometimes known online as 'Party and Play' or 'PnP'. Engaging these people is crucial to increasing testing rates. It is essential that these men can easily access HIV testing.

Injecting steroid use in Australia has been increasing, with steroids becoming more popular among people who start injecting illicit substances, and more popular among young men than either methamphetamines or heroin at their peaks.¹⁰⁰ A significant number of gay men, and a higher proportion of gay men than heterosexual men, have been reported to be users of steroids.^{101,102} Sharing needles to inject steroids involves the same risks as sharing needles to inject recreational drugs, including transmission of HIV, hepatitis C and hepatitis B.¹⁰³ Although studies so far have shown low levels of sharing

needles,^{104,105} people who use steroids may not identify with or access services perceived as catering primarily to opiate users such as NSPs, and could be missing out on harm reduction information.¹⁰⁶ It is important that people who inject steroids are aware of the potential risks of blood-borne viruses (such as HIV), harm reduction information, and any need for increased testing.

Transgender people

There is a paucity of data about HIV among transgender people. According to the Kirby Institute's *Annual Surveillance Report 2013*¹⁰⁷, of the total 34,029 diagnoses since the beginning of the epidemic, 86 were among transgender people and 249 among people whose sex was not reported. However, it has been noted that these numbers are likely to be inaccurate. This is in part due to the fact that HIV surveillance forms are completed by doctors rather than patients, and doctors do not always ask 'are you male or female', particularly when the answer seems self-evident. In relation to engagement with the health system, it has also been noted that some Transgender people feel alienated from mainstream gay community organisation, and do not engage with services.¹⁰⁸

Setting-specific testing issues

In settings with limited access to testing, increasing testing rates can be complex. Gay men and other MSM are present in these settings and face particular issues.

Custodial settings

There is uncertainty regarding rates of HIV transmission for people in custodial settings.¹⁰⁹ The "National Prison Entrants' Bloodborne Virus and Risk Behaviour Survey Report 2004, 2007 and 2010" found no cases of HIV were detected among the prisoners screened in 2010. This was a small decrease from 2004 and 2007, both of which reported less than 1% nationally.¹¹⁰

Despite the absence of evidence of HIV transmissions attributable to injecting drug use in custodial settings, the *National HIV Testing Policy* states that "Australian prisoners should be able to access free, voluntary, confidential, timely, non-discriminatory HIV testing, counselling and treatment services during incarceration." This is in recognition of Australian prisoners being at generally high risk of contracting blood-borne viruses due to higher levels of engagement in HIV risk behaviours such as injecting drug use, sexual risk behaviours, amateur tattooing, body piercing, and violence.¹¹¹ Programs targeting men pre and post release could increase testing rates. Programs such as these have been implemented in the Northern Territory, especially among Aboriginal and Torres Strait Islander men.

Rural and remote settings

There is no comprehensive Australia-wide data comparing testing rates between urban and rural and remote settings. A community survey comparing Sydney and regional New South Wales showed some differences in testing rates between Sydney and regional NSW.¹¹² Men from Sydney were significantly more likely to have been ever tested for HIV than men from regional NSW (92.6% vs 88.9%). In regional NSW there was a lower proportion of HIV-positive men and a higher proportion of untested/unknown status men than in Sydney.

Sydney men tended to have been tested for HIV more recently than men in regional areas, and Sydney-based men were more likely to have been tested for HIV in the last six months than men from regional NSW (62.5% vs 56.3%). However, the likelihood of having been tested for HIV in the last 12 months was very similar in both samples (71.1% vs 70.1%). There was a higher proportion of men who had tested for HIV over two years ago in regional NSW, compared with Sydney (16.5% vs 11.9%).

Barriers to regular testing for people in rural and remote settings can include inconvenient service hours, limited access points, confidentiality or privacy concerns, issues related to lengthy travel times to and from testing points, and lack of access to newer testing modalities such as express clinics, and delays in receiving test results.

Universal or Routine Testing

Universal or routine testing means a policy of offering testing to all people coming in contact with a health service, such as a sexual health clinic or hospital. For example, Universal testing is distinct from mandatory testing, which is defined in the 2011 *National HIV Testing Policy* as testing in “situations where people may not either participate in certain activities or access certain services unless they agree to be tested.”¹¹³

There have been recent developments in respect of universal HIV testing both locally and internationally. Locally, Darwin hospital began offering routine testing on admission for General Medical patients in the second half of 2012¹¹⁴ (see next paragraph for further detail); while at the international level, the U.S. Preventive Services Task Force (USPSTF) is proposing the routine testing of adults and adolescents, albeit in the context of a more generalised epidemic.¹¹⁵

Darwin Hospital

The Northern Territory Department of Health has issued a guideline entitled: *HIV Testing Guideline for Adults Admitted Under a Division of Medicine Bedcard*. The guideline, in describing who should test, states¹¹⁶:

As a general rule, all adults admitted under a Division of Medicine bedcard. HIV testing to be considered part of routine assessment on admission for General Medical patients.

Regarding consent, the guideline states:

Routine informed consent is appropriate. Testing for HIV does not need to be preceded by any special counselling beyond routine informed consent – the patient should be advised of the tests performed, and the method by which results will be communicated. Patients can opt out of such testing in line with standard medical practices.

Issues

Those who support universal or routine testing (in certain circumstances) argue that in order to achieve an increase in testing overall, universal or routine testing is a necessary component. Research on syphilis diagnosis among HIV-positive gay men and other MSM, indicates that opt-out testing was particularly successful in significantly increasing rates of syphilis diagnosis.¹¹⁷ It is argued that universal or routine testing is of particular use in populations with high rates of late diagnosis. Regarding late diagnoses, the Northern Territory AIDS and Hepatitis Council (NTAHC) stated that “Northern Territory populations are more likely to be diagnosed late and also often fall outside of the recognised risk groups being mainly gay men and other MSM and people (both heterosexual and homosexual) who travel to and from high prevalence countries.”¹¹⁸

In support of its routine or universal testing approach, the Northern Territory Department of Health has referred to the fact that routine opt out testing for HIV on admission to all health facilities is now recommended in the USA, UK and France.

Critics of universal or routine testing argue that studies of opt-out screening performed in emergency department settings have thus far yielded disappointing results, identifying few new cases of HIV in persons without known risk factors, many of whom were diagnosed in symptomatic or late stages of disease.¹¹⁹ Also, it needs to be recognised that policies developed in response to HIV epidemics in Europe and the USA may be unsuitable for Australian contexts, given that epidemiology of HIV varies greatly between countries, with the US, for example, having a more generalised epidemic and much higher rate of late diagnoses than Australia.¹²⁰

One paper has reported on the costs and consequences of the recommendations from the US Centers for Disease Control and Prevention (CDC) for opt-out testing. The CDC recommended opt-out testing (testing without the need for risk assessment

or counselling) in all health care encounters in the US for persons 13–64 years old. The paper found that for the same programmatic cost, targeted counselling and testing services would be preferred to opt-out testing, finding that targeted services would newly diagnose and prevent more HIV infections at a lower gross cost per infection averted.¹²¹

Alignment with Testing Policy

The 2011 *National HIV Testing Policy* stipulates that testing should be conducted voluntarily with informed consent¹²², “except for rare occasions when a legal order is made for compulsory testing or in emergency settings. On these rare occasions when informed consent cannot be obtained, pre-test discussions and the provision of appropriate information to the patient should still take place.”

It also states that in terms of informed consent, “In situations where protocols dictate that HIV testing is undertaken unless a person opts-out, practice should ensure that people who choose not to ‘opt-out’ are free of any form of real or perceived coercion.”¹²³

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