

National HIV Testing Policy 2006

2006 National HIV Testing Policy
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EXECUTIVE SUMMARY

Principles of HIV testing

The six basic principles that guide HIV testing in Australia are that:

- confidential voluntary testing with informed consent is fundamental to Australia's HIV/AIDS response;
- testing is of the highest possible standard;
- testing is of benefit to the person being tested;
- testing is accessible to all those at risk of HIV infection;
- testing is critical to understanding the epidemiology of HIV infection in the community; and
- testing is critical to interruption of transmission.

Key Points

Indications for HIV testing

- Indications for HIV testing should be assessed on the basis of the following risk factors:
 - unprotected male-to-male intercourse;
 - sharing of injecting equipment;
 - being the sexual partner of an HIV positive person;
 - being from a country with a high HIV prevalence;
 - having recently travelled overseas;
 - presenting for post-exposure prophylaxis (PEP) after occupational or non-occupational exposure to HIV;
 - pregnancy;
 - requesting an HIV test in the absence of clear risk factors; and
 - diagnosis of a sexually transmissible infection
- Routine pre-operative testing for HIV is not supported.

Pre- and Post-Test Discussions

- The term 'pre- and post-test discussion' should be adopted in place of 'HIV test discussion and post-test counselling'.
- Clinicians delivering the test result should use their best judgement in establishing the most appropriate way to deliver the test result. Things to consider include a person's testing history, gender, culture, behaviour and language.
- Pre- and post-test discussions form an integral part of HIV testing. Provision of information and support associated with testing is consistent with the goal of the fifth *National HIV/AIDS Strategy*, which includes minimising the personal and social impacts of HIV infection.

Surveillance and Research

- Systematic surveillance of the occurrence of newly diagnosed cases of HIV infection and its advanced disease manifestation, AIDS, is recognised as a key component of the Australian response to the HIV epidemic.
- Laboratories performing confirmatory testing must notify the relevant State and Territory health authorities of any new positive results in accordance with the relevant legislation
- The results of HIV antibody testing have been used to analyse trends in HIV diagnoses, to report on the trends identified in HIV testing carried out at sentinel sites, and for special annual surveys.
- The delinked anonymous survey method can be considered for surveillance purposes where there is no other feasible method for reasonably obtaining appropriate data. It should be subject to scientific justification and be endorsed by an institutional ethics committee constituted in accordance with the requirements prescribed by the National Health and Medical Research Council.

Health Care Workers

- Health care workers have a professional obligation to know their HIV status if they are performing exposure-prone procedures (EPPs).
- Health care workers who have a confirmed positive HIV antibody test must not perform EPPs.
- Testing and if appropriate, post-exposure prophylaxis should be offered to health care workers following occupational exposure to blood or body substances, for example through needlestick injury.

Antenatal Testing

- HIV testing should be routinely offered to all women antenatally.
- Antenatal testing must only be performed with the informed consent of the woman. Routine HIV testing without consent is not supported.
- All women contemplating pregnancy or seeking antenatal care should be made aware of the benefits of diagnosis of HIV infection and management, and prevention strategies available for both the mother and the infant.
- Women should receive materials (in written and other formats) outlining the tests that will be offered antenatally and the testing procedure should be explained to the woman by a member of the team involved in her antenatal care. Health care workers in antenatal settings should be trained in appropriate assessment and pre- and post-test discussion.
- Women with limited literacy, or for whom English is a second language, require appropriate educational resources. It may be necessary to provide education material using other media (video, audio, multimedia) and in languages other than English.
- Women with a first language other than English should be offered access to accredited interpreting services.

Aboriginal and Torres Strait Islander People

- Strategies to improve access to testing need to be developed locally and reflect local HIV transmission routes, risk practices and patterns of health service use.

- Local pre- and post-test discussion guidelines should take into account local issues of stigma and shame.
- Fear of breaches of patient confidentiality may be reduced through the development and publication of local confidentiality policies and the use of short-incubation tests as appropriate.
- Specific State and Territory and regional initiatives are needed to improve access to confidential testing and continuity of care for Aboriginal and Torres Strait Islander people moving through the corrections system.
- Antenatal care for Aboriginal and Torres Strait Islander women should include testing according to the guiding principles of this policy and consistent with relevant Aboriginal and Torres Strait Islander Health Frameworks, along with appropriate pre- and post-test discussions for Aboriginal and Torres Strait Islander people.

Post-exposure Prophylaxis

- Testing should be offered and performed urgently after occupational or non-occupational exposure to HIV.
- Refer to the 2006 National NPEP Guidelines.

Quality Assurance and HIV Testing

- The Therapeutic Goods Administration (TGA) has regulatory responsibility for in-vitro diagnostic devices (IVDs). Only HIV assays approved by the TGA may be supplied in Australia.
- In accordance with the conditions applied to the registration of HIV IVDs by the TGA, sponsors may only supply HIV IVDs to laboratories that participate in approved quality assurance programs prescribed by the TGA.
- Laboratories that perform HIV testing must comply with National Pathology Accreditation Advisory Council (NPAAC) standards. The ability to comply is assessed by the National Association of Testing Authorities, Australia/Royal College of Pathologists of Australasia (NATA/RCPA) Medical Testing Program.

Short-Incubation (Rapid) Testing for HIV

- The use of short-incubation testing by practitioners before minor surgical procedures performed in non-hospital settings is not supported.
- The use of short-incubation tests should be limited to situations where:
 - testing is conducted in, or backed up by, a clinical setting;
 - testing is conducted under the auspice of a NATA/RCPA Medical Testing accredited laboratory;
 - reliable TGA approved short-incubation tests are available;
 - high quality information on the tests and their use is available and provided;
 - the health worker performing the test is suitably trained in conducting and interpreting the test, and has the skills to provide pre and post-test information/discussion (if conducted outside an accredited laboratory); and
 - quality assurance programmes are available to assure ongoing competency of healthcare workers performing the tests.

- The availability and use of short-incubation tests in clinical settings is supported:
 - for the rapid identification of HIV-infected individuals to guide clinical decision making;
 - in situations where there are difficulties with access to testing and returning for results (e.g. in rural areas or remote communities); and
 - in the management of occupational and non-occupational exposure to blood or body fluids.

Home Based (self) testing in Australia

- Home-based testing (also known as self testing) for HIV and home-based collection of samples to be tested for HIV is not supported.

Funding of HIV Testing

- From 1 November 2005, HIV diagnostic testing was listed on the Medicare Benefits Schedule (MBS).
- States and Territories should ensure that capacity is retained to support provision of free and de-identified HIV testing in circumstances where a person at risk of HIV infection would not otherwise access or consent to testing.

Human T-Cell Lymphotropic Virus (HTLV) Testing Policy

- The testing principles that apply to HIV testing should also apply to testing for HTLV.
- HTLV testing is conducted on all blood and tissue donors in Australia.
- In Aboriginal populations, testing is recommended as clinically indicated in people who have blood dyscrasias, neurological signs, severe scabies or Strongyloides infection.
- Occupational injury is a potential indication for testing, where the source is considered to be at risk of being infected with HTLV.

INTRODUCTION

Background and Context

Revision of the 1998 HIV Testing Policy was identified as an area for priority action in the fifth *National HIV/AIDS Strategy 2005-2008*¹. A Steering Group was formed to review the HIV Testing Policy. This was a joint group of the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis (MACASHH) HIV/AIDS and Sexually Transmissible Infections (STIs) Subcommittee (HASTI) and the Intergovernmental Committee on AIDS, Hepatitis and Related Diseases (IGCAHRD).

The revised draft National HIV Testing Policy 2006 was widely disseminated for public consultation in July 2006. Relevant stakeholders included HIV community organisations; the medical, research and scientific sectors; and members of both ICGAHRD and HASTI. Comments on the draft National HIV Testing Policy 2006 were incorporated into a final draft and this document was endorsed by HASTI in November 2006.

The HIV Testing Policy has been revised in accordance with the changing epidemiology, technology and social context of the HIV epidemic in Australia. This testing policy maintains and reinforces the guiding principles of successive National HIV/AIDS Strategies since 1989.

For the first time, this policy also addresses Human T-Cell Lymphotropic Virus (HTLV) (see Chapter 12). The rationale for this is that HTLV is a retrovirus similar to HIV and is blood-borne. It is an important health issue for Aboriginal populations, and testing should be conducted in accordance with the Guiding Principles in this policy. This policy incorporates a new section on HIV testing in prison settings (see Appendix 7).

Steering Group – Terms of Reference

- To review and provide advice to the MACASHH HIV/AIDS and STIs Committee (HASTI) and the Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases (IGCAHRD) on the 1998 Australian National Council on AIDS and Related Diseases (ANCARD)/IGCARD HIV Testing Policy and provide advice and input to the new HASTI/IGCAHRD Testing Policy.
- Consult with the key stakeholder groups regarding issues to be included in the Review of the HIV Testing Policy.
- To identify emerging issues in new technology and other important policy issues which have emerged since the 1998 HIV Testing Policy was developed including:
 - Testing technologies and point of care testing;
 - Antenatal testing;
 - Postnatal management;
 - Pre-test information and post-test counselling; and
 - Consent and privacy issues.

A list of members of the Steering Group can be found at Appendix 1.

1) GUIDING PRINCIPLES FOR HIV TESTING IN AUSTRALIA

Principles of HIV testing

The six key principles that guide HIV testing in Australia are that:

- confidential voluntary testing with informed consent is fundamental to Australia's HIV/AIDS response;
- testing is of the highest possible standard;
- testing is of benefit to the person being tested;
- testing is accessible to all those at risk of HIV infection;
- testing is critical to understanding the epidemiology of HIV infection in the community; and
- testing is critical to interruption of transmission.

Specific implications of the principles

Testing policies and practices must comply with all relevant Commonwealth and State and Territory anti-discrimination and public health legislation, and other relevant laws.

An important implication of these principles is that policies relating to HIV testing, specific to individual States, Territories or institutions, should be consistent with the objectives and intentions of the national policy. This includes providing the education, support, and investment necessary for a high-quality and ethical approach to HIV testing. One implication of this is that State and Territory governments should continue to support access to free and de-identified testing for individuals at risk of HIV infection who would not otherwise access or consent to testing. Further, individuals who do not wish to disclose their name or Medicare number should have access to de-identified testing. All testing, whether voluntary or mandatory, should be accompanied by pre- and post-test discussion and conducted with informed consent (see Chapter 3).

Although many aspects of this policy remain similar to those in the 1998 National HIV Testing Policy, there are some notable changes, the implementation of which will require the education of health care workers and those likely to be providing HIV testing (see Chapter 5). The recommendation that HIV testing be routinely offered in the antenatal context will require the development of targeted education to ensure that those providing or offering HIV testing are equipped with up-to-date information about HIV; HIV treatment and management; and information for referral on to care and support services (see Chapter 6).

There may be circumstances where anonymous delinked testing is performed; when it is deemed to benefit public health. Such testing should occur only where there is compelling scientific justification (see Chapter 4). This should be independently judged by an ethics committee constituted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research.

Testing does not diminish the need for standard precautions in handling blood and body fluids in all health care settings in accordance with the Australian Government

Department of Health and Ageing's *Infection Control Guidelines for the prevention of transmission of infectious diseases in the health care setting* (2004)².

There are some circumstances where mandatory or compulsory testing may be appropriate:

- Mandatory testing refers to situations where people may not either participate in certain activities or access certain services unless they agree to be tested. Circumstances in which mandatory testing is appropriate include: prior to blood, tissue and organ donation; for immigration purposes; for armed services personnel; and for purchasing some types of insurance.
- Compulsory testing occurs in the context of a legal instruction, such as in certain rare situations where the welfare of others in the community depends on the testing of an individual (e.g. if a person suspected on reasonable grounds of being HIV positive persistently behaves in a way that places others at risk of infection). In all circumstances testing should be conducted in accordance with the principles in this policy.

The principles outlined above also have implications for investment in an appropriate laboratory infrastructure. Some changes have specific implications (e.g. the extension of testing recommendations, the availability of HIV testing through Medicare, and developments such as rapid testing). For this policy to be effective, there needs to be adequate support provided to laboratories carrying out HIV testing, as well as ongoing support for quality assurance and quality control programs that ensure all HIV testing is of the highest technical standard.

HIV testing should be promoted and conducted in a culturally appropriate way. Late diagnoses and lower HIV/AIDS awareness levels in culturally and linguistically diverse (CALD) and Aboriginal and Torres Strait Islander communities requires targeted approaches to HIV testing. Appropriate access to testing is especially important for people at risk of HIV infection, and given there is an increasing number of people from CALD backgrounds who are living with HIV and AIDS in Australia, improving access to, and uptake of, HIV testing is important.

It is important that people involved in HIV testing (such as health care workers ordering tests and/or conducting pre- and post-test discussions) use accredited interpreters where appropriate. Options associated with interpreting services, such as face-to-face or telephone interpreting should be outlined to those involved in HIV testing to ensure individuals are fully engaged in the discussion.

2) INDICATIONS FOR HIV TESTING

Key Points:

- Indications for HIV testing should be assessed on the basis of the following risk factors:
 - unprotected male-to-male intercourse;
 - sharing of injecting equipment;
 - being the sexual partner of an HIV positive person;
 - being from a country with a high HIV prevalence;
 - having recently travelled overseas;
 - presenting for post-exposure prophylaxis (PEP) after occupational or non-occupational exposure to HIV;
 - pregnancy;
 - requesting an HIV test in the absence of clear risk factors; and
 - diagnosis of a sexually transmissible infection
- Routine pre-operative testing for HIV is not supported.

Clinical indications and case detection

For a person presenting for primary health care, indications for HIV testing should be assessed on the basis of a history of potential exposure and/or specific signs and symptoms.

Clinical features of HIV-related illness may be wide-ranging and non-specific, and can overlap with a range of other potential diagnoses. The clinical manifestations have been well-described³.

In considering whether an HIV test is indicated, an assessment of a person's risk or history should be made in the context of what is known about the history of HIV transmission and its epidemiology in Australia (or country of origin, especially if high prevalence), and any identifiable or known risk factors.

An HIV test should be offered following a sexual assault, in the context of adequate risk assessment and counselling. A sexual assault is not necessarily a high risk event for HIV transmission; however, the psychological benefit in being offered a test is significant.

Risk assessment and indications for testing

Unprotected male-to-male anal intercourse

By far the most frequent means of transmission of HIV in Australia is unprotected anal intercourse between men. This mode of transmission accounts for around 80% of all HIV infections in Australia. A history of unprotected male-to-male anal intercourse is a strong indication for offering testing.

People who share injecting equipment

A history of injecting drug use involving shared equipment is a strong indication for offering testing for HIV and other blood borne viruses. The sharing of injecting equipment between injecting drug users is a well-documented mode of HIV transmission. Whilst hepatitis C is common in injecting drug user populations in Australia, the prevalence of HIV has remained less than 2% in this population, except in male injecting drug users who also report homosexual contact.

Sexual partners of people with HIV

The sexual partners of people with HIV are at higher risk of HIV infection, and therefore HIV testing should be offered.

People from countries with a high HIV prevalence and their sexual partners

People from countries with a high HIV prevalence, and their sexual partners, are at increased risk of HIV infection. (High prevalence countries are those with HIV prevalence of about 1% or higher.) Such countries now include: the Caribbean, Sub-Saharan Africa, Southeast Asian countries including Thailand and Cambodia, as well as Papua New Guinea.

People who have recently travelled overseas

People who have recently travelled from Australia to countries with a high HIV prevalence, and have had unprotected sex, injected drugs, had dental, medical or cosmetic treatment, or a blood transfusion whilst in such countries, are at increased risk of HIV infection and should be offered an HIV test.

People presenting for post-exposure prophylaxis after occupational or non-occupational exposure to HIV

People presenting for post-exposure prophylaxis must be tested for HIV prior to, and upon completion of, any course of antiretroviral therapy. Follow up HIV antibody testing should be performed at 2-4 weeks, at 3 months and at 6 months post-exposure. Refer also to the Australian Government Department of Health and Ageing's *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*² and the *2006 National NPEP Guidelines*⁴ (see Chapter 8)

Antenatal women (see Chapter 6 and Appendix 3)

Pregnancy, per se, is not an indicator of risk of HIV infection. However, undiagnosed HIV infection during pregnancy has serious implications for the health of both the woman and her child. These implications can be mitigated by appropriate management. As a consequence, routine offering of HIV testing to this group is warranted.

People requesting an HIV test in the absence of clear risk factors

The incidence of HIV is very low where there is an absence of recognised risk factors. In people without a clear history of risk or clinical indications of HIV infection, there is no basis for systematically or routinely offering testing. 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 recognised and HIV testing should be conducted.

A small number of people will present repeatedly for HIV tests with no risk factors displayed; this behaviour should be addressed through appropriate discussion. Individual factors should play a role in the discussion between doctor and patient, as well as in the decision whether or not to proceed with an HIV test.

People diagnosed with a sexually transmissible infection (STI)

Diagnosis of an STI should be considered as an indication for HIV testing. People infected with an STI, particularly ulcerative STIs, are generally at higher risk of acquiring and transmitting HIV, and should be offered an HIV test.

Donor testing for blood transfusion and tissue transplantation (see Appendix 2)

HIV testing is mandatory for a person who donates blood or tissue. The donation or a blood sample from the donor is tested for HIV and other blood-borne pathogens. The present risk of acquiring HIV infection through a transfusion has been estimated at approximately 1 in 7 million⁵.

HIV testing in prison settings (see Appendix 7)

Prisoners should be offered testing for HIV as part of the reception medical examination and prior to release. This testing should be offered in accordance with the guiding principles of this policy, with the issue of the special circumstances of disclosure of medical information clearly addressed during the consent process.

Pre-operative testing

Routine pre-operative testing for HIV is not supported.

Consistent with the *Infection Control Guidelines for the prevention of transmission of infectious diseases in the health care setting*²:

“Preoperative testing of a patient for infectious agents should be on the basis of clinical indication, and medical practitioners should exercise their professional judgement in ordering any clinically relevant test. Discretion and patient confidentiality must be maintained in all circumstances.”

In a person with an identified risk of HIV infection and/or clinical indications of infection, pre-operative HIV testing should be performed only if it will benefit the patient, and informed consent has been obtained after pre- and post-test discussion.

The use of rapid testing pre-operatively for elective surgery is not supported.

3) PRE- AND POST-TEST DISCUSSIONS

Key Points:

- The term ‘pre- and post-test discussion’ should be adopted in place of ‘HIV test discussion and post-test counselling’.
- Clinicians delivering the test result should use their best judgement in establishing the most appropriate way to deliver the test result. Things to consider include the person’s testing history, gender, culture, behaviour and language.
- Pre- and post-test discussions form an integral part of HIV testing. Provision of information and support associated with testing is consistent with the goal of the fifth *National HIV/AIDS Strategy*¹, which includes minimising the personal and social impacts of HIV infection.

Informed consent

Gaining informed consent of an individual to be tested is fundamental to an effective, best-practice testing process. Typically, informed consent should be obtained during pre-test discussion. Pre-test discussion should also incorporate an assessment of risk, an explanation of the testing process, as well as a discussion of the possible outcomes of the test.

The Medicare Benefits Schedule (MBS) advises that the requesting practitioner should ensure that the patient has given informed consent, appropriate pre-test discussion should be provided to the patient and that further discussion may be necessary upon receipt of the test results.

It is important that people involved in HIV testing (such as health care workers ordering tests and/or conducting pre- and post-test discussions) use accredited interpreters where appropriate for people from culturally and linguistically diverse (CALD) backgrounds and Aboriginal and Torres Strait Islander people. Options associated with interpreting services, such as face-to-face or telephone interpreting should be outlined to those involved in HIV testing to ensure individuals are fully engaged in the discussion.

Confidentiality and privacy issues are a major concern for people undergoing HIV testing. Therefore, confidentiality and privacy issues should be explained in detail, and it may be necessary to give examples to make sure the meaning of confidentiality and privacy is understood.

Changes to terminology

The 1998 National HIV Testing Policy recommended that the terms ‘HIV test discussion’ and ‘post-test counselling’ replace ‘pre- and post-test counselling’. The purpose of recommending this change in terminology was not in any way to diminish the role of this discussion, but rather to acknowledge the increasing complexity of factors that may be involved in these discussions. Further, the complexity of discussion will vary from person to person depending upon their risk factors and experience (if any) of previous testing.

Counselling is an appropriate term for the longer-term management of a person who has tested positive. Counselling may also be an option for an HIV-negative person who requires support with changing personal behaviours that may be placing them at risk. In many cases, counselling needs to be delivered at a more specialised level of care than can be provided by generalist health care professionals.

The position of this policy is that the term ‘pre- and post-test discussion’ should be adopted in place of ‘HIV test discussion and post-test counselling’.

Pre-test discussion

Pre-test information aims to prepare individuals for HIV testing and to obtain informed consent. When a person requests or is offered a test, the practitioner should give appropriate information about risk, points of referral if necessary, assurances about confidentiality and privacy, and assessment of the person’s preparedness to be tested.

Specifically, the HIV test discussion should provide accurate information about safe practices that are appropriate to the person’s gender, culture, behaviour and language. The discussion should include:

- information on how HIV is transmitted (where appropriate);
- risk assessment and discussion of the reason for testing;
- timing of the risk event and options for PEP;
- possible desirability of other STI testing;
- information about confidentiality and privacy;
- information about the testing process including how results are to be provided, the window period, and the difference between HIV and AIDS;
- information about what happens to test results;
- seeking informed consent for the test to be conducted;
- assessment of the person’s preparedness to be tested and assurance that the person wishes to proceed with the test;
- information about what a negative or positive result means; and
- assessment of support mechanisms while waiting for the test result and/or if the result is positive.

Post-test discussion

Positive test results must be given in person. Negative test results and the associated post-test discussion should be conducted on the basis of the person’s education and HIV awareness and specific circumstances and should be appropriate to their gender, culture and language. Post-test discussion provides the opportunity to discuss health issues, referrals and prevention issues.

This policy recognises the impact of a positive HIV test result for an individual and their clinician, and recommends that information be provided to both at the time the positive result is confirmed. This may be most easily achieved via cooperation of the laboratories doing reference testing. Laboratories in States and Territories should consider using the methodology currently seen in NSW, with provision of a fact sheet with the result to the clinician. The fact sheet refers the clinician and newly

diagnosed individual to organisations with the capacity to provide more detailed information on education and support.

The post-test discussion should include:

- giving the test result in person and in a manner that is sensitive and appropriate to gender, culture, behaviour and language; and
- re-assessing support mechanisms and requirements of the person and making immediate referral to a support agency to be accessed at the person's discretion.

If the result is negative, the discussion should include reinforcing education and information messages about safe behaviours, and examining any difficulties or issues that the person may have in practising safe behaviours. It should be emphasised that a negative test result following a risk event does not indicate that it is likely to be safe to repeat risky behaviour. The relief associated with receiving a negative test result may also impede the processing of information and advice at that time.

If the result is positive the discussion should include, at an appropriate time, issues such as:

- immediate needs and support;
- safe behaviours – education, information and support;
- whom the person should tell and how, including information around the person's rights regarding disclosure;
- managing or understanding strong emotions, feelings, reactions and changes; including ways to deal with loss and grief, depression, anger and anxiety;
- options in drug treatments and medical management;
- ongoing counselling or therapy if required;
- complementary/alternative management options;
- strategies for managing HIV that are flexible and appropriate to the person's needs; and
- legislative requirements (notification, contact tracing, storage and coding).

Services responsible for HIV testing should ensure all staff are adequately trained for pre- and post-test discussions. Health care workers should refer to the National Health and Medical Research Council Guidelines regarding the provision of information to patients when proposing pathology testing and giving results: *Communicating with Patients: Advice for Medical Practitioners*⁶.

4) SURVEILLANCE AND RESEARCH

Key Points:

- Systematic surveillance of the occurrence of newly diagnosed cases of HIV infection and its advanced disease manifestation, AIDS, is recognised as a key component of the Australian response to the HIV epidemic.
- Laboratories performing confirmatory testing must notify the relevant State and Territory health authorities of any new positive results in accordance with the relevant legislation.
- The results of HIV antibody testing have been used to analyse trends in HIV diagnoses, to report on the trends identified in HIV testing carried out at sentinel sites, and for special annual surveys.
- The delinked anonymous survey method can be considered for surveillance purposes where there is no other feasible method for reasonably obtaining appropriate data. It should be subject to scientific justification and be endorsed by an institutional ethics committee constituted in accordance with the requirements prescribed by the National Health and Medical Research Council.

Background

The broad aims of HIV/AIDS case surveillance are to:

- monitor trends and patterns in HIV transmission and the outcomes of HIV infection;
- guide and evaluate interventions; and
- provide early warning of changing patterns of HIV transmission and disease.

In Australia, surveillance for HIV and AIDS has been carried out under the framework of the Australian HIV Surveillance Strategy, endorsed at a national level in 1992. It has been implemented through the National Centre in HIV Epidemiology and Clinical Research in collaboration with State and Territory health departments and a range of other agencies and organisations. Within the framework of the surveillance strategy, the results of HIV antibody testing are used in the following ways:

- **Compilation and analysis of HIV diagnoses**

Cases of newly diagnosed HIV infection are reported via State and Territory health departments to the National HIV Database. All information is in a coded form that allows for the elimination of duplicate cases while fully protecting confidentiality. Diagnoses of newly acquired HIV infection, defined as cases of newly diagnosed HIV infection with a previous negative test or occurrence of an HIV seroconversion illness within 12 months of HIV diagnosis, provide an indication of the current pattern of HIV transmission in Australia.

As diagnoses of newly acquired HIV infection depend on frequent HIV antibody testing or presentation to medical practitioners familiar with the symptoms of HIV seroconversion illness, surveillance for newly acquired HIV infection provides a

lower bound of the extent of HIV transmission. New assays for recent infection such as the detuned, BED and IgG₃ assays have the potential (when available) to provide a more complete indication of the extent of newly acquired HIV infection among cases of newly diagnosed HIV infection.

- **Reporting of laboratory results**

Laboratories performing confirmatory testing (the test that defines a sample as truly HIV positive) must notify the relevant State and Territory health authorities of any new positive results in accordance with the relevant legislation.

- **Reporting of the results of HIV testing carried out at sentinel sites**

HIV testing is routinely carried out at a number of sentinel sites such as sexual health clinics, prisons, needle and syringe programs and blood transfusion services. The numbers of people tested, and the proportion with diagnosed HIV infection, are reported on a regular basis from these sites and provide estimates of HIV prevalence and incidence in various population groups.

- **Unlinked HIV testing and research**

Research may occur in settings where specimens are collected and tested without an ability to link the results to individuals. For example, since 1995, a national network of needle and syringe exchanges has been carrying out an annual survey of clients over a one week period, which involves obtaining a finger prick blood specimen for HIV testing. The subjects are assured that the specimens are tested under code, so the results cannot be linked back to individuals. Such research should be subject to scientific justification and be endorsed by an institutional ethics committee in accordance with the requirements prescribed by the National Health and Medical Research Council.

- **Delinked anonymous 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 can not be linked back to the individual who originally provided the specimen. This method is well accepted overseas for surveillance purposes, but has only rarely been used in the Australian setting. The survey method should be considered for Australian surveillance purposes only where there is no other feasible method for reasonably obtaining appropriate data; and should be subject to scientific justification and be endorsed by an institutional ethics committee in accordance with the requirements prescribed by the National Health and Medical Research Council.

Research

Considerable research effort towards combating and understanding HIV is conducted in Australia. Much of this work is collaborative and may be carried out as part of international partnerships. This work may require the use of IVDs not in use in

Australia and those that have not been submitted for evaluation. The supply of an unapproved HIV test for research is appropriate if no diagnosis is to be made and the identities of the individuals are unknown. These IVDs may be used by applying to the Therapeutic Goods Administration under the Clinical Trial or Special Access Schemes.

5) HEALTH CARE WORKERS

Key Points:

- Health care workers have a professional obligation to know their HIV status if they are performing exposure-prone procedures (EPPs).
- Health care workers who have a confirmed positive HIV antibody test must not perform EPPs².
- Testing, and if appropriate, post-exposure prophylaxis, should be offered to health care workers following occupational exposure to blood or body substances, for example through needlestick injury.

HIV testing of health care workers should be conducted in accordance with the general principles set out in this policy regarding consent, privacy and access to appropriate pre-test information, post-test discussion and clinical care.

In order to ensure compliance with this recommendation, it is essential that appropriate support is available to health care workers who test positive for HIV, given the potential major psychological, social and financial costs to the individual.

To encourage compliance with these obligations, health care workers should receive regular reminders of their responsibilities (for example through inclusion of prompting questions as part of medical, dental and nursing registration renewal processes), and easily accessible, free confidential testing and counselling arrangements. The health care system must also support health care workers by creating a work environment that minimises the risk of infection including appropriate training in infection control techniques and provision of equipment that reduces the risk of exposure.

In general the risk of HIV transmission in the Australian health care setting is low, and routine HIV testing of all health care workers is not recommended.

Transmission of HIV from health care worker to patient

There is a small risk of HIV transmission from an infected health care worker to their patients during the performance of EPPs⁷.

In view of the risk, albeit low, of transmission of HIV from infected health care workers to patients during the performance of EPPs, health care workers who perform EPPs must know their HIV status by seeking serologic testing if either:

- untested and currently performing EPPs;
- about to commence performing EPPs;
- it is 12 months or longer since their last test if they are performing EPPs;
- they have experienced a significant occupational exposure (such as percutaneous, ocular, mucous membrane to blood or potentially blood-contaminated secretions²); or
- non-occupational exposure has been identified, including needle sharing with a person infected with or at increased risk of HIV and/or unprotected sexual intercourse with a person infected with or at increased risk of HIV.

Health care workers who have a confirmed positive HIV test must not perform EPPs².

For health care workers who do not perform EPPs, HIV testing should be encouraged either on the basis of clinical assessment, or following an occupational exposure to potentially infectious blood or other body fluids.

If a patient is exposed to blood or body fluids (e.g. through needlestick injury) during the provision of health care, the health care worker involved has a responsibility to provide information or consent for testing that enables the safe management of the exposed patient. Consent for testing should be obtained in accordance with the guiding principles of this policy. The health care worker should be advised of the types of tests that may be needed and the consequences to them of the results of tests².

Transmission of HIV from patient to health care worker

Patients may transmit infections to health care workers. The level of risk relates to the transmissibility of the infection, the availability of a route of transmission, the susceptibility of exposed people, and the success of applied control measures (e.g. standard precautions).

All health care workers who have clinical contact with patients can potentially be exposed to blood and other body fluids. Other workers may also be exposed to blood and other body fluids in the course of their work (e.g. laboratory workers, cleaning staff).

If a health care worker is occupationally exposed to blood or body fluids (e.g. through needlestick injury), testing should be offered and performed urgently, for the purposes of post-exposure prophylaxis (PEP) prescription. PEP is not indicated if the source (in this case, the patient) is known to be HIV negative. Clinicians should refer to the *Infection Control Guidelines for the prevention of transmission of infectious diseases in the health care setting*².

The patient involved has a responsibility to provide information or consent for testing that enables the safe management of the injured health care worker. Consent should be obtained in accordance with the guiding principles of this policy. The patient should be advised of the types of tests that may be needed and the consequences for them of the results of those tests². If the patient declines to have an urgent HIV test then it should be assumed, for the purposes of PEP prescription, that they have HIV infection (see Chapter 8).

6) ANTENATAL TESTING

Key Points

- HIV testing should be routinely offered to all women antenatally.
- Antenatal testing must only be performed with the informed consent of the woman. Routine HIV testing without consent is not supported.
- All women contemplating pregnancy or seeking antenatal care should be made aware of the benefits of diagnosis of HIV infection and management, and prevention strategies available for both the mother and the infant.
- Women should receive materials (in written and other formats) outlining the tests that will be offered antenatally and the testing procedure should be explained to the woman by a member of the team involved in her antenatal care. Health care workers in antenatal settings should be trained in appropriate assessment and pre- and post-test discussion.
- Women with limited literacy, or for whom English is a second language, require appropriate educational resources. Material using other media (video, audio, multimedia) and in languages other than English may be necessary.
- Women with a first language other than English should be offered access to accredited interpreting services.

Background

For more information and background on the decision to recommend that HIV testing should be routinely offered to all women antenatally, refer to Appendix 3.

The goals of antenatal testing for HIV are to:

- decrease the incidence of mother-to-child HIV transmissions;
- enable an HIV positive woman to receive optimal medical and psychosocial care for herself; and
- decrease the risk of transmission to sexual partners.

HIV testing should be routinely offered to all women antenatally, in accordance with the guiding principles of this policy. Women contemplating pregnancy or seeking antenatal care should be made aware of the benefits of diagnosis of HIV infection and management, and prevention strategies available for both the mother and the infant.

The primary rationale for antenatal testing for HIV is to prevent mother to child transmission of infection. HIV testing of pregnant women is not a useful means of case-finding for HIV in a low prevalence country such as Australia.

It is recommended that during antenatal pre-test and post-test discussion, the clinician assists the woman to identify risks factors for HIV infection. HIV testing must be offered in the context of appropriate risk assessment and discussion. Examples of those at higher risk of infection include:

- female sexual partners of HIV infected men and men at high risk of HIV, including men from countries of high HIV prevalence;
- women with a history of injecting drug use;

- women from countries of high HIV prevalence; and
- women with a history of blood transfusion or recipients of other donor tissues in the period prior to May 1985.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists position statement of 2004 recommends “all women should be offered HIV testing at their first antenatal visit and as required after potential exposure by at-risk behaviour for infection”.

Testing of infants born to HIV infected mothers

HIV testing in infants of HIV infected women should be performed as soon after birth as possible, so that appropriate treatment interventions can be implemented quickly. Diagnosis of HIV infection in infants born to HIV-infected mothers is complex. These infants will acquire IgG antibodies to HIV transplacentally, and will thus show serological reactivity similar or identical to their mothers. These antibodies will be lost progressively over the first 12-18 months of life. Nucleic acid amplification tests are required to make the diagnosis of HIV infection in an infant.

7) ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLE

Key Points:

- Strategies to improve access to testing need to be developed locally and reflect local HIV transmission routes, risk practices and patterns of health service use.
- Local pre- and post-test discussion guidelines should take into account local issues of stigma and shame.
- Fear of breaches of patient confidentiality may be reduced through the development and publication of local confidentiality policies and the use of short-incubation tests as appropriate.
- Specific State and Territory and regional initiatives are needed to improve access to confidential testing and continuity of care for Aboriginal and Torres Strait Islander people moving through the corrections system.
- Antenatal care for Aboriginal and Torres Strait Islander women should include testing according to the guiding principles of this policy and consistent with relevant Aboriginal and Torres Strait Islander Health Frameworks, along with appropriate pre- and post-test discussions for Aboriginal and Torres Strait Islander people.

Background

For more information and background on HIV testing for Aboriginal and Torres Strait Islander people, refer to Appendix 4.

The first objective of the *National Aboriginal and Torres Strait Islander Sexual Health and Blood Borne Virus Strategy 2005-2008*⁸ (NATSISH&BBV) is to improve access to testing, diagnosis, treatment and care of HIV/AIDS, STIs and other blood borne viruses for Aboriginal and Torres Strait Islander people. It is important to align the goals of this testing policy with current epidemiology around routes of transmission of HIV among Aboriginal and Torres Strait Islander people, including the higher rate of infection through heterosexual contact and intravenous drug use⁸.

Improving access to testing requires an awareness of the differences among groups within the Aboriginal and Torres Strait Islander populations and the distinctive barriers that exist in their access. It may require local primary health services to develop locally adapted approaches for young people, prisoners, people who inject drugs, women, sex workers, gay and other homosexually active men, and transgendered people, including Sistergirls⁹.

These approaches will be best developed in the context of strong local partnerships between the Aboriginal community-controlled health sector and mainstream services that specialise in the provision of services to clients at higher risk for HIV, STIs and other blood borne viruses (e.g. sexual health clinics, family planning services, AIDS Councils and services for injecting drug users). Coordination and leadership from State and Territory Aboriginal and/or Torres Strait Islander Sexual Health Committees may be needed to encourage partnerships that develop innovative and locally relevant approaches to service provision and raising awareness in the

Aboriginal and Torres Strait Islander community about the need for testing, treatment and management of HIV.

Pre and post test discussion

For many Aboriginal and Torres Strait Islander people, high levels of stigma are associated with HIV. The stigma associated with the illness is compounded by its transmission through routes that are also highly stigmatised, such as drug use or same sex activity, or otherwise associated with shame about any sexual activity. Shame for some Aboriginal and Torres Strait Islander people may be incapacitating in the context of HIV testing, particularly if there are differences between individual and practitioner in terms of race, age and gender. In some areas of the country ceremonial status, moiety and clan may also be important, particularly in contexts where blood has a ceremonial significance. Policies must be developed locally, so that health care workers are correctly advised and health services generate culturally appropriate policies and programs.

Local health service providers need to take these matters into account when developing a testing policy, and in the guidelines around provision of pre- and post-test discussions. Some success has been achieved in clinics providing pre-test information on cassette or CD recorded in local language or plain English, so that the individual can listen to it privately through headphones without shame. The use of interpreters should also be considered.

Confidentiality

An added complication is that fear of a positive test may include fear of a breach of confidentiality, made worse when the provider is known to the person or when the test is provided in a local clinic that employs members of the person's family or community. Particularly in rural and remote clinics, the provision of any pathology test may routinely involve documentation passing through a number of hands, and results may be filed with relatively open access. Any variation to this routine may publicly signal that a "confidential" test is being done and unintentionally breach the person's right to privacy. There is no evidence that this fear is realistic, but it is likely to provide an additional barrier to someone seeking a test. Local health service providers should ensure that local guidelines regarding testing have agreed protocols on the handling of confidential information.

A publicised confidentiality policy may assist in reducing this barrier to testing. Such a policy should state that clients' privacy and confidentiality will be respected. It should refer to relevant State or Territory legislation that governs privacy and confidentiality and note that all staff have been trained in the confidentiality requirements of providing care in that service. The policy should also outline a grievance procedure if a client feels that their confidentiality has been breached. It may give examples of what will be done with person's information, and what will not be done with it. It may also detail areas where the person's right to privacy cannot be respected, for example, where mandatory reporting is required under other State or Territory legislation.

The provision of short-incubation tests where results can remain between the individual and provider may also assist in reducing barriers to testing and follow up. Provision of short-incubation tests should take into account the issues discussed in

Chapter 10 of this policy. These measures should be coupled with a health promotion program that reduces the stigma associated with taking a test or getting a positive result.

Aboriginal and Torres Strait Islander Prisoners

Prison settings have been identified as a risk environment for transmission of HIV, as well as for other STIs and blood borne viruses. Strategies to improve access to prevention measures, testing, treatment and care should include provision of continuity of care for those affected by HIV, STIs and hepatitis C. There is a disproportionate representation of Aboriginal and Torres Strait Islander people in prison settings and juvenile detention centres, and risk of transmission is increased with considerable movement of people in and out of the prison system.

Specific initiatives at the State and Territory and regional levels should be developed in partnership between State and Territory Departments of Corrections, State and Territory Health Departments, prison service providers and the Aboriginal and Torres Strait Islander community-controlled health sector. Such initiatives could include improved access to testing in prisons including routine risk assessment conducted in a culturally safe manner, preventive approaches that consist of health promotion and prevention education, and re-entry to the community strategies for prisoners.

Antenatal Women

Recent trends suggest that Aboriginal and Torres Strait Islander women may be at increased risk of acquiring HIV. It is critical that antenatal testing for Aboriginal and Torres Strait Islander women is conducted in accordance with the guiding principles of this policy, especially regarding informed consent and pre- and post-test discussions for Aboriginal and Torres Strait Islander women. The NATSISH&BBV Strategy strongly recommends the incorporation of HIV, STIs and hepatitis C testing guidelines into antenatal clinical care guidelines. Antenatal HIV testing for Aboriginal and Torres Strait Islander women should occur with appropriate consideration of culturally appropriate resources, and in a manner that is sensitive to the woman's safety and cultural security.

8) POST-EXPOSURE PROPHYLAXIS

Key Point:

- Testing should be offered and performed urgently after occupational or non-occupational exposure to HIV.
- Refer to the 2006 National NPEP Guidelines⁴.

Post-exposure prophylaxis (PEP) and non-occupational post-exposure prophylaxis (NPEP) against HIV is the provision of anti-retroviral drugs soon after occupational or non-occupational exposure to HIV with the aim of preventing HIV infection. This section is not a comprehensive guide to the use of PEP. Rather, it highlights some aspects of HIV testing that are specific to the PEP situation. The 2006 National NPEP Guidelines⁴ [to be released in January 2007] set out detailed protocols for the use of PEP for non-occupational exposures to HIV.

Testing of the exposed individual at initial presentation

There are at least two reasons why it is important for an individual who presents for PEP to receive urgent HIV testing before commencing therapy. First, it is possible that the person already has HIV infection. In an Australian study of NPEP, approximately 0.5% of those presenting for NPEP were found to be HIV positive at baseline. In such a case, the person should be referred for a full diagnostic workup and consideration of commencement of therapy for HIV, rather than be prescribed NPEP. Second, the efficacy of PEP is highly dependent on the duration between HIV exposure and commencement of therapy. Guidelines recommend the commencement of NPEP within 72 hours of exposure, but therapy should be commenced as soon as possible, as a delay of a few hours may reduce the efficacy of therapy. It is important that an HIV test result be obtained as quickly as possible.

HIV testing with rapid turn around of results should be available in all settings where people are assessed for PEP. If there is likely to be a delay of more than two hours in receiving test results, it should be assumed that the exposed person is uninfected and PEP commenced. In this situation, test results should be followed up within 24 hours and PEP stopped or modified if necessary.

Testing of the source

PEP is not indicated if the source is known to be HIV negative. An active attempt should be made by the individual to contact the source. With the consent of the individual, this may be carried out by the assessing doctor, contact tracer or public health unit. If the source is contactable, they should be invited to have an urgent HIV test. If the source declines to have an urgent HIV test then it should be assumed, for the purposes of PEP prescription, that they have HIV infection.

Follow up testing

Follow up HIV antibody testing should be performed at 2-4 weeks, as HIV infection is likely to become evident at this time in a proportion of cases. Further follow up testing should then occur at 3 months and then 6 months post-exposure, in order to conclusively rule out HIV infection.

9) QUALITY ASSURANCE AND HIV TESTING

Key Point:

- The Therapeutic Goods Administration (TGA) has regulatory responsibility for in-vitro diagnostic devices (IVDs). Only HIV assays approved by the TGA may be supplied in Australia.
- In accordance with the conditions applied to the registration of HIV IVDs by the TGA, sponsors may only supply HIV IVDs to laboratories that participate in approved quality assurance programs prescribed by the TGA.
- Laboratories that perform HIV testing must comply with the National Pathology Accreditation Advisory Council (NPAAC) standards. The ability to comply is assessed by the National Association of Testing Authorities, Australia/Royal College of Pathologists of Australasia (NATA/RCPA) Medical Testing Program.

Background

For more information and background on HIV IVD regulation and quality assurance, refer to Appendix 5.

Pre-market quality assurance of HIV IVDs

The Therapeutic Goods Administration (TGA) has regulatory responsibility for in-vitro diagnostic devices (IVDs) through the *Therapeutic Goods Act 1989* and its associated regulations. The TGA conducts a full pre-market evaluation on IVDs for HIV and the hepatitis C virus to demonstrate that they meet the quality, safety and efficacy standards required for registration in Australia. The TGA currently contracts the performance section of these evaluations to the National Serology Reference Laboratory Australia (NRL). Only HIV assays approved by the TGA may be supplied in Australia.

The TGA is developing a new regulatory framework for IVDs that is in keeping with international best practice. The IVD framework will be based on internationally agreed principles. It is proposed the framework will be implemented during 2007.

Under the new framework, all IVDs will be required to comply with a set of essential principles for quality, safety and performance. A risk-based classification scheme will be introduced, in which an IVD will be assigned to one of four classes, designated 1 to 4, where Class 4 is of highest risk. This risk is assigned according to whether the risk posed by failure applies to an individual and/or to public health in general.

High risk (Class 4) IVDs will undergo a full performance evaluation, including performance testing where appropriate, prior to approval for supply in Australia. The new framework places greater emphasis on the use of appropriate quality management systems for the design and production of IVDs to ensure the ongoing safety of performance.

Class 4 IVDs include those for use in screening blood, blood components, cells, organs and tissues for transfusion/transplantation purposes. This class also includes those intended for use in the detection of structural components or surrogate markers of transmissible agents in a diagnostic or genotypic analysis capacity, including first-line assays and supplemental assays. Included in Class 4 will be IVDs for certain markers to HIV, hepatitis C virus, hepatitis B virus, and HTLV.

Post-marketing quality assurance of HIV IVDs

The TGA also has responsibility for post-market monitoring of the IVD. The TGA has the power to remove from the market any IVD that is not performing to the expected standard or that is known or demonstrated to be defective.

Currently, a condition of TGA registration of HIV and hepatitis C virus IVDs is that tests may only be used in laboratories participating in the quality assurance program coordinated by the NRL. This program includes:

- the external quality assessment scheme (EQAS);
- the quality control program (QC); and
- the program for monitoring of kit lot information and performance (specificity monitoring).

The QC and specificity monitoring programs are intended to monitor in-field assay performance, and thus supplement the information obtained for quality of overall performance between laboratories gained from the EQAS program. This EQAS is designed as a monitoring tool rather than as a proficiency testing program. Participation in the NRL's EQAS does not preclude participation in other quality assessment programs.

It is proposed that under the new regulatory framework the TGA will institute a mechanism to use the information from quality assurance programs to obtain information on in-field test kit performance. This will incorporate both quality control and monitoring components.

Categorisation of HIV IVDs for regulatory purposes

The TGA has the authority to impose conditions on the registration of products including the categorisation of HIV IVDs according to their intended use. Tests are currently classified as standard (or screening) tests (those with a performance that is suitable for blood donor screening and determining the HIV antibody status of a sample), and reference (or supplemental) tests (those that are used to clarify the nature of the reactivity of a sample following initial standard tests). Tests are further categorised according to their intended use as requiring different levels of evaluation (Levels 1 to 4), as outlined in Appendix 5.

This additional level of categorisation enables the TGA to recognise a wider range of test functions. Technological advances have led to the production of IVDs that are suitable for purposes other than screening and confirmation of diagnosis, such as surveillance and monitoring, and possibly for use in emergency situations.

The advantages of the HIV testing categorisation system (outlined at Appendix 5) is that it provides:

- a wider choice of testing protocols;
- indications of current usage;
- possible models for accommodating new technologies;
- a framework for establishing the extent of evaluation for each type of test kit; and
- a categorisation that can be generalised to other areas of serology.

Quality assurance of HIV testing

Laboratories that perform HIV testing must comply with National Pathology Accreditation Advisory Council (NPAAC) standards. The ability to comply is assessed by the National Association of Testing Authorities, Australia/Royal College of Pathologists of Australasia (NATA/RCPA) Medical Testing Program. An additional NATA requirement is that all laboratories must participate, where possible, in an EQAS program. These programs are designed to assess the competency of all laboratory processes involved in the production of an HIV result to the requesting practitioner. EQAS programs are readily available within Australia and are provided by the RCPA QAP Pty Ltd and the NRL.

Laboratory Requirements for HIV Testing

The NPAAC *Standards and Guidelines for Laboratory Testing of Antibodies to the Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV)*⁴¹ and the *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis*⁴² provide the frameworks for assessment by NATA/RCPA of the extent to which laboratories must meet the requirements for performance of standard and/or reference HIV testing.

10) SHORT-INCUBATION (RAPID) TESTS FOR HIV

Key Points:

- The use of short-incubation testing by practitioners before minor surgical procedures performed in non-hospital settings is not supported.
- The use of short-incubation tests should be limited to situations where:
 - testing is conducted in, or backed up by, a clinical setting;
 - testing is conducted under the auspice of a NATA/RCPA Medical Testing accredited laboratory;
 - reliable TGA approved short-incubation tests are available;
 - high quality information on the tests and their use is available and provided;
 - the health worker performing the test is suitably trained in conducting and interpreting the test, and has the skills to provide pre and post-test information/discussion (if conducted outside an accredited laboratory); and
 - quality assurance programmes are available to assure ongoing competency of healthcare workers performing the tests.
- The availability and use of short-incubation tests in clinical settings is supported:
 - for the rapid identification of HIV-infected individuals to guide clinical decision making;
 - in situations where there are difficulties with access to testing and returning for results (e.g. in rural areas or remote communities); and
 - in the management of occupational and non-occupational exposure to blood or body fluids.

Background

For more information and background on short-incubation and home-based testing technologies, refer to Appendix 6.

Short-incubation tests, also known as rapid tests, may be defined as those that can be performed in relatively short times and in less time than manually performed anti-HIV enzyme immunoassays (EIA). Short-incubation tests are manually performed and read subjectively (a person views the results and makes a decision concerning the interpretation of the results). Instrument-based test results are also now available within 30 minutes¹⁰.

A limited number of short-incubation tests are registered by the TGA for use in Australia. Short-incubation tests are relatively easy to use, like other assays, but are subject to error if protocols are not followed exactly. Their interpretation may lead to errors in results because they are subjectively read. Testing should be conducted by suitably trained laboratory personnel in a NATA/RCPA accredited medical testing pathology service.

The published sensitivities and specificities of the short-incubation tests now approach those of the standard EIAs in positive and negative samples. The negative

predictive value of short-incubation tests is such that infection can be confidently excluded if the test is negative¹¹. However, these tests are more likely to miss seroconversion because they are less able to detect low levels of antibody. Confirmatory testing, to distinguish false from true positive results, must be performed on each reactive sample.

The limitations in the uses of short-incubation tests deserve consideration within the Australian context.

Indications for the use of short-incubation tests

Clinical

Individuals presenting with severe and possibly HIV-related illness may require urgent adjunctive supportive evidence of the diagnosis. For example, delay in the diagnosis of *Pneumocystis jiroveci* pneumonia (PJP) in an individual previously undiagnosed with HIV may be life-threatening.

Limited access to testing facilities

Short-incubation testing would be of benefit in situations where there are difficulties with access to testing and delays in returning results (e.g. in rural areas or remote communities or for the Australian Defence Force when in the field).

Short-incubation testing may also be considered for community-based testing interventions for high risk or hard to reach populations. However, a positive or indeterminate result raises additional difficulties with post-test discussion and follow-up care that is not always available in the limited infrastructure environment of rural and remote locations. Similarly, this policy also acknowledges there may be problems providing adequate training and support to health care workers in rural and remote locations.

Occupational and non-occupational injuries

People exposed to HIV through occupational or non-occupational means must be offered testing. For example, all health care workers who have clinical contact with patients can potentially be exposed to blood and other body fluids. Other workers may also be exposed to blood and other body fluids in the course of their work (e.g. laboratory workers and cleaning staff).

Guidelines for post-exposure prophylaxis (PEP) in occupational and non-occupational exposure to HIV call for the timely initiation of combination anti-retroviral therapy. Rapid confirmation (or exclusion) of HIV infection in the source of exposure helps decision-making in this context. Under normal circumstances most pathology services should be able to provide quick turn around of test results. HIV testing with rapid turn around of results should be available in all settings where people are assessed for PEP. If there is likely to be a delay of more than two hours in receiving test results, it should be assumed that the exposed person is uninfected and PEP commenced.

Outside of normal working hours (i.e. on weekends and public holidays) the use of short-incubation tests may be appropriate and could be performed by suitably trained medical laboratory staff from core or express laboratories rather than dedicated

serology laboratories. If there is exposure from a high-risk source person and some delay in testing, it is recommended that initiation of PEP should not be delayed (see also Chapter 8).

Home based (self) testing in Australia

Key Point:

- Home-based (self) testing for HIV and home-based (self) collection of samples to be tested for HIV is not supported.

Background

Home-based testing (also known as self testing) refers to a process where HIV testing is conducted outside a medical or clinical setting. The process is similar to conducting a home-based pregnancy test, in which the test is performed and interpreted by an individual in a non-medical setting. Home-based testing can also mean that an individual collects a sample at home (or collects their own sample) and sends it to a centralised laboratory for formal testing and interpretation. For the purposes of this policy, the former will be referred to as 'home-testing' and the latter as 'home-collection'.

HIV testing in Australia should always be performed in a clinical context, where there is an appropriate level of interaction between the individual being tested and a suitably qualified health professional. Introduction of home-testing and home-collection for HIV in Australia is not supported. Owing to the low positive predictive value inherent in HIV testing in the general population, the risk of misinterpretation of the test outweighs any possible advantages of home-testing.

It is important to note that home-testing and home-collection IVDs have not been approved for supply in Australia by the TGA. As home-testing IVDs are currently available for purchase over the internet from overseas suppliers, it is important that access to and use of these tests is monitored through social research, anecdotal reports and observation. Health promotion interventions may be necessary if the practice of home-testing becomes prevalent.

11) FUNDING OF HIV TESTING

Key Point:

- From 1 November 2005, HIV diagnostic testing was listed on the Medicare Benefits Schedule (MBS).
- States and Territories should ensure that capacity is retained to support provision of free and de-identified HIV testing in circumstances where a person at risk of HIV infection would not otherwise access or consent to testing.

Current Situation - Levels of HIV testing in Australia

Approximately 900,000 diagnostic HIV antibody tests are performed annually in Australia (excluding blood bank testing and supplemental testing). These statistics are compiled by the NRL as part of their post market surveillance activities.

Funding arrangements for HIV diagnostic tests

From 01 November 2005, funding for anti-HIV assays has been made available as a subsidy through the MBS.

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. State and Territory governments, which prior to 1 November 2005 were responsible for fully funding the cost of HIV antibody testing, should ensure that capacity is retained to support provision of free and de-identified testing in such situations (e.g. via public specialist sexual health clinics).

12) HUMAN T-CELL LYMPHOTROPIC VIRUS TESTING POLICY

Key Points:

- The testing principles that apply to HIV testing should also apply to testing for HTLV.
- HTLV testing is conducted on all blood and tissue donors in Australia.
- In Aboriginal populations, testing is recommended as clinically indicated in people who have blood dyscrasias, neurological signs, severe scabies or Strongyloides infection.
- Occupational injury is a potential indication for testing, where the source is considered to be at risk of being infected with HTLV.

Introduction

Human T-Cell Lymphotropic Virus (HTLV) is a retrovirus similar to HIV that is also blood-borne. In Australia the virus is endemic in some Indigenous groups (thought to mainly involve Central Australia up to the Katherine region) where it is predominantly acquired vertically (usually through breast milk after 6 months of age¹²). The prevalence of HTLV-I in some Aboriginal communities has been shown to be up to 13%¹³. The virus is also present in some immigrants from southern Europe and elsewhere in the world where it may be endemic (e.g. southern Japan and South America). HTLV may be transmitted through exchange of body fluids and the sharing of injecting equipment. HTLV can be transmitted sexually but is less easily transmitted than HIV.

There are two types of HTLV, designated HTLV-I and -II. HTLV is usually detected using immunoassays to detect anti-HTLV antibodies in blood. The two types of HTLV are immunologically similar and may be distinguished serologically. However, nucleic acid tests are the best for differentiation. The virus can be blood-borne and can be transmitted by blood transfusion, therefore all blood donations are screened for HTLV antibody. In Australia the virus is rarely found in blood donors. HTLV-I is the type found in Aboriginal people, while in injecting drug users, especially in North America, HTLV-II is more commonly found. HTLV-I is more pathogenic than HTLV-II. Infection with HTLV-I may result in neurologic manifestations after many years of infection. Less serious manifestations may occur earlier. HTLV-I has been linked with a spastic paraparesis called HTLV-associated myelopathy or tropical spastic paraparesis (HAM/TSP), and perhaps with other neurological syndromes. It is also associated with an increased incidence of pneumonia and bronchitis, inflammatory conditions such as arthritis, and perhaps with increased mortality. It is also associated with crusted scabies and severe Strongyloides infection and standard treatment may be ineffective for HTLV-I related scabies and Strongyloides¹⁴⁻²⁰. Children infected with HTLV may be immunosuppressed. HTLV-II is not consistently associated with any particular manifestations of clinical significance nor are they observed with any frequency.

Guiding Principles

The guiding principles that apply to HIV testing should also apply to testing for HTLV.

Indications for HTLV Testing

HTLV testing is conducted on all blood and tissue donors in Australia. In Aboriginal groups, testing is incidental when the person presents for other clinical reasons. Otherwise testing is carried out as clinically indicated in people who have blood dyscrasias, neurological signs, severe scabies or Strongyloides infection.

The other potential indication for testing is occupational injury, where the source is considered to be at risk of being infected. In practice, this may mean an anti-HTLV assay being requested when the source individual is an Aboriginal person from the area in Central Australia south of Katherine.

HTLV Testing

HTLV diagnosis is carried out using testing strategies that employ the same types of tests used to diagnose HIV i.e. immunoassays followed by specific western blots. The virus is blood-borne and so all blood and tissue donors are screened for HTLV. Therefore, approximately one million tests per annum are performed in Australia by the ARCBS. It is not always possible to differentiate HTLV -I from HTLV-II by serology and often laboratories need to fall back on nucleic acid methods. As the prevalence of HTLV is low, except in particular groups, few laboratories conduct testing for HTLV.

Regulation

Within the TGA's proposed IVD Framework HTLV tests will fall into Class 4. It is expected that the tests will be regulated in the same way as HIV and hepatitis tests.

APPENDIX 1

Members of the joint Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis (MACASHH) and Intergovernmental Committee on AIDS, Hepatitis and Related Diseases (IGCAHRD) HIV Testing Policy Steering Group

Chairs

Professor Frank Bowden, Chair of the HIV/AIDS and STIs Subcommittee of MACASHH

Ms Kim Stewart, Chair of IGCAHRD

Members

Associate Professor Andrew Grulich, National Centre in HIV Epidemiology and Clinical Research

Dr Gary Lum, AM, Public Health Laboratory Network

Associate Professor Elizabeth Dax, AM, National Serology Reference Laboratory, Australia

Professor Marian Pitts, Australian Research Centre for Sex, Health and Society

Ms Kirsty Machon, National Association of People Living with HIV/AIDS

Mr Mark Bebbington, Australian Federation of AIDS Organisations

Dr Jon Willis, representative from the Indigenous Australians' Sexual Health Committee of MACASHH

Dr Cathy Pell, Australasian Society for HIV Medicine

Dr Nick Medland, Australasian Society for HIV Medicine

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Ms Fiona MacIver, HIV/AIDS and STIs Section, Department of Health and Ageing

Ms Gayle Anderson, HIV/AIDS and STIs Section, Department of Health and Ageing (May 2005-August 2006)

Ms Lynne Clune, HIV/AIDS and STIs Section, Department of Health and Ageing (August 2006-December 2006)

APPENDIX 2 DONOR TESTING

It is mandatory for donated blood samples to be tested for HIV and other blood-borne pathogens. The ARCBS conducts more HIV tests than any other laboratory group in Australia. Approximately one million donations are tested annually. In the last five years, the numbers of HIV tests performed by ARCBS has been 954,468 (2001), 1,009,073 (2002), 1,048,061 (2003), 1,106,451 (2004) and 1,083,514 (2005). With the use of donor declarations, and screening with anti-HIV immunoassays as well as nucleic acid testing for viral RNA recipients of blood, blood products or tissue, have a minimal risk of acquiring HIV.

Only one case of HIV transmission via blood donation is known to have occurred since testing began in 1985. It was this transmission that precipitated the discussion and then implementation of nucleic acid screening of all blood donations. Essentially, in the number of donations that had been made and tested, this case represented the predicted chance of transmission in serological screening. This was the chance of transmission from a donor in the very early stages of infection before antibody has been produced (the risk of receiving a transfusion or transplant when the donor was in the 'window period'). Although the testing of all blood and tissue donors in Australia is extensive, fewer than 20 donors each year are identified as HIV positive. Since nucleic acid screening was implemented in 2000, two HIV NAT-positive: antibody-negative donations have been identified.

Blood, which includes both labile blood components and fractionated blood products, are required to conform to the Council of Europe Guide for the preparation, use and quality assurance of blood components. In addition, blood products must conform to the British/European Pharmacopeia. Facilities testing blood and tissue donations must be licensed by the TGA.

APPENDIX 3 ANTENATAL TESTING

Epidemiology

The annual number of HIV diagnoses in women in Australia has remained between 60 and 90 over the past 10 years and, as a result, vertical transmission of HIV is rare. A total of 206 children with perinatal exposure to HIV infection were identified between 1994 and 2003 i.e. approximately 20 per year. There were 34 cases of transmission reported in that period by the National Centre in HIV Epidemiology and Clinical Research:

	Before the birth no. exposed	No. with HIV	At or after the birth no. exposed	No. with HIV	Total no. exposed	No. with HIV
1994 - 1995	24	7	20	8	44	15
1996 - 1997	16	3	10	7	26	10
1998 - 1999	36	0	7	3	43	3
2000 - 2001	46	0	7	5	54	5
2002 - 2003	38	1	1	0	39	1
Total	160	11	45	23	206	34

National Centre for HIV Epidemiology and Clinical Research

In 2003, approximately 251,000 births were registered in Australia giving a crude rate estimate of known perinatal HIV exposure of 0.008%, assuming 20 HIV positive antenatal women per year²¹.

Approaches to antenatal testing

Policy options for antenatal testing for HIV can take the following forms:

- Universal offer of testing – all pregnant women are offered HIV testing regardless of their risk of exposure;
- Targeted testing – women are offered testing if they have specific risk factors identified after a risk assessment; or
- Mandatory screening – all women are screened, with or without their consent or knowledge.

Mandatory screening is not consistent with the guiding principles of HIV testing in Australia and is not supported.

A risk-assessment approach to testing will identify a proportion but not all of the cases of unrecognised HIV infection. Practitioners working outside high case-load areas are often reluctant to take detailed sexual, alcohol and other drug histories²¹ and it has been shown that up to 70% of women do not self-acknowledge risk factors for HIV infection^{22, 23}. Cohort and case-control studies have demonstrated in the US that targeted HIV testing of pregnant women with identifiable risk factors will find between 8 and 57% of those who are infected²²⁻²⁷. It can be argued that a risk assessment approach appears to work in Australia at present because the prevalence of HIV in at-risk individuals is very low. As the prevalence increases, the risk-assessment approach is likely to proportionally miss more cases of infection.

Universal offer of testing does not mean universal testing will occur. All women who are offered the test are at liberty to refuse to participate. Indeed it has been shown in a randomised clinical trial that, while universal offer of testing significantly increases

the uptake of antenatal testing compared with no offer, the average rate of testing in the universal offer group was only 35%, compared with 6% in the 'no offer' group²⁸. There are no reliable data relating to the rate of antenatal HIV testing in Australia - anecdotally it is believed that approximately 50% of women are screened. A proportion of those are not informed about the testing and their consent is not obtained. This testing is not in accordance with best-practice principles.

Potential benefits and risks of antenatal testing

Regardless of the testing strategy employed (targeted or universal), antenatal testing carries with it potential benefits and risks.

Potential benefits

- A reduction in mother to child transmission of HIV infection.
- Informed choices facilitated regarding the current and future pregnancies.
- The opportunity for assessment and commencement of antiretroviral treatment, if indicated.
- Sexual partners and children from previous pregnancies have the opportunity to be screened for HIV infection.
- Opportunity to discuss safer sexual behaviours with women found to be HIV negative or positive (and their sexual partners).

Potential risks

- Complications of antiretroviral therapy used to reduce mother-to-child transmission.
- Caesarean section rate may increase.
- Avoidance of breastfeeding could be associated with adverse bonding issues between mother and child.
- Failure to obtain informed consent and unexpected detection of HIV in a woman can result in psychosocial upset, exacerbated in the context of pregnancy.
- Anxieties while waiting for initial HIV test results or while waiting for results of repeat testing for women with biological false positive results (including indeterminate western blot results).

Reduction in transmission risk

The risk of transmission of HIV from an infected mother to her child without intervention is approximately 25%. The effectiveness of zidovudine monotherapy in reducing this risk to around 8% was demonstrated in 1994²⁷. Since then the use of combination antiretroviral therapy has further reduced the risk of transmission to less than 1%²⁸. Other strategies to reduce transmission are avoidance of breastfeeding and modification of delivery practice, including the use of caesarean section.

Informed choices about current and future pregnancies

Antenatal women should have the opportunity to consider all options in light of the current knowledge of transmission risk. This knowledge also helps them in their decision-making regarding current and future pregnancies.

Antiretroviral therapy is safe in pregnancy for both the woman and foetus (providing drugs with proven teratogenic potential, such as efavirenz, are avoided). There are some risks associated with antiretroviral drugs and a small number of women offered therapy to reduce mother to child transmission will suffer side-effects. In rare circumstances these can be severe.

Mode of delivery

Caesarean section has been shown to decrease the HIV transmission risk in the absence of antiretroviral therapy and this means of delivery has been recommended for HIV infected women. The magnitude of the additional benefit for women on highly active antiretroviral therapy and with low/undetectable viral loads is likely to be very small.

False positive results

In a low prevalence population, the positive predictive value of testing for HIV is low. In 2003, there were approximately 251,000 registered live births in Australia. If a seroprevalence of 0.025% is assumed, and all these women were tested, it is estimated that 63 HIV infected women would have been identified. In Australia the average specificity of HIV testing in blood service laboratories is 99.86% (NRL monitoring figures). Tests in diagnostic laboratories operate at lower specificity. If the specificity were 99.9%, 251 women would be identified as EIA reactive but not infected, that is, they would have a false positive result. In practice, due to the slightly lower specificity, it is likely that between 500 and 1000 women would fall into this category in Australia each year. It must be noted that many of these women will have a negative western blot and therefore require no further testing. Assuming a rate for indeterminate western blot as 4-20%^{29,30} approximately 50 women would require repeat testing after the initial screen before they could be reassured they were not infected. While virtually all pregnant women requiring repeat HIV testing will not be infected with HIV, the testing process results in considerable anxiety for the women waiting for the results.

Obtaining informed consent

While the majority of women will return a negative result, procedures must be in place to ensure that the small number of women who test positive for HIV are provided with immediate and appropriate support, post-test discussion and follow-up. With more widespread antenatal testing, it is likely that a larger number of service providers will detect the anticipated small number of positives. This means that referral information, telephone support and easy access to specialist HIV services must be facilitated.

Cost-effectiveness

Studies on cost-effectiveness of universal antenatal HIV screening have been undertaken in high-income countries. These have supported a universal approach

when the seroprevalence of HIV is reported or assumed to be greater than 0.01%³¹⁻³⁵. Some of these studies have demonstrated that in low prevalence areas with only 50% uptake, a universal strategy may not be more effective than a well-run selective strategy³⁶. Other studies in low prevalence settings have reported a universal strategy to be cost-effective^{37,38}.

The one published cost-effectiveness analysis in an Australian setting suggests that a universal antenatal HIV screening approach would be cost-effective at a very low prevalence³⁹. This study found a universal screening approach to be cost-effective at a seroprevalence of 0.004372% (1 case/22,872 population). Net benefits accrue at higher prevalence and some Australian population groups may have prevalence higher than 0.004%. This report remains unchallenged in Australia, and similar estimates have been made for New Zealand.

Other antenatal serological testing

All antenatal serological testing should be performed with informed consent. Testing for a variety of infectious diseases is currently undertaken but whether appropriate consent is generally obtained is believed to be variable.

Special circumstances/populations

Women presenting late in pregnancy or in labour and who have not received any antenatal care may be at increased risk of HIV infection. HIV testing may need to be performed urgently in these settings to ensure that antiretroviral therapy can be instituted if the woman is found to be positive.

Antenatal testing for HIV in Aboriginal and Torres Strait Islander women deserves special mention. Women make up a higher proportion of Aboriginal and Torres Strait Islander infections than in the non-Indigenous population. HIV infection is still relatively rare in the Aboriginal and Torres Strait Islander population but it is likely to increase over time. Late presentation is common for many Aboriginal and Torres Strait Islander people and antenatal care may be delayed or not utilised at all. Risk factor based testing is unlikely to be able discriminate between those at higher risk of HIV infection, and a policy of universal offer of testing should be adopted.

APPENDIX 4 ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLE

Increasing testing in Aboriginal and Torres Strait Islander Communities

The NATSISH&BBV⁸ recommends several initiatives to increase HIV testing in Aboriginal and Torres Strait Islander communities.

Techniques to improve access to testing should include:

- staff development for workers in primary health care services through dissemination of information and facilitating access to new testing and treatment regimes;
- improved linkages between service providers, including linkages between ACCHSs and mainstream services, as well as those between primary health care and specialist and tertiary services; and
- ensuring access for Aboriginal and Torres Strait Islander communities to technological advances and their application in clinical care.

Implement population based screening programs where indicated through:

- national surveillance data used to inform priority groups to be targeted for screening programs;
- continual expansion of comprehensive primary health care services to Aboriginal and Torres Strait Islander people ;
- increased collaboration and partnership between Aboriginal and Torres Strait Islander community controlled health services to increase capacity to priority groups; and
- ensuring community education and consultation is undertaken, and appropriate consent is given by Aboriginal and Torres Strait Islander peoples prior to conducting population based screening.

Facilitate access to new testing and treatment regimens by:

- dissemination of information on new testing and treatment regimens to Aboriginal community controlled health organisations, mainstream health services and community based organisations;
- support for research into the development of sensitive and specific diagnostic tests suitable for use in remote locations; and
- investigation of the use of new point of care testing technologies in different settings.

The Torres Strait Region

There is an urgent requirement for a coordinated public health approach to the threat of HIV in the cross-border region of the Torres Strait, including the facilitation of improved access to HIV testing in both the Torres Strait region and in the Western Province of Papua New Guinea (PNG). This approach should include health promotion, surveillance, screening, treatment and management. The Australian and Queensland Governments, in partnership with key stakeholders from the Torres Strait and PNG, need to develop plans and allocate resources to deal with the potential risks

in the region. Consideration also needs to be given to the infrastructure needs of the Western Province of PNG. It should include the development of a comprehensive prevention plan that includes:

- opportunities for enhancing staff capacity through training and exchange;
- developing infrastructure (both clinical and general IT/communications);
- provision of technical support, both clinical (e.g. infection control, case management, laboratory) and administrative (e.g. human resource management); and
- the establishment of communicator positions in Australia and PNG to raise awareness about the prevention of HIV transmission in the Torres Strait region.

Epidemiology and testing research

Both the NATSISH&BBV Strategy and the *National Sexually Transmissible Infections (STIs) Strategy*⁴⁰ recommend improvements to the collection, analysis and use of surveillance data, particularly increased use of Indigenous identifiers, for nationally notifiable diseases and other locally significant STIs. The Department of Health and Ageing should work with the Communicable Diseases Network of Australia to improve surveillance data by building on recent analysis and recommendations for improving Indigenous identification in communicable diseases reporting systems. In line with this, State and Territory jurisdictions should review notification forms and procedures, and implement measures to increase use of Indigenous identifiers.

The STIs Strategy also recommends support for the development and use of short-incubation as well as non-invasive tests in Aboriginal and Torres Strait Islander communities. Its recommendation includes continuing support for research into the development of sensitive and specific diagnostic tests suitable for use in remote locations, and continued support for the use of non-invasive diagnostic technologies in remote communities. It also recommends investigating the use of new technology to allow rapid (immediate) testing in remote areas, including consideration of ways to improve cost effectiveness of such technology/programs, but emphasises the requirement for an adequate framework for gaining consent to testing and appropriate post-test discussion for delivering diagnoses (see Chapter 10).

APPENDIX 5 QUALITY ASSURING HIV TESTING

HIV was identified in 1983 and the first available serological testing kit was made available commercially by 1985. In March 1985, Australia became one of the first countries to implement universal screening for blood donations. Immunoassays of high and ever-improving quality have been used diagnostically and for blood screening. Nucleic acid amplification tests (NAT) for screening of blood donations commenced in 2000 and laboratories have used NAT for confirmatory testing since 1997. NAT have been used as the technique of choice for quantifying viral loads since the mid-90s.

The tests or assays most used as first-line standard assays are immunoassays (blood services also use NAT screening). If someone has specific antibodies to HIV it is likely that they have been exposed to the virus. The immunoassays are designed to recognise any antibody in the blood that is an HIV antibody or looks like an HIV antibody (false reactivity). About 1 in 500 - 1000 people who are not infected will react to an HIV immunoassay. Occasionally, two or more reference or supplemental assays will have to be performed to distinguish true from false reactivity in the immunoassay¹⁰.

In the absence of a definitive test result, locally developed guidelines should draw attention to the possibility of unnecessary repeat testing and ensure staff are appropriately trained in test result interpretation.

The most commonly used reference test to confirm that antibody reactivity is true (i.e. the test is truly positive) is the western blot. This is only true where carefully evaluated criteria used to interpret the results confer specificity on the interpretation of the result. Sometimes reactivity in western blots gives results that are indeterminate (neither positive nor negative), prompting further testing. The test that defines a sample as HIV positive is the confirmatory assay¹⁰.

Nucleic acid tests to detect and/or quantify virus in blood have become available and are widely used to assist in clinical management of HIV and its therapy. These tests are used not only to secure diagnoses (qualitative DNA) but to determine prognosis and the effects of treatment (quantitative RNA). The tests are based on nucleic acid amplification techniques including polymerase chain reaction (PCR), signal amplification (branched chain DNA assay, bDNA) or presently for blood screening, transcription-mediated amplification (TMA). Modified versions of NAT may be used to distinguish particular types of virus (for example HIV-1 from HIV-2) or to identify other sub-types of HIV¹⁰.

Roles of the Regulator and the Assurance of Quality in HIV Testing

The TGA has the regulatory responsibility for ensuring the quality, performance and safety of HIV and other IVDs through the *Therapeutic Goods Act 1989* and its associated regulations. The objective of the TGA is to assure the safety, quality, efficacy and timely availability of all IVDs in Australia at a standard at least equal to that of comparable countries. The TGA has authority to remove from the market any test that does not perform to the expected standard or that is known or demonstrated to be defective.

The TGA is responsible for the pre-market evaluation and post-market monitoring of HIV IVDs. Current TGA pre-market assessment includes a review of evidence of

manufacturer's quality management system, kit performance, kit presentation, labeling and promotional material and reagent safety and stability. The TGA currently contracts evaluation of a kit's performance to the NRL, to ensure it will be suitable for the Australian population. Evaluations are made to levels commensurate with the risks associated with failure in their use. If the performance and other regulatory issues are deemed acceptable, the IVDs are included on the Australian Register of Therapeutic Goods (ARTG) as 'registered' goods. The registration (AUST R) number must then be included on the label of the kit.

The TGA has mechanisms for investigation and recall of faulty IVDs. This includes the Incident Report Investigation Scheme (IRIS) for the investigation of all reports submitted to the TGA on adverse events or problems associated with the use of medical devices, including HIV tests. IRIS can be used by laboratories noting performance and safety issues with an assay.

IRIS is also used by the NRL as the mechanism to report observed deficiencies arising from the NRL's post market monitoring of the assays. The NRL is subcontracted by the TGA to monitor these assays using the mandated quality assurance programs that laboratories performing HIV testing participate in. There are also arrangements for withdrawing faulty IVDs through the TGA Recalls Coordinator, and if necessary, to question or cancel product registration.

Quality Assurance Programs

Specificity Monitoring

Ongoing performance of IVDs is maintained through specificity monitoring. If the level of false reactivity in tests in large numbers of samples is monitored, both assay and laboratory problems can be detected. There is usually a low rate of false reactivity, but the accumulated data are used as a measure of an assay's continued performance. A sudden increase in the false reactivity rate could suggest that the assay's performance is unsuitable.

External Quality Assessment Schemes (EQAS)

EQAS, also commonly referred to as proficiency testing, are designed to assess the accuracy of the laboratory testing process, from receipt of the specimen to delivery of the test result. It is a NATA requirement that laboratories shall participate in inter-laboratory comparisons such as those organised by external quality assessment schemes (Refer ISO 15189:2003). Quality Assurance providers supply a panel of specimens at regular intervals to participating laboratories for testing. The panels are constructed so that aspects of the testing process and the kit in use can be assessed. The laboratories are able to compare their results with reference results and with the results of similar laboratories. This allows problems to be identified and follow up provides for resolution of the problems, particularly those that are kit-based. It also creates a networking ability across laboratories so performance evaluation is enhanced.

Quality Control Samples

Laboratories use quality control samples to continuously monitor the accuracy of HIV antibody and nucleic acid tests. When used in every assay run, the samples allow for confirmation that the test results are reproducible and reliable. Monitoring the reactivity of a quality control sample, which should deliver consistent results across runs and batches, means that intra-laboratory and batch-to-batch variability can be tracked and aberrations in performance can be assessed as laboratory or test based.

Laboratory Requirements for HIV Testing

The NPAAC *Standards and Guidelines for Laboratory Testing of Antibodies to the Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV)*⁴¹ and *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis*⁴² provide the frameworks for assessment by NATA/RCPA of the extent to which laboratories must meet the requirements for performance of standard and/or reference HIV testing.

Reference Testing

Reference Testing serves as a reference point for HIV serology samples whose status cannot be resolved at the standard or reference laboratory level. Specialised testing strategies are used, among them selected tests not used by other laboratories. This provides an extra layer of testing for samples that are difficult to diagnose using screening laboratories' usual methods. It is also a base for testing samples to be used in quality programs to assure their integrity and stability.

Categorisation

As discussed in Chapter 9, HIV IVDs are categorised according to Table 1 (as follows).

Table 1: Categorisation of HIV IVDs for evaluation and use

Purpose or uses of IVDs	Test categories ^A	
	Standard ^B	Reference ^C
Donor Testing – screening of blood and tissue donations.	Enzyme immunoassay Particle agglutination assay Machine-based immunoassay NAT screening tests Level 1*	Enzyme immunoassay Western blot Line assay Rapid assays
Diagnostic Testing – to determine the infection status of a sample for clinical purposes e.g. diagnosis, antenatal screening, pre-operative, visa, insurance, emergency, testing and supplemental and confirmatory purposes.	Enzyme immunoassay Particle agglutination assay Machine-based immunoassay Rapid test Alternative sample assay Level 2*	Antigen enzyme immunoassay Discriminatory NAT assay Qualitative amplification assay Quantitative amplification assay Level 3*
Unlinked epidemiological surveillance – or definition of infection status of a population where no results are conveyed to individuals from whom samples are taken.	Rapid test Alternative sample assay Level 3*	
Monitoring and management – quantifies or characterises the virus for clinical management.		Amplification assay Antigen enzyme immunoassay Typing assays Assay for the detection of drug-resistant types of virus Level 4*

* Denotes the minimum level of evaluation (see below).

- (A) **Test categories:** Laboratories perform standard and/or reference testing.
- (B) **Standard tests:** Standard tests may be used by laboratories performing diagnostic or screening testing to identify the HIV negative antibody status of samples using screening or standard assays. Any test may be used for screening purposes provided it is evaluated to the appropriate level and shown to be appropriately sensitive and specific. Those samples yielding non-reactive results do not need to be further tested unless clinical considerations demand it. Reactive samples must be subjected to supplemental testing to distinguish true reactivity from false reactivity. The reference testing must confirm the presence of specific antibody or virus before the result is accepted as a true positive.
- (C) **Reference tests:** Reference tests are used by laboratories to conduct confirmatory or additional special testing. This testing is conducted to confirm true positive status by distinguishing true from false reactivity. Usually this testing is conducted within a diagnostic strategy and a western blot is used; but other reference testing situations occur (e.g. in a setting of possible seroconversion illness) when the first-used reference tests may include nucleic acid tests for proviral DNA. Laboratories may also use rapid tests for reference testing in appropriate settings. Other reference tests may be used once the HIV status is confirmed to quantify viral load, characterise the virus or identify sensitivity of the virus to anti retroviral drugs. These tests may be conducted outside reference laboratories as long as any TGA conditions for the kit registration are met.

Test kit evaluations (indicated by Levels 1, 2, 3, and 4 in Table 1)

The level of evaluation for any test is commensurate with the risk of delivering a false result associated with its use:

- Level 1** Number of samples selected to fully determine all characteristics of the assay in a statistically valid manner and within narrow confidence limits. A full scale Level 1 evaluation involves estimation of sensitivity and specificity in sufficient samples to yield statistically valid assay comparison. Samples for estimation of sensitivity include samples from infected people through the entire course of infection including seroconversion.
- Level 2** Full evaluation of sensitivity often within a multi-site protocol and with more limited determination of specificity (i.e. in fewer samples and therefore with a wider confidence interval around the estimation).
- Level 3** Evaluation only in a characterised sensitivity panel, with testing in a limited number of negative samples which have potential for or established false reactivity. Rapid test or alternative sample assays, if used for screening, should be evaluated as screening tests (i.e. at Level 1 or 2).
- Level 4** Evaluation protocol designed on submission of the assay. Post-market monitoring or collection of data that indicate how the test is performing as it is used will be required as a condition of supply of the IVDs. The conditions will be indicated on the TGA registration certificate.

APPENDIX 6 SHORT-INCUBATION (RAPID) AND HOME BASED (SELF) TESTING

A number of issues remain regarding short-incubation, also known as rapid testing, testing in Australia. Short-incubation testing does not necessarily mean easy testing. Accurate interpretation of short-incubation tests requires considerable experience. Not all medical staff will have the appropriate laboratory training to conduct the tests and community-based practitioners are unlikely to see enough positive samples to gain adequate experience in the interpretation of the tests.

There are concerns that informed consent for HIV testing may not always be obtained when short-incubation tests are employed. While this is not a sufficient reason in itself to reject their use, it highlights the importance of maintaining the highest ethical standards and following the principles of HIV testing if performing rapid HIV testing.

The concept of the positive predictive value (PPV), discussed in the section on home-based testing, is also relevant here. In low prevalence populations, a greater proportion of reactive results detected in screening by short-incubation tests will be false positives. Therefore, confirmatory testing must always be performed to distinguish false from true positive results. There is a danger of serious emotional distress whenever false positive test results are conveyed to an individual.

There is a need for thorough pre-operative assessment of elective surgery patients, based on clinical indications. There is a range of tests that can be performed which may include HIV. Other examples include hepatitis B and C serology, electrocardiography and chest x-rays. When a surgeon considers it necessary to know the serological status of an individual before surgery it should be for the benefit of the patient. Testing should be conducted by suitably trained laboratory personnel in a suitably accredited medical testing pathology service and satisfy all relevant legal obligations.

Some practitioners may have an interest in the HIV status of individuals they are treating, especially in emergency situations. Clinicians may be falsely reassured by negative HIV tests, but be at risk of contracting other blood-borne pathogens that are not tested for. The risk of false negative results in seroconverters must also be considered.

Short-incubation testing cannot be seen as a means of infection control. The principles of 'standard precautions' as defined by the Infection Control Guidelines² must be followed.

Background – Home-Based (Self) Testing

Home-based HIV tests (also known as self testing) are not currently registered for use in Australia.

Home(self)-testing

In home-based testing, the customer is able to purchase IVDs from a pharmacy or other distributor such as through mail order or via the Internet. After reading the product insert the individual collects a sample (usually blood from a finger prick specimen or saliva obtained from an oral swab) and performs the test. The individual then interprets whether the test is positive, negative or equivocal.

Reasons suggested for the need for this form of testing include:

- the inability of some groups to afford medical consultations and testing;
- the fact that many people do not return for results of HIV testing after the period required for conducting confirmatory testing;
- reluctance to attend medical services due to concerns about confidentiality or a general mistrust of such services; and
- desire to learn rapidly his/her serostatus before having sexual intercourse—here the test would be used in the course of so-called ‘safe-sex negotiations’.

There are a number of issues which bring the practicality and value of home-based testing into question:

- People testing at home are removed from any clinical interaction. Individuals may be unaware of the limitations of the test (such as the possibility of false positives) or of the concept of the ‘window period’ of infection. There is no chance for immediate follow-up and discussion with this type of testing and there is a real possibility of significant and harmful emotional distress.
- The opportunity for safe-sex/safe-drug use discussion is lost with home-based testing.
- Proper storage and use within the shelf life cannot be guaranteed.
- The PPV of a particular test kit, which is determined by the prevalence of HIV in the population being tested, is likely to be below 10% even in a group at moderate to high risk. If the PPV were 1% this means that at least 99 out of 100 tests that appear positive at home will be false positives, even assuming laboratory level performance of the kit. In the first time blood-donor population, the PPV of laboratory-based HIV tests is less than 0.001%.
- Concerns have been expressed that home-based testing will lead to the abandonment of safe-sex practice, as individuals use the test immediately before sex and adjust their behaviour according to the test result. One major flaw in this strategy is that false negatives may occur in individuals (especially those at risk) in the window period of infection, or because of kit misuse. This is particularly important in populations with an emerging HIV epidemic where prevalence is low and the incidence of new infections is high.

Home (self) collection

The United States Food and Drug Administration (FDA) approved a home-collection kit as a means of HIV testing in 1996. With this method, an individual obtains a sample collection kit from an outlet such as a pharmacy, mail order or Internet provider. A finger-prick sample of blood is collected on a filter paper and then sent by mail to a centralised testing agency. The sample is coded and the individual waits a prescribed time before telephoning for the results. After providing the code number, the individual is given a pre-recorded message which includes safe-sex/safe-use information if the test were negative, or transferred to a telephone counsellor if the

test were positive. The counsellor then makes an assessment and refers the individual to the nearest health service provider.

Home-collection has advantages over home-testing, but there are still several issues to be considered:

- Home-collection avoids the risk of inexperienced operator error because the actual testing of the sample is done in certified laboratories. Confirmatory testing is performed before the release of positive results, thus distinguishing the majority of false positive tests on the screening assay.
- Although the accuracy of the testing procedure in adequate samples is similar to clinical-based testing, in home-collection the person with a positive test may be left in a vulnerable position. The opportunity to provide immediate support is lost and, as for home-based testing, there is a real risk of harmful emotional distress.
- Currently in the United States, home-collection testing requires the sponsoring company to establish a considerable infrastructure—telephone ‘hotlines’, trained counsellors and laboratory facilities. A similar infrastructure would be required if home-collection testing were approved in Australia.
- Owing to the widespread availability of HIV testing in Australia, where cost is rarely an impediment to accessing health care, it is unlikely that home-collection would have a significant market. Home-collection testing is likely to cost the individual more than testing performed through the normal health care system. Even in remote areas of Australia, HIV testing is available through local medical services.
- There is presently limited demand for home-collection in Australia and the costs associated with its establishment could be prohibitive for a sponsoring company.

APPENDIX 7 HIV TESTING IN PRISON SETTINGS

People entering prison and those about to be released from prison are a high risk population for HIV infection, due to their high rates of injecting drug use (IDU) compared with the general population. During incarceration prisoners have limited access to means of prevention for all blood borne viruses including HIV. There is evidence that IDU continues within prisons⁴³.

Epidemiology

Rates of HIV infection in Australian prisons are low by international standards and reflect the lower rates of HIV infection in the IDU population in Australia. In 2004 the rate of HIV infection found in Australian Needle and Syringe Program (NSP) survey participants was less than 2%, except among men also reporting sex with other men when the rate was 29%⁴⁴. These rates are higher than community HIV rates. The proportion of participants in the Australian NSP surveys reporting injecting drugs while incarcerated over the last 12 months was 53% in the 2004 survey, 33% in 2003, and 42% in 2000. These sustained high rates of injection during incarceration highlight the potential for HIV transmission within prisons, particularly if HIV rates in IDU increase in the future. Lack of access to means of HIV prevention such as clean needles and syringes and condoms within most custodial settings also increases the risk of HIV transmission associated with risk behaviours.

HIV Testing of Prisoners

Offering testing of prisoners on reception, during incarceration and prior to release has the potential to identify new cases of HIV infection, allowing appropriate assessment, treatment and education to be provided to those individuals. This has clear benefits to the individual, their sexual partners, those with whom they may share injecting equipment and to public health. Both positive and negative consequences of a positive HIV test result need to be addressed in pre-test discussion for informed consent to be given by the prisoner.

States and Territories are encouraged to develop policies that offer HIV testing to inmates on reception and during incarceration and, where appropriate, arrange referrals to community health services for testing following an individuals' release from prison.

Guidelines for Health Services

The custodial system in Australia is State and Territory based. This leads to diversity in arrangements for the delivery of health services to prisoners across jurisdictions. In an attempt to provide authorities with guidance, the document entitled *Standard guidelines for corrections in Australia*⁴⁵ (the Standard Guidelines) was revised in 2004. The document contains guidelines that characterise a national statement of intent, around which each Australian State and Territory jurisdiction must develop or continue to develop its own range of relevant legislative, policy and performance standards. There are no specific recommendations in this document about HIV testing, however, there are guidelines relating to health services.

The Standard Guidelines state that prisoners should have access to health services of a standard comparable to that of the general community, on reception to prison (within

24 hours of arrival) and thereafter as necessary. In reference to infectious disease, the Standard Guidelines state that “*the prisoner should be managed by the health services so as to minimise the possibility of contamination of the prison environment*”.

Confidentiality of medical information should be maintained to preserve all individuals’ right to privacy, unless: the individual consents to disclosure; disclosure is in the interests of the individual’s welfare; or where maintaining confidentiality may jeopardise the safety of others or the good order and security of the prison.

The loss of confidentiality is permitted only in the circumstance that the good order and security of the prison is jeopardised. The special circumstances of disclosure of confidential medical information should be addressed during the consent and pre test discussion process prior to testing. This is the only area in which the Standard Guidelines conflict with the guiding principles of HIV testing policy.

Prisoners are recognised as being at higher risk of HIV infection than the general population and at higher risk of transmission during incarceration due to ongoing injection risk and lack of access to HIV preventive measures.

APPENDIX 8

The Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis (MACASHH) and the Department of Health and Ageing wish to acknowledge the contribution of many organisations and individuals to the development of this policy:

The HIV/AIDS and STIs Subcommittee of MACASHH

The Indigenous Australians' Sexual Health Committee

The Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases

The National Association of People Living with HIV/AIDS

The Australian Federation of AIDS Organisations

Therapeutic Goods Administration

National Centre for HIV Epidemiology and Clinical Research

National Centre for HIV Social Research

Australian Research Centre for Sex, Health and Society

Public Health Laboratory Network of Australia

National Serology Reference Laboratory, Australia

Australasian Society for HIV Medicine

Royal Australian College of Surgeons

Royal Australasian College of Physicians

Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Royal Australian College of General Practitioners

Royal College of Pathologists Australasia

The Burnet Institute

The Alfred Hospital, Victoria

WA Department of Corrections

Justice Health New South Wales

Dr Michelle Giles, Infectious Diseases Physician, Centre for Epidemiology and Population Health Research at the Burnet Institute

Professor John Ziegler, Sydney Children's Hospital Department of Immunology & Infectious Diseases

The HIV Team at the Royal District Nursing Service

The Australian Injecting and Illicit Drug Users' League

SDS Pathology, Sydney

Department of Infectious Diseases and Albion Street Centre at the Prince of Wales Hospital

The NSW Ministerial Advisory Committee on HIV and STIs

The Department of Human Services Victoria

The Ministerial Advisory Committee on Blood-borne and Sexually Transmissible Infections Victoria
The Federation of Ethnic Communities Councils of Australia
Aboriginal Health and Medical Research Council
Scarlet Alliance
Australian Association of Pathology Practices Inc.
National Aboriginal Community Controlled Health Organisation
The Communicable Disease Control Branch, Department of Health, South Australia
Federation of Ethnic Communities Councils of Australia
Communicable Diseases Unit, Queensland Health
Northern Territory, Department of Health
Australian injecting & Illicit Drug User's League
Western Australia, Department of Health
Nganampa Health Council

GLOSSARY

ACCHSs	Aboriginal Community Controlled Health Services
AIDS	acquired immunodeficiency syndrome
Anonymous delinked tests	testing of samples which have been irreversibly de-identified
ARCBS	Australian Red Cross Blood Service
ARTG	Australian Register of Therapeutic Goods
BED assay	an enzyme immune assay (EIA) that detects increasing levels of anti-HIV IgG after seroconversion and can be used for detecting recent HIV infection. It uses a branched peptide that includes gp41 immunodominant sequences from HIV-1 subtypes B, E, and D. Developed by the US Centers for Disease Control, the test is approved in the US for use for surveillance purposes only
bDNA	branched chain DNA assay
CALD	culturally and linguistically diverse background
Compulsory testing	where a person had no choice in being tested e.g. as directed under a public health order
Confirmatory test	the test that actually defines the anti-HIV status of a sample. Confirmatory testing must occur on each reactive sample.
De-identified testing	de-identified is the term applied to notification of HIV, where identifying information is not provided to the laboratory that conducts the antibody test, nor to any other party
Detuned assay	a reduced sensitivity ELISA antibody test. It is used in combination with a standard ELISA assay to determine whether the infection is recent (within the last 4-6 months). A positive standard assay with negative detuned assay indicates recent infection.
DNA	deoxyribonucleic acid
EIA	enzyme immunoassay – test allowing the detection of an antigen-antibody interaction using enzyme activity as the indicator
EPPs	exposure prone procedures – defined by the <i>Infection Control Guidelines</i> ² as a subset of ‘invasive procedures’ characterised by the potential for direct contact between the skin (usually finger or thumb) of the health care 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 health care worker to patient during medical or dental procedures
EQAS	external quality assessment scheme
HIV	human immunodeficiency virus
HTLV	human T-cell lymphotropic virus (HTLV) is a retrovirus similar to HIV and may be blood-borne. There are two types of HTLV, designated HTLV-I and -II. They are immunologically similar and while they may be distinguished serologically they are better distinguished using nucleic acid testing
IDU	injecting drug use
I_gG	immunoglobulin G
I_gG₃	test (assay) for a specific immunoglobulin G found only in early HIV infection, used to distinguish early from established infection.
IVD	in-vitro diagnostic device
Mandatory testing	refers to situations where people may not either participate in certain activities or access certain services unless they agree to be tested. Examples of circumstances in which mandatory testing is appropriate include prior to blood, tissue and organ donation, or for immigration purposes
MBS	Medicare Benefits Schedule
NAT	nucleic acid tests
NATA/RCPA	the accreditation process is carried out by NATA/RCPA, a joint initiative between the Royal College of Pathologists of Australasia (RCPA) and the National Association of Testing Authorities, Australia (NATA)
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
NPV (negative predictive value)	the probability that a person with a negative test result is truly disease-free
NRL	National Serology Reference Laboratory, Australia
NSP	needle and syringe program
Occupational exposure	an exposure that may place an employee at risk of HIV 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)
PCR	polymerase chain reaction – a technique by which nucleic acid (cell genetic material) is amplified to detect

	the presence of particular and specific nucleic acid sequences
PEP	post-exposure prophylaxis
PPV (positive predictive value)	the probability that a person with a positive test result actually has the disease
Predictive values	the predictive value of a test is a measure of the times that the value (positive or negative) is the true value. That is, the probability that a person has the disease being tested for. Predictive values are parameters that define the chance of a reactive test result being truly positive (the PPV) or a non-reactive test result being truly negative (the NPV) for the substance that a test is designed to detect
QA	quality assurance – the series of methods used to assure the overall integrity of tests
Qualitative result	a result that detects the presence of an agent or substance without measuring the level or quantity of that agent or substance
Quantitative result	a result that detects the presence of an agent and by comparison with quantitative standards, gives the level or amount of the agent
Reference testing	testing conducted to clarify the nature of samples' reactivity or status following initial tests conducted with standard tests in the same or another laboratory
RNA	ribonucleic acid
Sensitivity	the probability that a person with the disease will have a positive test result
Serology	the testing for the presence, evidence of, or quantity of antibodies specific for infectious or other agents, biochemistry, or substances in blood (serum or plasma or whole blood)
Serostatus	the condition of having or not having detectable antibodies to a disease in the blood as a result of infection. Serostatus is either positive or negative.
Sistergirl	Sistergirl is an Aboriginal and Torres Strait Islander sexual and cultural identity. Sistergirls are most often transgender, which may include sex change. An individual who cross-dresses can also identify as a Sistergirl.
Specificity	the probability that a person without the disease will have a negative test result
STI	sexually transmissible infection
Supplemental test(s)	tests performed following initial, standard or screening testing to clarify the serostatus of a repeatedly reactive sample

TGA	Therapeutic Goods Administration. It is anticipated that a new single agency will be established to regulate therapeutic goods in Australia and New Zealand. It will be referred to as the Australian New Zealand Therapeutic Products Authority (ANZTPA). It is expected to be established during the life of this policy
TMA	transcription-mediated amplification
USA CDC	United States of America Centers for Disease Control and Prevention

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