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National HIV Testing Policy

2020

National HIV Testing Policy v1.5

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Disclaimer:
This Testing Policy has been developed as a concise source of standardised, currently available information to inform those involved in ordering and performing Human Immunodeficiency Virus (HIV) testing. This Policy is not a set of clinical guidelines and it should not be used as a guide for the clinical management of HIV.

This Policy was written by the National HIV Testing Policy Expert Reference Committee, funded by the Australian Government Department of Health. The review process was coordinated by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM).

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The web-based version of the National HIV Testing Policy allows for regular revision, and access to related resources (e.g. related policies, operational guidelines, evidence of best practice) with a download and print function which can be found at: http://testingportal.ashm.org.au. Any references or web links to products, services or information contained in this publication do not constitute an endorsement of those references or web links.

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Blood Borne Viruses and Sexually Transmissible Infections Standing Committee

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Contents

1.0 INTRODUCTION

1.1 Background and context

Human Immunodeficiency Virus (HIV) is a major global public health threat, with 37.9 million estimated to be living with HIV as at the end of 2018[1]. In Australia, it was estimated that 28,180 people were living with HIV as at the end of 2018[2]. Among people living with HIV in Australia in 2017, 74.9% were estimated to be men who were exposed to HIV through sex with other men, 22.4% were people exposed through heterosexual sex, and 2.1% were people exposed through injecting drugs[3]. Late diagnosis of HIV can lead to increased morbidity and mortality among those diagnosed, and unwitting transmission of HIV to others.

The HIV testing landscape in Australia

Australia has a high-quality, comprehensive multi-sector pathology service. Until recent years, Australia's policy for HIV testing had an exclusive focus on testing in formal laboratory settings. A review of the National HIV Testing Policy was necessitated by the recent Therapeutic Goods Administration (TGA) approval of an HIV self-test; the adoption of the Eighth National HIV Strategy 2018-2022, which set a target to increase the proportion of people with HIV (in all priority populations) who are diagnosed to 95%; and the ongoing high rate of late HIV diagnoses in some sub-populations.

HIV tests supplied in Australia must pass evaluation by the TGA before entry onto the Australian Register of Therapeutic Goods (ARTG). The TGA can place conditions on this entry. The TGA has established guidance on clinical performance requirements for manufacturers and suppliers of HIV tests.

The National Pathology Accreditation Advisory Council (NPAAC) sets quality standards for pathology laboratories and the National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA) accredit medical testing facilities against these standards. Professional standards for pathology practice are established by NPAAC and the RCPA. Some tests can be used outside of the laboratory, such as HIV point-of-care tests or HIV self-tests. They may therefore be performed outside the laboratory accreditation framework offered by NATA/RCPA.

The Medical Services Advisory Committee (MSAC) advises which tests should be subsidised through the Medicare Benefits Schedule (MBS). It can also recommend any restrictions on eligibility. Tests for blood-borne viruses, including HIV tests, undergo the most stringent of pathology test evaluations. Accreditation by NATA/RCPA is required in order for pathology services to be eligible for the MBS rebates.

The policy aims to provide guidance to health-care workers to ensure that users of HIV tests, both inside and outside of the laboratory setting, are aware of the need to check that the device (i.e. test) being used is:

- fit for purpose and approved by the TGA (unless otherwise exempt)
- of an appropriate quality
- where relevant, used by individuals who are appropriately trained
- in the case of self-testing, supplied with appropriate information and instructions to enable individuals to perform and interpret tests independently and with confidence
- subject to procedures to ensure public safety and confidence.

1.2 Purpose and scope

This policy brings together in one place the principles, aims and arrangements for HIV testing in Australia and is consistent with the aims of the Eighth National HIV Strategy 2018-2022. It fulfils three main purposes:

- To bring together and reference standards for registered HIV tests and their usage in Australia
- To explore and describe how Australia will consider new testing technologies as these emerge and provide a framework against which new technologies for HIV diagnosis will be evaluated for use in Australia
- To maintain an Expert Reference Committee (ERC) which comes together from time to time to consider issues relating to HIV testing and which provides advice to governments and regulators about what is best practice. Its membership reflects the breadth of stakeholders with an interest in HIV testing.

The policy has broad scope and applies to laboratory, point-of-care and self-testing for HIV infection. It is also flexible, allowing for the consideration of new technologies as these emerge. Through the work of the ERC, it should also allow for the identification of standards, legislation or processes which may need to be modified to keep in step with evolving evidence, expectations and attitudes toward HIV testing.

This policy recognises that HIV testing is vital to stopping the transmission of HIV and is also a precursor to the initiation of treatment for HIV. It provides a framework for best practice approaches to appropriate high-quality HIV testing in the Australian context.

1.3 Principles for HIV testing

This policy supports the World Health Organization (WHO) in adhering to five key components in relation to testing, also known as the "5 Cs"[4]:

- Consent
- Confidentiality
- Counselling
- Correct test results
- Connection/linkage to prevention, care and treatment.

The key principles which guide HIV screening and diagnostic testing in Australia are that testing:

- is conducted ethically
- is voluntary, not harmful to the person being tested, and is performed with the informed consent of the person being tested, as with all pathology testing
- provides for an understanding of the epidemiology of HIV infection in the population and a measurement against which to evaluate National Strategy goals.

In relation to evaluation, selection, quality and performance

- Tests are evaluated on the basis of being fit-for-purpose and meeting the TGA's public guidance on clinical performance requirements.
- HIV point-of-care tests should be selected for use with particular populations, taking into account the characteristics of the population being tested, in particular the expected HIV prevalence, incidence and likely proportion of recent infection (i.e. acute) cases, based on an understanding of HIV epidemiology in the sub-population and the sensitivity and specificity of the test to be used.
- Due to the longer window period (the period of time after infection and before seroconversion during which markers of infection are still absent or too scarce to be detectable) compared to laboratory tests, when HIV point-of-care tests are used, consideration should be given to undertake a complete sexual health screen. This includes parallel laboratory-based venous HIV testing (e.g. in high incidence populations such as gay, bisexual and other men who have sex with men, and for testing patients following a recent HIV risk exposure).
- HIV testing in the context of the initial assessment and management of patients on pre-exposure prophylaxis (PrEP) should be performed on gold standard laboratory tests (i.e. 4th generation immunoassays and other tests available at reference laboratories).

- All reactive screening tests, whether performed in a laboratory setting, point-of-care setting or by self-testing, require further confirmatory testing by a NATA-accredited reference laboratory.
- Persons performing HIV testing are required to undertake training appropriate to the steps in the process for which they are responsible, including for: gaining informed consent and meeting consent requirements within their relative jurisdiction, collecting the sample, interpreting any result, conveying that result, and collecting a sample for confirmatory testing if necessary.
- Persons performing HIV testing should strive to provide high-quality testing services, and quality assurance mechanisms should be in place to ensure the provision of correct test results. Quality assurance may include both internal and external measures and should include support from a recognised quality assurance provider.

In relation to access, availability and confidentiality

- Barriers to accessing quality, safe, and cost-effective HIV testing and screening should be minimised.
- Testing must be accessible to all those at risk of HIV infection regardless of immigration or insurance status. This may require access to specialist services such as translators to ensure access for and consent of people from a non-English speaking background.
- Anonymous testing should be available to individuals, subject to the need to obtain de-identified demographic information from those being tested to inform surveillance.
- HIV rapid testing (i.e. point-of-care testing) is offered in clinical settings, and in community settings which may include trained peer-to-peer test facilitators.
- HIV self-testing is testing technology that can be performed by an individual in the absence of a health-care provider or trained operator.
- All screening and diagnostic test results must remain confidential and only shared with individuals with a clinical need to know in accordance with jurisdictional legal and policy restrictions on sharing of information regarding a person's HIV positive status.
- Services offering testing should ensure that test results are conveyed to the person being tested in a timely manner, which will be contingent on the nature of the test performed. It would be reasonable to expect negative screening tests for HIV to be available within two business days however confirmatory tests for reactive samples may take some days longer.
- Where regulations or legislation allow for restrictions to be placed on individuals who are aware they have HIV,[5] a reactive result by the initial HIV test, including an HIV point-of-care test or HIV self-test, will be considered evidence of HIV infection unless reference testing subsequently shows the individual to be free of HIV. Consequently, pending the outcome of confirmatory testing, individuals who are reactive on a screening test should be made aware of likelihood of the test being a true positive, based on the type of test used and the result. Practitioners should seek specific advice from their laboratory if necessary, and testing services using point of care tests should be aware of the positive predictive value of the test used. The person tested should also be made aware of the transmission restrictions placed upon a person with confirmed HIV infection[6].These restrictions may be through the use of public health powers and/or legislation in some jurisdictions.
- Testing practices must comply with all relevant Commonwealth and State and Territory antidiscrimination and public health legislation, and other relevant laws and regulations[5] including those governing Commonwealth funding of pathology tests, storage of medical and personal information and confidentiality and privacy protections.[7]

2.0 TYPES OF HIV TESTING

This policy covers laboratory-based testing and non-laboratory-based testing. The TGA has produced guidance to assist and inform its evaluation of HIV tests: TGA Clinical Performance Requirements and Risk Mitigation Strategies for HIV Tests

This guidance sets out differential performance requirements for laboratory tests, HIV point-of-care tests and HIV self-tests. It recognises that a lower performance threshold may be acceptable in a test which is part of a screening protocol requiring confirmatory testing, and that confirmatory testing must be able to demonstrate the highest quality and performance. It also specifies the need for training. It is essential that those using any test are familiar with its limitations and can communicate these limitations to the person being tested or, in the case of a self-test, that the package insert addresses these limitations.

This TGA guidance document is prospective and relates to any tests which may be submitted to the TGA for evaluation.

2.1 HIV seroconversion window period

As with most infectious diseases, the human body responds to HIV infection by producing antibodies in an expected manner. These antibodies are usually produced within several weeks after infection, although in rare cases they may not be detected for a number of months. Immediately after infection has occurred it is not possible to detect any markers of infection. This period of time generally lasts for about 10 days after infection and is referred to as the 'eclipse period'. Currently, the first marker that is detected following the eclipse period is viral nucleic acid (RNA or proviral DNA) or p24 antigen if nucleic tests are not used. HIV antibodies are generally detected within 4 weeks, but this depends on the type of tests used including HIV point-of-care tests (rapid HIV tests) where detection of antibodies may take longer.

In Australia, most laboratories use 4th generation HIV antibody/antigen screening tests and the time to detection is generally 3-4 weeks from infection; however rare outliers have been reported. Following a possible exposure to HIV, it is important to provide certainty around clinical information regarding a person's infection status, so statistical confidence limits (99%) are applied to the average time that standard screening tests become detectable to declare a person is uninfected. This period is typically set at 12 weeks. Therefore, a clinician can say with confidence that a person with a negative HIV antibody test has not acquired HIV infection after 12 weeks, provided there has not been any further risk exposure. This approach considers all antibody-based tests including rapid HIV tests, where longer seroconversion periods have been observed.

Reference laboratories perform a range of laboratory-based testing strategies that will detect and confirm HIV infection earlier than 12 weeks, so it is reasonable for such laboratories applying testing strategies that contain 4th generation (antigen containing) and nucleic acid tests that the window period may be reported as 6 weeks.

2.2 Laboratory-based testing

Laboratories are subject to requirements established by the NPAAC. Laboratory staff are also subject to professional standards established by the RCPA and international standards under which laboratories receive NATA/RCPA accreditation.

- NPAAC Requirements for Laboratory Testing of Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)
- Royal College of Pathologists of Australasia: Professional Standards
- ISO 15189 Standard for Medical Laboratories
- NPAAC Requirements for Medical Pathology Services

2.3 Point-of-care testing

Most point-of-care tests require longer window periods to detect an infection compared to laboratory-based tests (immunoassays and nucleic acid detection). In this policy, reference to point-of-care tests refers to rapid HIV tests being used at point of care. Australian evaluations of point-of-care tests have shown that many acute (very recent) infections would not be detected if point-of-care tests alone were used among people from high HIV incidence populations, such as gay and bisexual men.[8,9]

In addition to the guidance on performance requirements issued by the TGA, point-of-care HIV testing services are additionally subject to requirements established by the jurisdictions and health-care workers performing point-of-care tests. Additionally, jurisdictions may require those performing HIV point-of-care tests to contribute to surveillance data collection. Examples of these additional requirements include:

- The NSW Framework and Standard Operating Procedure for HIV Point of Care Testing
- The NRL Requirements for Participation in a specific External Quality Assessment Scheme (EQAS)
- The Royal Australian College of Pathologists External Quality Assurance Program

Sites that perform point-of-care testing should be enrolled and actively participate in a relevant external quality assurance program. It is recommended that the site contribute to jurisdictional or national data collection.

The application of these requirements is the responsibility of the director of any service which provides HIV testing. The TGA requires that an appropriately trained health-care worker is responsible for performing or supervising all aspects of the testing process from sample collection to test interpretation. All staff, including voluntary service providers, who perform HIV point-of-care testing should be able to demonstrate competency in the performance of the tasks for which they are responsible. Training should cover test operation, sample collection and interpretation as well as issues of consent, conveying the result, and any confirmatory testing processes.

Staff should also receive specific training on the operation of any newly introduced point-of-care test or sample collection process being used in a facility.

Services providing point-of-care testing should have a clear linkage to clinical and pathology services for the conduct of confirmatory testing. This includes when point-of-care testing is performed in community-based testing services and in outreach settings, such as a mobile clinic or pop-up site.

2.4 HIV self-testing

HIV self-testing involves a person collecting their own specimen (e.g. blood from a finger prick) for HIV testing, applying it to a testing kit or device and interpreting the test result. Currently, there are no devices allowing for oral fluid self-testing approved by the TGA for supply in Australia. Self-testing for HIV provides opportunities for improving access to testing and increasing frequency of testing among people at risk of HIV infection. Self-testing minimises the barriers associated with conventional testing e.g. the need to attend a health service to access a test, time taken for test results to be available, poor access to health-care providers, feelings of stigma associated with testing, and the risk of discrimination.[10] Self-testing can also support autonomy, and provide added confidentiality, privacy and convenience for people who may not otherwise engage in HIV testing. It has been shown in multiple studies, including in Australia, to be highly acceptable and easy to use with little to no support from trained staff.[10,11] A randomised controlled trial among Australian gay and bisexual men attending sexual health services showed that the provision of HIV self-testing increased the uptake and frequency of HIV testing, without diminishing the frequency of sexual health screening at services.[11]

To maximise the potential benefits of self-testing devices, the instructions for use (the package insert) must be sufficiently illustrative and comprehensible so that a user can perform the test correctly and interpret the result accurately. In addition, the package insert must explain sensitivity and specificity limitations including the predictive value when used in high- and low-prevalence populations, the window period, the need for confirmatory testing, and referral points.

In 2018, the first self-testing device was approved by the TGA. This device allowed self-testing to be performed in the absence of a health-care provider or trained operator. Requirements for the online supply of the first HIV self-test were that the sponsor provide an online instructional video for users to view prior to using the test, provision of an HIV telephone helpline providing 24-hour customer support, training in the correct use of the device and interpretation of results, and information about how to access psychosocial support in the event of a reactive result. Additionally, where the sponsor supplies the test for use by healthcare workers (in organisations that employ health professionals (e.g. medical practitioners, registered nurses) to perform or supervise[6] the performance of testing by appropriately trained staff)[7], those healthcare workers must have received training in the delivery and administration of HIV testing in accordance with the requirements of this Policy, and organisations must have an established relationship (in relation to the referral and testing of specimens) with a NATA-accredited medical testing laboratory.

2.5 Novel testing technologies and sample collection processes

Before their availability in Australia, any new testing technology or sample collection device must be approved by the TGA. Currently, there is no TGA-approved HIV test that is intended for use with self-collected samples, such as oral fluid or dried blood spots. However, there are various provisions for exemption, such as for a clinical trial, that allow for regulated access to unapproved devices.

Self-sampling is when a person collects their own biological sample for HIV testing (e.g. oral fluid or blood from a finger prick) and after collection sends it to a laboratory for testing. Unlike HIV point-of-care testing and self-testing, the analysis of a self-collected sample is performed in the laboratory and a confirmed result is obtained. Dried blood spot sampling for HIV and hepatitis C testing has been successfully used in a government-led pilot study in New South Wales since 2016.[12] The study is being conducted under a clinical trial exemption from the TGA.

Self-sampling for HIV testing may provide opportunities for improving access to testing and increasing frequency of testing among people at risk of HIV infection through minimising the barriers associated with conventional testing e.g. the need to attend a health service to access a test, poor access to health-care providers, stigma, poor venous access, and the risk of discrimination. Self-sampling can also support autonomy, and provide added confidentiality, privacy and convenience for people who may not otherwise engage in HIV testing. International research suggests self-sampling for HIV is highly acceptable and easy to use with little to no support from trained staff, although return rates for self-sampling kits may vary.[13,14]

3.0 INDICATIONS FOR HIV TESTING

Jurisdictional and community-based approaches, guidelines and protocols developed in line with the Eighth National HIV Strategy 2018-2022 should reflect local epidemiology and demographic data to facilitate the appropriate testing frequency among populations at risk of HIV. These approaches support firstly the public health goal of diagnosing at least 95% of those living with HIV, in accordance with the specific targets of the Eighth National HIV Strategy 2018-2022 to work towards the elimination

of HIV; and secondly the individual benefit of people unknowingly living with HIV in Australia, especially the still significant proportion of people living with HIV who present late (with a CD4+ cell count at diagnosis below 350 µL) who would have a significant health benefit from an earlier diagnosis. In Australia, between 2013 and 2017, almost 50% of new HIV diagnoses among people reporting heterosexual exposure, or origin from a high prevalence country, and 26% of new diagnoses among gay and bisexual men, were late HIV diagnoses.[15] Testing for HIV infection is currently considered to be cost effective even when the prior likelihood of positivity is as low as 1 in 1000,[16] so the perceived risk does not have to be high in order to test.

HIV testing is indicated in a number of contexts:

Behavioural and epidemiological indicators

- Gay men and other men who have sex with men, in accordance with the Australian Sexually Transmitted Infection & HIV Testing Guidelines 2019: For asymptomatic men who have sex with men
- Transgender women and people who identify as gender diverse who have sex with men
- Aboriginal and Torres Strait Islander peoples
- People who inject drugs
- People who have recently changed partners, who have multiple concurrent sex partners, or who have had multiple partners since their last HIV test
- Sexual and injecting partners of all the above groups of people, including those coming forward following contact tracing and the sexual and injecting partners of people known to be living with HIV
- A reported high-risk exposure, including: unprotected sexual intercourse with a partner whose HIV status is unknown or a person diagnosed with HIV with a detectable viral load, the reported reuse of equipment used for skin penetration including for recreational drugs or cosmetic procedures such as tattooing or piercing
- Individuals who report a history of incarceration
- Individuals who have received care in certain health-care settings, such as services overseas where there may be poor infection control practices or where infection control breaches have been identified
- People from high-prevalence countries (*see table on p.14*), recently-arrived refugees, asylum-seekers and people who have arrived as humanitarian entrants or other refugee-like circumstances
- The following countries were recognised by UNAIDS to be high HIV prevalence countries (national HIV prevalence above 1%) between 2008-2017:[15] (*See list on p.13*)
- People who have travelled to countries of high prevalence and engaged in risk behaviour/ exposure, especially unprotected sex with a person not known to be HIV-negative
- A health-care worker conducting exposure-prone procedures. *See section 7.1* of this policy, The Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 and the Communicable Diseases Network of Australia (CDNA) policy on infected health care workers for more information. To meet CDNA guideline requirements, testing of health-care workers should be performed in accredited laboratories. Health-care workers should not perform or request tests for themselves, including laboratory tests; self-testing in any form does not meet CDNA testing requirements.

Clinical indicators

- In the setting of contact tracing
- A patient-initiated request to a health-care service for an HIV test
- Patients admitted with recreational drug-related mental health conditions or mental health conditions leading to risk taking behaviour
- Any patient admitted to a hospital with methamphetamine-related illness because of the high association of methamphetamine and related stimulant use reported among people who acquire HIV
- Pregnant women (retesting should occur if there is

ongoing acquisition risk during pregnancy)
- People with particular medical conditions (*please see p.14 for a list of these indicators*)
- People who received a blood transfusion or blood from overseas in a context where safety of the blood supply and other human-derived tissues may not be assured
- An individual who reports having a reactive or invalid result on an HIV point-of-care test, HIV self-test or an HIV test performed overseas
- In the context of Post-Exposure Prophylaxis (PEP), subject to national and jurisdictional guidelines and policy[17]
- As part of an initial and ongoing assessment for Pre-Exposure Prophylaxis (PrEP) or in the management of a patient taking PrEP[18]
- HIV testing should be recommended in clinic-based settings servicing groups of known high HIV prevalence e.g. men who have sex with men, intravenous drug users, and migrants from high prevalence countries. The UK National Guidelines for HIV Testing (2008) recommend universal HIV testing in areas where the prevalence of HIV is above a threshold of 2:1000.[14]
- Some jurisdictions have implemented programs to screen individuals presenting to emergency departments with symptoms that may indicate HIV infection, such as fever of unknown origin
- The presence of any symptom or diagnosis which could be indicative of HIV infection (a so-called indicator condition*) when HIV would be in the differential diagnosis as underlying such a condition, especially opportunistic infections, or impact the way a disease is managed (such as tuberculosis [TB], or in a condition which shares a transmission route with HIV, such as any sexually transmissible infections [STI], hepatitis B [HBV] or hepatitis C [HCV]). *See list on p.14*.

List 1. HIV prevalence countries (national HIV prevalence above 1%) between 2008-2017

Sub-Saharan Africa			
Angola	Djibouti	Lesotho	South Africa
Benin	Ethiopia	Liberia	Swaziland
Botswana	Equatorial Guinea	Malawi	Tanzania
Burkina Faso	Gabon	Mali	Togo
Burundi	Gambia	Mozambique	Uganda
Cameroon	Ghana	Namibia	Zambia
Central African Republic	Guinea	Nigeria	Zimbabwe
Chad	Guinea-Bissau	Rwanda	
Republic of the Congo	Kenya	Sierra Leone	

Americas	**Eastern Europe**	**North Africa**	**Southeast Asia**
Bahamas	Russian Federation	South Sudan	Thailand
Barbados	Ukraine		
Dominican Republic			
Guyana			
Haiti			
Jamaica			
Panama			
Suriname			
Trinidad and Tobago			

Table 1. Indicator conditions for HIV testing

	AIDS-defining conditions	Other conditions where HIV testing should be offered
Sexually transmissible infections		Gonorrhoea, chlamydia, hepatitis B, hepatitis C, syphilis, or any other sexually transmissible infection
Respiratory infections	Tuberculosis Pneumocystis Recurrent bacterial pneumonia	Aspergillosis
Neurological diseases	Cerebral toxoplasmosis Primary cerebral lymphoma Cryptococcal meningitis Progressive multi-focal leukoencephalopathy	Aseptic meningitis/encephalitis Cerebral abscess Space occupying lesion of unknown cause Guillain–Barré syndrome Transverse myelitis Peripheral neuropathy Dementia Leukoencephalopathy
Dermatological diseases	Kaposi sarcoma	Severe or recalcitrant seborrhoeic dermatitis Severe or recalcitrant psoriasis Multi-dermatomal or recurrent herpes zoster (shingles)
Gastroenterological diseases	Persistent cryptosporidiosis Oesophageal candidiasis	Chronic oral candidiasis Oral hairy leukoplakia Chronic diarrhoea of unknown cause Weight loss of unknown cause Nontyphoidal salmonella (bacteraemia, osteomyelitis and septic arthritis), recurrent enteric salmonellosis, shigellosis or campylobacter Hepatitis B infection Hepatitis C infection
Oncology	Non-Hodgkin lymphoma	Anal cancer or high grade anal squamous intraepithelial lesion Penile cancer Seminoma Human papillomavirus-related head and neck cancer Hodgkin lymphoma Castleman disease
Gynaecology	Cervical cancer	Vaginal, vulval or cervical or high-grade intraepithelial lesion
Haematology		Any unexplained blood dyscrasia including: • thrombocytopenia • neutropenia • lymphopenia
Ophthalmology	Cytomegalovirus retinitis	Infective retinal diseases including herpesviruses and toxoplasma
Ear, Nose and Throat		Lymphadenopathy of unknown cause Chronic parotitis Lymphoepithelial parotid cysts
Other		Mononucleosis-like syndrome (primary HIV infection) Pyrexia of unknown origin Any lymphadenopathy of unknown cause Any sexually transmissible infection

* Clinical indicator diseases for adult HIV infection (adapted from UK National Guidelines for HIV Testing 2008)

[i] For ease of reading, the term 'patient' is used throughout this document to refer to the person being tested and should be read interchangeably with the term 'client'.

3.1 Normalisation of HIV testing

Although HIV-related stigma and discrimination still exists in many settings, treatment for HIV is highly effective. With treatment, people living with HIV can expect a normal or near-normal life expectancy. Failure to diagnose HIV can result in serious illness and onward transmission to others. HIV testing should be offered in conjunction with STI and viral hepatitis screening to all patients who have had any risk exposure such as partner change or injecting drug use, and identification of a new clinical indicator condition (*as defined in Table 1, located on p.14*). The absence of an identified epidemiological or behavioural risk factor should not preclude HIV testing in appropriate clinical circumstances (see the previous *section 3.0 Indications for HIV Testing* for a list of HIV indicator conditions). Obtaining a detailed history is not a prerequisite for testing, especially in the context of an individual request to be tested or another clear indication for testing such as the presence of an indicator condition. HIV testing should be routinely offered to pregnant women as part of the suite of screening tests performed in the first antenatal visit.

3.2 Indicator triggered testing

Inclusion of HIV in a differential diagnosis of a number of clinical conditions will help normalise HIV testing. All attempts should be made to access existing clinical data to facilitate the identification of HIV in those people with HIV infection who are undiagnosed.

The use of pathology results or hospital admission data should be considered to identify indicator diseases and raise greater awareness among clinicians treating diseases that might suggest HIV. *See section 3.0 Indications for HIV Testing* for a list of HIV indicator conditions.

Where feasible during service planning or revisions, electronic clinician support tools should be automated to prompt testing when indicators for HIV arise.

3.3 Patient-initiated testing in the absence of indications

A small number of people will request a test but will not disclose risk factors. In this case, a person's preference not to disclose risk factors should be respected and HIV testing should be conducted.

3.4 Testing in the context of contact tracing

Individuals may seek testing because they have been contacted as a person who may have been at risk of exposure to HIV. Most facilities conducting contact tracing establish a communication wall between the identity of the source patient and the contact (*see also section 5.1 Contact tracing and partner notification*).

These patients are a priority for testing and should be afforded prompt access to testing. They may be unaware of their potential exposure and may have additional needs for counselling and information. They should be tested using a standard laboratory test in addition to any point-of-care test.

3.5 HIV testing in the context of research

There may be circumstances where, on public health grounds (e.g. prevalence studies), anonymous delinked testing is legitimately performed in accordance with this policy. Such testing should occur only where there is compelling scientific justification, and ethical and administrative approval (*see section 6.0 Surveillance and Research*). Those responsible for the project should consider making test results available on a confidential basis to participants who wish to receive their results. These

studies must be independently judged by an ethics committee constituted in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research.

HIV prevalence studies conducted before 2010 with gay and bisexual men in Australia found high levels of undiagnosed HIV (20-31%) but could not provide test results to participants because they took part anonymously.[19,20] More recent community-based prevalence studies have given participants the choice of receiving their test results, consistent with ethical obligations and international guidelines.[21,22]

Recent prevalence studies with gay and bisexual men have found declining levels of undiagnosed HIV (< 10%) but have experienced difficulty in recruiting participants due to increasing levels of HIV testing and PrEP use in the population.[20,23,24] International guidelines suggest that bio-behavioural prevalence studies should only be conducted in populations with the highest HIV prevalence, with a minimum sample size of 500, and these studies should provide results quickly to participants.[21]

3.6 Mandatory and compulsory screening and testing

Mandatory screening refers to situations where people may not participate in certain activities or roles, or access certain services unless they agree to be screened. Circumstances in which mandatory screening is currently required under separate policy or legislation include:

- as a condition of blood, tissue and organ donation
- as a mandatory part of the health requirement assessment for specified visa subclasses
- as a condition for entering training or service in the armed forces
- as a condition for purchasing some types of insurance.

Compulsory testing refers to situations where a person has no choice in being tested, e.g. as directed under a public health order, or as authorised under legislation (e.g. in the context of a forensic or coronial inquiry, or under legislation in some jurisdictions that allows for forced testing of individuals accused of certain offences). While mandatory or compulsory testing may be performed in some situations, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) do not support mandatory or compulsory testing of individuals on public health grounds.[25]

The processes involved in securing a sample and conveying an HIV test result, in the context of mandatory and compulsory testing, should be in accordance with the relevant enabling legislation and the principles in this policy and basic human rights pertaining to privacy of health information to the extent these rights do not contradict existing legislation. Situations deemed necessary to impose mandatory or compulsory screening should be closely scrutinised from an evidence-based perspective on a regular basis to ensure that decision-making guidelines are adequate, and that the breach of the principle that testing be voluntary is still warranted. There may be an extra need for psychosocial support for the person tested in such a circumstance. The decision to use a laboratory or non-laboratory-based test will be a decision for the agency requiring the test to be performed, based on any practical considerations (*see section 7.5 Testing in prisons*). However, in situations where testing is being undertaken to exclude transmission of HIV, the most sensitive available laboratory test (i.e. tests that directly detect the HIV virus) rather than antibody tests such as antigen or nucleic acid tests, would be recommended.

3.7 Public health management of HIV

The Communicable Diseases Network Australia (CDNA) has produced a Series of National Guidelines (SoNGs) on the public health management of HIV. The SoNGs outline management of individuals with HIV infection and generally outline indications

for testing: *National Guidelines for Managing HIV Transmission Risk Behaviours 2018*. Individuals identified as contacts of a source patient may require special assistance as they may be unaware of their risk of exposure. SoNGs are endorsed by the Australian Health Protection Principal Committee (AHPPC) which provides advice and recommendations to the Australian Health Ministerial Advisory Council.

4.0 INFORMED CONSENT FOR HIV TESTING

All pathology testing requires informed consent, given verbally. Informed consent includes that the person being tested understands:

- the type of test
- the reasons for testing
- the potential implications of not being tested.

Using their professional judgment, clinicians can:

- explain the testing procedure
- assess the person's understanding of the HIV test results
- inform the person being tested about how they will get their results (note: clinicians should ensure that they confirm the patient's phone number)

See section 3.6 Mandatory and compulsory screening and testing for rare occasions when a legal order is made for compulsory testing or in emergency settings.

When offering testing to patients with low English proficiency, clinicians who do not speak the preferred language of the patient should use an accredited interpreter obtain informed consent. There are publicly funded health interpreting services available in most states and territories The Translating and Interpreting Service (TIS National) is available to registered health services 24 hours a day. **TEL: 1300 131 450**.

4.1 When informed consent cannot be provided by the patient

Professional judgment should be exercised in determining whether a person has capacity to make a decision to undergo an HIV test. 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 or 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. The potential impact of the test result on the person being asked to provide consent needs to be considered.

In an emergency situation, when no guardian or appropriate person can be identified, professional judgment should be used in requesting an HIV test. See the HIV/AIDS Legal Centre matrix for the hierarchy of responsibility in each jurisdiction.

5.0 CONVEYING HIV TEST RESULTS

The process of conveying an HIV test result to the person who has been tested, irrespective of the specific result, is affected by the type of test performed, the setting of the consultation and testing, and the extent, if any, of additional testing required to determine the person's true HIV status. Examples are provided for reference in Appendixes B and C. The site director and the person who requests the test are responsible for ensuring that appropriate mechanisms are in place for delivering the test result.

Community perceptions of HIV have changed over time as has the way people give and receive information. Nevertheless, even for those familiar with HIV, a positive diagnosis of a lifelong condition is a significant psychosocial event, in which some

people display symptoms consistent with post-traumatic stress disorder (PTSD).[26,27,28] For people visiting Australia and potentially returning to regions with poor access to treatment, a positive result may understandably be received as a traumatic and life-threatening diagnosis. Aboriginal and Torres Strait Islander people and those from culturally and linguistically diverse backgrounds may experience heightened difficulty in adjustment and linkage to services.[29,30,31,32] These populations continue to climb as a proportion of those diagnosed in Australia.[15]

Preferably a positive HIV test result should be given in person. However, current practice includes the provision of test results over the phone, by email or phone text message (SMS), or via apps such as Facetime, when it is considered appropriate. It is important for those performing the test to use professional judgment in deciding how results will be delivered. The decision should be based on the understanding of the person being tested. Counselling may be required by some individuals and should be offered to all receiving a positive diagnosis. Counselling should preferably be undertaken by doctors or nurses experienced in this area, or a trained allied health professional e.g. psychologist, social worker or counsellor. The National Standards for Psychological Support for Adults with HIV may be used as a guide.[33] Operational guidance on conveying positive HIV test results, negative HIV test results, and a decision-making flow chart, are provided for reference in Appendixes B, C and D. Arrangements can be made between services that are not experienced in delivering HIV positive results (e.g. Emergency Departments) and sexual health services so that the sexual health service provides the result to the newly diagnosed person; this facilitates testing within inexperienced services.

5.1 Contact tracing and partner notification

It is the responsibility of the person conveying a positive HIV test result to ensure that the patient is aware of the legal obligations relevant to their jurisdiction and of the need for former partners to be advised that they may have been at risk of exposure to HIV.

Those conveying positive results are referred to the Australasian Contact Tracing Guidelines and state and territory policies on contact tracing. Practical assistance can be provided to the health-care provider and patients by ASHM, the local public health unit or sexual health clinics. The details of the source patient must be treated confidentially, and the contact must not be provided with the source patient's name or details. It can be helpful for facilities performing contact tracing to create an information wall between the person who gets information from the source patient and the person speaking to the contact. Site-specific approaches to contact tracing should be included in standard operating procedures of facilities conducting HIV testing.

5.2 Confidentiality of HIV test results and testing data

Currently, pathology test results identified as sensitive are not sent to the Australian MyHealthRecord. Such tests include HIV tests and tests used to manage HIV infection (e.g. viral load, drug resistance); STIs; genomics tests; pregnancy-related tests in minors (under 16 years of age) drug and alcohol tests; ABO blood-typing paternity group; MCS (genital) tests and autopsy test results. HIV results from a pathology laboratory will only be released to the requesting medical practitioner or to the clinical service team responsible for the patient's care and management. Confirmed HIV-positive results are also notified to the relevant jurisdictional health authority for the purpose of public health disease notification. However, some information that may be perceived as surrogate information about an individual's serostatus, such as pharmacy prescriptions, may be transmitted to MyHealthRecord. Subject to the arrangement between the site and the reference laboratory, patient information may be shared between a specialist HIV physician, an s100 prescribing

clinician or a sexual health service for the purpose of ensuring that a patient is informed of their test result. Part of the informed consent process should involve an explanation of how a patient can expect to receive their result.

Services are responsible for the security of HIV testing data and should develop mechanisms to restrict access to HIV pathology information in the same manner that other health information is protected. For example, there must be a security hierarchy within the information systems to restrict access to this information to those individuals directly involved with the care of the patient, noting that, with electronic medical record (EMR) systems it is not possible to restrict access to health information to those individuals directly involved with the treatment and care of an individual. This access is therefore managed by local codes of conduct, privacy and health record confidentiality legislation, and having EMR systems that include an audit trail, whereby a record is kept of every instance of access to a medical record, who accessed the record and the date and time of access.

It is reasonable to expect that pathology test results are available on a patient's record and that all staff with a legitimate clinical reason have access to the patient's HIV test information, including the range of non-HIV-related service staff who may be involved in the patient's health care.

Any person involved in HIV testing must not disclose any personal or medical information about a patient to any other person, in accordance with privacy provisions.

5.3 Assistance to doctors new to diagnosing HIV

Some jurisdictions and ASHM provide assistance to doctors who are unfamiliar with diagnosing HIV. Assistance is most easily facilitated by the laboratory performing the HIV test. Services of this nature support the diagnosing doctor and improve the immediate management of the patient, including initiating contact tracing and assessment for treatment. These services can also facilitate the collection of routine surveillance data, and act to encourage the doctor to support the patient with access to ongoing HIV management; counselling on prevention; support for partner notification; psychosocial assessment and support; and linkage to other services.

6.0 SURVEILLANCE AND RESEARCH

Laboratories performing confirmatory testing must notify the relevant state and territory health authorities of any new positive laboratory diagnosis in accordance with the relevant legislation and regulations.

Where information is available to identify and monitor rates of newly acquired HIV infection, this information should be reported to the local state or territory health authority as appropriate. Laboratory evidence of acute or recent HIV infection is useful to monitor rates of incident HIV infection and to evaluate interventions.

6.1 Delinked blood surveys

Delinked anonymous surveys are studies in which specimens taken for other purposes (e.g. the neonatal heel prick specimen survey in 1989–90) are tested for HIV infection without consent after they have been coded, so that the results cannot be linked back to the individual who originally provided the specimen. The survey method should be considered for Australian surveillance purposes only where there is no other feasible method for reasonably obtaining appropriate data. Surveys must be subject to scientific justification and be endorsed by an institutional ethics committee (IEC) in accordance with the requirements prescribed by the NHMRC.

6.2 Identity unlinked HIV testing

Research using identity unlinked HIV testing can provide useful epidemiological data. In such studies, specimens used must be endorsed by an appropriate IEC in accordance with requirements prescribed by the NHMRC (*see section 3.5 HIV testing in the context of surveillance*).

6.3 Data linkage projects

An increasing amount of clinical data is becoming available as a result of the development of electronic data storage. Linkage projects tied to HIV notification data can provide timely and relevant feedback on practice. Linkage to data including Medicare data, cancer registries, enhanced notification data and treatment and testing data must be endorsed by an appropriate IEC in accordance with requirements prescribed by the NHMRC. For example, in NSW, the *NSW Public Health Act 2010* allows, and provides a framework for, the linkage of HIV notification data to data from some NSW Health administrative datasets including hospital admission data, death register data and emergency department data.

6.4 Use of stored blood for research on diagnostic technologies

Retrospective analysis of stored samples, particularly for the testing of new diagnostic technology or testing epidemiological hypotheses, must be conducted only on delinked or de-identified samples or be subject to appropriate ethical review and be endorsed by an IEC in accordance with the NHMRC.

6.5 Use of unregistered in-vitro diagnostic medical devices (IVDs)

Before its availability in Australia, any new testing technology or sample collection device must be approved by the TGA. However, IVDs not currently approved by the TGA (such as dried blood spot kits and tests which use alternative sample types) may be required to be used in research.

The TGA can provide access to an unapproved device through various exemption provisions. Access to an unapproved device for use in research can be sought through a clinical trial exemption.

7.0 TESTING IN SPECIFIC POPULATIONS

7.1 Health-care workers

The CDNA has published updated guidelines which include expert consensus in relation to health-care workers and their blood-borne virus (BBV) status.[34,35] The 2018 guidelines state that all health-care workers should be aware of their BBV status and all health-care workers who perform exposure prone procedures (EPPs) must take reasonable steps to know their BBV status and should be tested for BBVs at least once every 3 years. Health-care workers who perform EPPs and assess their risk of exposure to be high should consider more frequent BBV testing. Examples of EPPs can be found in the CDNA's information sheet Guidance on classification of exposure prone and non-exposure prone procedures in Australia. Additionally, all student health-care workers should be aware of their BBV status and should be offered testing at or before entry to their course.[33]

Any HIV testing done in the above context should be performed in accordance with this policy. Where testing of a health-care worker is undertaken, confidentiality is paramount and must be maintained. If a health-care worker who performs EPPs tests positive for HIV infection, they must stop performing these procedures immediately and seek specialist advice.[33] The CDNA's guidelines (2018) provide very clear advice about the circumstances in which a health-care worker who has been diagnosed with HIV can perform EPPs.[33] If the health-care worker is found to have HIV infection, adequate confidential psychosocial support should be provided.

To meet CDNA guideline requirements, testing of health-care workers should be performed in accredited laboratories. Health-care workers should not perform or request tests on themselves, including laboratory tests, and self-testing in any form does not meet CDNA testing requirements.

7.2 Routine antenatal testing

Antenatal HIV testing is recommended for all pregnant women and should be included as routine in tests associated with the first antenatal visit, in line with the Department of Health Clinical Practice Guidelines: Pregnancy Care (2019)[36] and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidelines which state that, in the absence of complications, all pregnant women should be recommended to have HIV screening at the first antenatal visit.[37] The woman should be informed about the tests being performed, including HIV testing, as part of the antenatal screen and should provide consent.

Jurisdictions should develop operational directives that support the RANZCOG guidelines through education and feedback on adherence, and that allow for periodic auditing of antenatal medical records to provide evidence that recommendations for best practice are being followed. These recommendations should include a clear referral pathway for women who are diagnosed with HIV so that they can be managed by appropriate specialist teams.

7.3 Testing of infants born to HIV-positive mothers

HIV testing with nucleic acid direct detection tests (such as proviral DNA) of infants of women with HIV infection should be performed within the first month after birth in parallel with testing of the mother, so that appropriate treatment interventions can be implemented quickly. Antibody tests are not helpful in this context due to the persistence of maternal antibodies in the infant for up to 18 months. Diagnosis of HIV infection in infants born to mothers with HIV infection is complex and expert advice must be sought promptly.[38,39]

Currently there are no HIV nucleic acid tests approved by the TGA for this purpose in Australia and there is no MBS reimbursement. However, access to an unapproved device can be sought from the TGA through certain exemption provisions (Special Access Scheme).

7.4 Aboriginal and Torres Strait Islander people

The 5th National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategy 2018-2022 prioritises testing for and treatment of STIs (including HIV) through annual, routine, systematic testing programs. Policies and guidelines which respect confidentiality must be developed locally so that health-care workers are correctly advised, and health services generate culturally appropriate policies and programs.

7.5 Testing in prisons

Australian prisoners are at high risk of contracting blood-borne viruses, including HIV, arising from their exposure to risks such as injecting drug use, sexual risk behaviours, amateur tattooing, body piercing, and violence resulting in injury. Offering HIV testing to prisoners during incarceration has the potential to identify new cases of HIV infection, allowing for prevention education, appropriate assessment, treatment and referral post release. Making HIV testing available has clear benefits for the individual, their sexual partners, those with whom they may share equipment for skin penetration (including injecting equipment) and the wider community.

Australian prisoners should be able to access free, voluntary, confidential, timely, non-discriminatory HIV testing, counselling and treatment services during incarceration, in accordance with this policy. High and unpredictable rates of prisoner movement between different correctional facilities and the community can create difficulty in ensuring engagement with care after a positive diagnosis. As a result, offering the use of point-of-care HIV testing in clinical practice in prisons may increase testing rates and facilitate the timely and accurate diagnosis of HIV.

8.0 QUALITY ASSURANCE OF IN-VITRO DIAGNOSTIC MEDICAL DEVICES (IVDS) FOR HIV TESTING

8.1 Pre-market quality assurance of HIV IVDs

The TGA has regulatory responsibility for IVDs under the Therapeutic Goods Act 1989 and its associated regulations. The TGA has published guidance on clinical performance requirements for HIV tests.

8.2 Post-market quality assurance of HIV IVDs

All diagnostic pathology laboratories performing HIV testing do so under medical testing accreditation standards regulated by NATA and NPAAC standards and guidelines. These accreditation standards set out requirements for internal and external quality assurance practices. In addition, sponsors (i.e. suppliers) of HIV tests have mandatory obligations to report adverse events that are associated with the use or performance of the device to the TGA. The TGA's Incident Reporting and Investigation Scheme (IRIS) manages all reports received by the TGA of adverse events or problems associated with medical devices including IVDs.

Users of HIV tests are also encouraged to report adverse events, including any malfunction of the test, to the TGA. Users can submit a report using the Users Medical Device Incident Report which can be accessed through the TGA website.

9.0 FUNDING OF HIV TESTING

The MSAC is responsible for the determination of any MBS reimbursement for any HIV laboratory, rapid HIV test for use at point of care rapid HIV test for self-testing, as well as any sample collection device. Funding for laboratory-based anti-HIV screening assays (up to 4th generation tests) is available as a rebate through the MBS. Confirmatory and supplementary tests used to confirm initial screening test reactivity (such as western blot) are not funded. Currently, no tests performed outside of accredited laboratories are eligible for MBS rebate, including approved self-tests which are purchased by the end user. States and territories and other jurisdictional organisations may negotiate the purchase of tests and sample collection devices which have been entered on the ARTG for use in their testing and public health programs. Unregistered tests and sample collection devices can be used for research purposes in line with the TGA conditions.

In some situations, it may be appropriate to make de-identified testing available free of charge to the individual being tested to ensure that individuals at high risk of HIV infection access and consent to testing.

10.0 GLOSSARY

10.1 Abbreviations and acronyms

AHPPC	Australian Health Protection Principal Committee
ARTG	Australian Register of Therapeutic Goods
ASHM	Australasian Society for HIV Medicine, Viral Hepatitis and Sexual Health Medicine
BBV	Blood-borne virus
BBVSS	Blood Borne Virus and Sexually Transmissible Infection Standing Subcommittee
CDNA	Communicable Diseases Network of Australia
DNA	Deoxyribonucleic acid
EMR	Electronic medical record
ERC	Expert Reference Committee
EPP	Exposure prone procedure
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IEC	Institutional Ethics Committee
IVD	In-Vitro Diagnostic Device
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
MSM	Men who have sex with men
NAT	Nucleic acid test
NATA	National Association of Testing Authorities
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
NRL	National Serology Reference Laboratory, Australia
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCPA	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RNA	Ribonucleic acid
SoNG	Series of National Guidelines
STI	Sexually Transmissible Infection
TGA	Therapeutic Goods Administration

10.2 Glossary

Compulsory Testing

Where a person has no choice in being tested, e.g. as directed under a Public Health Order.

Exposure Prone Procedure

Defined by the Communicable Diseases Network Australia's national guidelines as a subset of 'invasive procedures' characterised by the potential for direct contact between the skin (usually finger or thumb) of the healthcare worker and sharp surgical instruments, needles or sharp tissues (spicules of bone or teeth) in body cavities or in poorly visualised or confined body sites (including the mouth). In the broader sense, an exposure-prone procedure is considered to be any situation where there is a potentially high risk of transmission of blood borne disease from healthcare worker to patient during medical or dental procedures.

Mandatory testing

Refers to situations where people may neither participate in certain activities nor access certain services unless they agree to be tested. Examples of circumstances in which mandatory testing is appropriate include before blood, tissue and organ donation, and for immigration purposes.

Occupational exposure

An exposure that may place an employee at risk of HIV, HBV or HCV infection through percutaneous injury (e.g. a needlestick or cut with a sharp object, contact of mucous membranes, or contact of skin with blood, tissues or other potentially infectious body fluids to which Universal Precautions apply).

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APPENDIX A

HIV Testing Policy Expert Reference Committee

1. Terms of Reference

The Expert Reference Committee (ERC) meets from time to time to review the National HIV Testing Policy and to consider what action might be necessary to improve quality, uptake and regulation of HIV testing in Australia.

The ERC brings together all parties with an interest in HIV testing and provides a forum for discussion of policy matters raised by third parties in relation to HIV testing. It acts as a forum for identification of barriers and impediments to accessing HIV testing and provides a sounding board for the exploration of how these barriers and impediments might be removed.

The ERC provides background information to jurisdictions and the Commonwealth, the Blood Borne Viruses and Sexually Transmissible Infections Standing Committee (BBVSS) of the Australian Health Protection Principal Committee (AHPPC), regulatory and other advisory bodies.

The ERC provides a voice to raise issues relating to HIV testing with test providers, pathology companies and others.

Members are requested to participate in the ERC on a voluntary basis. No sitting fees are provided.

2. Membership and secretariat

(Name, position, organisation, affiliation with ERC)

Philip Cunningham
Chief Operating Officer
NSW State Reference Laboratory for HIV,
Centre for Applied Medical Research,
St Vincent's Hospital, Sydney
Co-Chair

Phillip Keen
Coordinator of the NSW HIV Prevention Partnership Project
The Kirby Institute, UNSW
Co-Chair

Aaron Cogle
Executive Director
National Association of People with HIV Australia (NAPWHA)
NAPWHA representative

Andrew Grulich
Professor and Program Head
The Kirby Institute, UNSW
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Brendan Crozier
Clinical Psychologist and Allied Health Unit Manager
Sydney Sexual Health Centre
Sexual Health Counsellors' Association of NSW representative

Cathy Pell
Sexual Health Physician and GP HIV s100 Prescriber
Taylor Square Private Clinic
St George Sexual Health Clinic
Clinician representative

Chris Lemoh
Infectious Diseases Physician
Monash Health (infectious diseases, general medicine and refugee health)
President
Victorian African Health Action Network
Invited member

Cherie Power
Senior Policy Analyst
Centre for Population Health, NSW Health
NSW Health representative

Darren Russell
Director
Cairns Sexual Health Service
Invited member

Heath Paynter
Deputy Chief Executive Officer
Australian Federation of AIDS Organisations (AFAO)
AFAO representative

Ian Woolley
Infectious Diseases Physician
Monash Health
Monash University
The Alfred Hospital
Invited member

Jeffrey Post
Infectious Diseases Physician
Prince of Wales Hospital
The Albion Centre
Justice Health and Forensic Mental Health Service, NSW
Prince of Wales Clinical School, UNSW
Invited member

Jules Kim
Chief Executive Officer
Scarlet Alliance, Australian Sex Workers Association
Scarlet Alliance representative

Kate Bath
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Martin Holt
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Melissa Kelly
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APPENDIX B

Conveying Positive HIV Test Results. Features of a Good Diagnosis: a guide for health practitioners

Summary:
A brief guide for health practitioners when conveying an HIV positive result, including when encountering challenging cases.

The process of conveying an HIV test result to the person being tested, irrespective of the specific result, is affected by the type of test performed, the setting of the consultation and testing and extent, if any, of additional testing required to determine the true HIV status of the person. The person who requests the test is responsible for ensuring that appropriate mechanisms are in place for delivering the test results.

Some laboratories provide information for the diagnosing practitioner to contact a more experienced clinician to discuss the procedure of giving a positive test result at the time the results of confirmatory testing are forwarded. Following notification by a laboratory of an HIV-positive test result, practitioners in New South Wales (NSW) will receive support from officers of the NSW Ministry of Health to assist in this process, and referral of the patient to specialist care if required. Any practitioner can use the resources listed below if they require support in this situation.

The first step to take before delivering an HIV-positive result is to check that the result has been confirmed as a true positive on confirmatory testing by a reference laboratory. Check with the laboratory if you are unsure if this has occurred.

A positive result should ideally be provided in person by asking the patient to return for the result as soon as possible. Some sexual health clinics have recently commenced delivering positive results over the phone where a patient has declined to re-attend the clinic quickly. Practitioners should use clinical discretion balancing the risk of not conveying test results when considering alternate communication methods.

Conveying a confirmed positive result – in the context of conventional testing

A positive test result has significant implications for an individual and their clinician. A positive result may result in considerable distress for an individual.

The discussion when conveying a positive result **should** include:

- giving the test result in person and in a manner that is sensitive and appropriate to the gender, culture, behaviour and language of the person who has been tested
- providing information about HIV infection and the benefits of early treatment to prevent illness and reduce the risk of transmission to others.
- providing an opportunity to immediately commence the patient on treatment if at an HIV service or rapid referral to such a service
- providing contact tracing and partner notification strategies, and whether there are any recent contacts of the person (within 72 hours of sexual contact) who would benefit from HIV post-exposure prophylaxis (PEP)
- assessing support mechanisms of the person and offering immediate referral to a support agency, or information to facilitate access at the person's discretion
- arranging appropriate referral for HIV-specific medical care
- discussing legal obligations relevant to the local jurisdiction about disclosure of HIV status (see ASHM's Guide to Australian HIV Laws and Policies for Healthcare Professionals)
- discussing transmission of HIV and how onward transmission may be prevented, including pre-exposure prophylaxis (PrEP) for HIV-negative partners
- offering a timely follow up appointment.

People who are given a new diagnosis often have difficulty absorbing information in the initial consultation. It is usually necessary to cover the issues above over a period of time and subsequent consultation, or referral to specialist care **should** be offered in a timely manner at the time of diagnosis.

Challenging cases

Indeterminate results

A small number of patients will have indeterminate results with conventional testing, where the presence or absence of infection is not established. Such a result may represent infection that cannot be definitively diagnosed at the point in time the test was performed or may represent non-specific test reactivity.

Patients unconvinced by a negative or positive result

Patients who fall into this category can be time consuming and may have psychological issues that need to be addressed. Assistance in dealing with these patients can be obtained from specialist services and the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine who can offer help to refer a patient in this predicament to an alternative service for a second opinion.

Patients who do not return for positive test results

These patients can place others at risk if they do not know their status. It is important to try to actively contact these patients. Clinicians should use discretion when relaying results by phone to the individual or in written correspondence. The request **should** be for the individual to re-contact the testing service.

The decision to stop trying to follow up a patient can be a difficult one. Attempts to contact patients **should** be documented in the patient's file. General practice, in particular, may have limited capacity to perform patient follow-up and general practitioners **should** pass this responsibility to the local public health unit if they have exhausted their resources.

The RACGP Standards for General Practices provides guidelines for follow-up of pathology results that should be referred to.

Post-mortem testing

HIV tests are not standardised in the post-mortem setting. A pathologist undertaking HIV testing as part of the process of a coronial examination or other post-mortem examination is responsible for ensuring that the other provisions of this policy are adhered to, including notification and contact tracing. Mortuary staff may need assistance in approaching contact tracing and this can be provided by public health units and sexual health clinics.

APPENDIX C

Conveying Negative HIV Test Results. Features of a Good Diagnosis

Summary:
A brief guide for health professionals when providing a negative HIV result.

The process of conveying an HIV test result to the person being tested, irrespective of the specific result, is affected by the type of test performed, the setting of the consultation and testing and the extent, if any, of additional testing required to determine the true HIV status of the person. The person who requests the test is responsible for ensuring that appropriate mechanisms are in place for delivering the test result.

The window period will be determined by the type of test used. More advanced HIV tests can detect infection sooner than others, however not all jurisdictions 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 they do not have that information, then a window period of 3 months should be used. Alternatively, the practitioner could contact the testing laboratory pathologist for window period information on their test type.

Conveying an HIV-negative result

The decision on how an HIV-negative test result is provided (e.g. in person, by phone, or other means) will be based on the clinical judgment of the person responsible for conveying the test result. This decision should take account the level of knowledge about HIV, the understanding of the testing process and psychological capacity to deal with the outcome of testing of the person being tested, as assessed at the time of sample collection.

It is imperative that the clinician makes all attempts to ensure that the result is being provided to the person who was tested e.g. in person, phone and SMS.

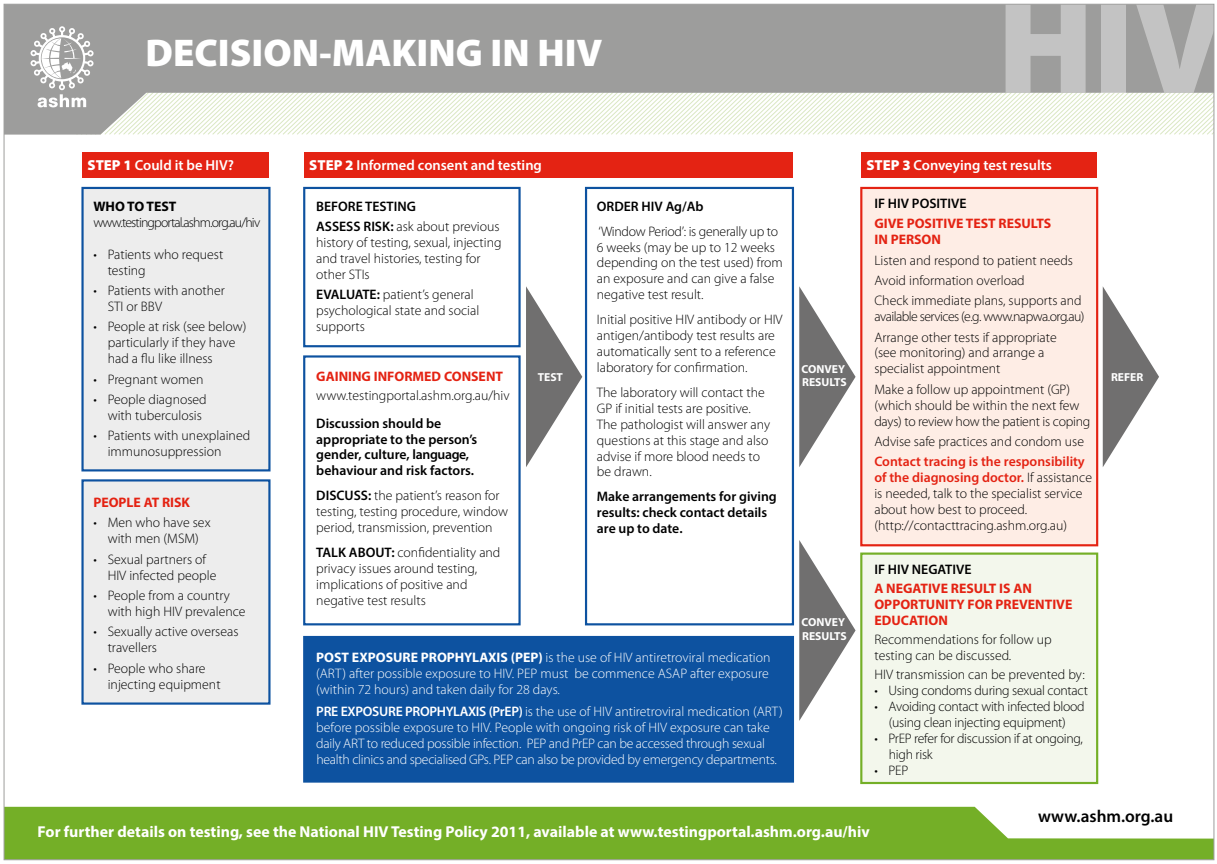
It is imperative to recheck that the person understands the duration of the window period of the test performed and the implications this has for that person. It is wise to recheck the risk history at the time the result is provided.

It is important to give advice about the need for further testing in light of the person's risk history within the window period and ongoing risk of acquiring HIV infection.

It is an opportunity to discuss and reinforce safer sex practices.

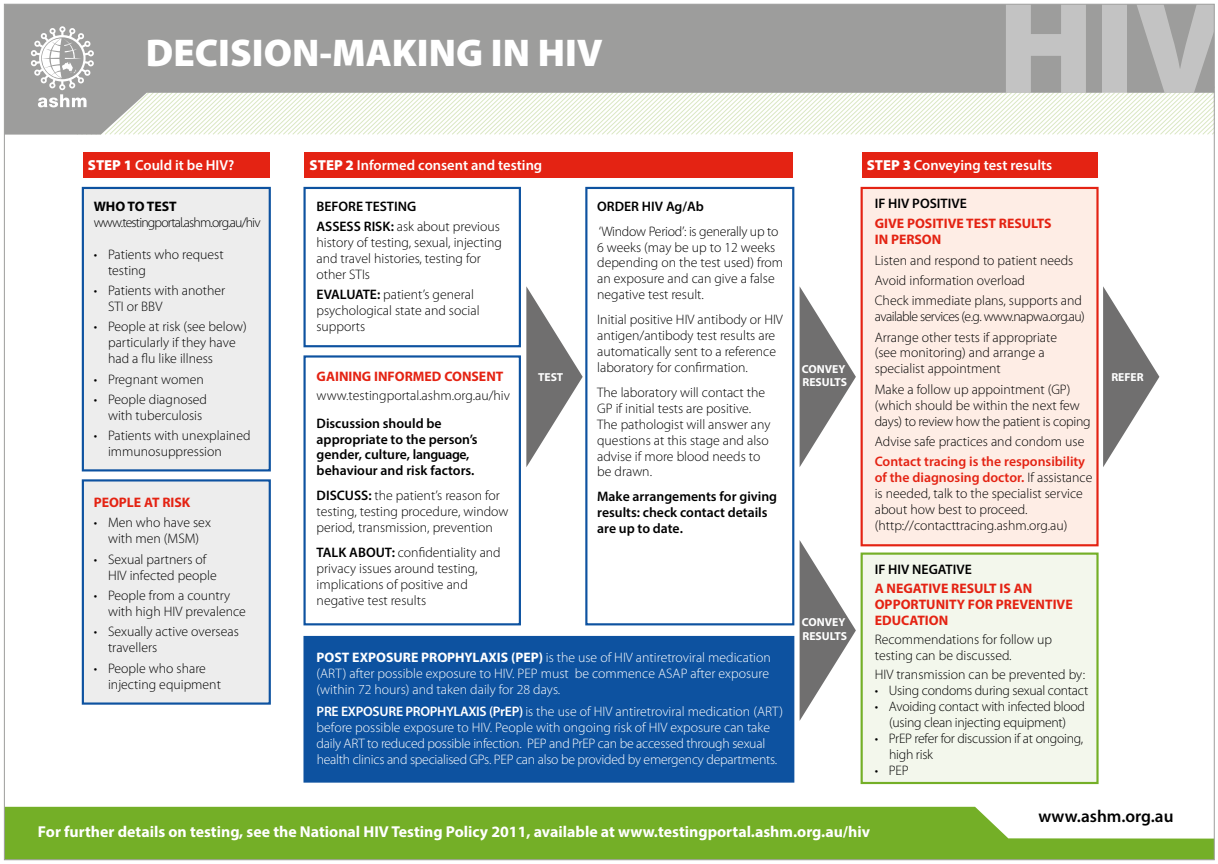
APPENDIX D

Decision-making in HIV



APPENDIX D

Decision-making in HIV



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