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## **Australian Federation of AIDS Organisations**

### **Submission to the Review of the HIV Testing Policy**

#### **1. Background**

Since the establishment of national guidelines for HIV testing, by ANCARD/IGCARD in 1998, there have been some significant changes and developments in the Australian epidemic.

These include:

- Reported rises in HIV diagnoses in some States.
- The development and approval of kits for rapid and home testing in other countries as well as the immanent application for these kits to be licensed in Australia.
- Recent discourse, both in Australia and overseas, regarding the effectiveness or otherwise of HIV testing as a means of reducing transmission of HIV.
- Calls for the introduction of across the board ante-natal screening for HIV.
- Discussions of the role of pre test counseling.

AFAO has based the recommendations in this paper on developments in the HIV epidemic within the Australian context and advances in HIV testing technology.

#### **2. Guiding principles of HIV testing**

AFAO advocates that the following principles must be central in any national HIV testing policy or guidelines.

- That HIV testing must be voluntary and undertaken with the full informed consent of the individual to be tested.
- That testing be available to those at risk of HIV infection

- That testing occurs in a sensitive and culturally appropriate manner and setting.
- That the pathology laboratory costs of HIV testing continue to be funded through the government health infrastructure.
- That testing occurs based on:
  1. Assessment of an individual's risk factors for HIV infection;
  2. Health and well being of the individual to be tested, particularly in hospitals or other health care sites;
  3. Availability of post testing support, care and treatment measures;
  4. Guarantee of full confidentiality;
  5. Continued legislative support for freedom from discrimination of HIV positive people;
- That in situations where HIV testing is mandatory, as for enlistment in the armed forces, that informed consent is obtained, pre and post test support and where appropriate counseling is provided, confidentiality of test results is maintained and that no discrimination occurs as a result of the test result.
- That routine screening for HIV of any group within the general community, for example pregnant women, prisoners or surgical patients, be recognised as being ineffective health policy and inefficient use of health funding. AFAO however acknowledges that HIV testing may be of benefit for individuals within these and any other societal groups providing that all the above listed guidelines are followed.

### **3. Informed consent and pre test discussion.**

AFAO believes the informed consent of the individual is fundamental to a legitimate and effective HIV testing process.

Revised HIV testing guidelines must affirm the need to gain the informed consent of the person being tested and the need to provide an adequate form of pre test discussion.

Typically informed consent should have been achieved during pre test discussion.

Pre test discussion should also incorporate an assessment of the risk of infection, an explanation of the testing process, and a discussion of the possible results and outcomes of the test.

While a requirement for pre test discussion has always been included in guidelines for HIV testing in Australia its interpretation and implementation has varied greatly.

The requirements of pre test counselling have changed through:

- Greater awareness and understanding of HIV, particularly amongst high prevalence communities.
- Developments in testing technology that have and may continue to change the methods and locations where tests are administered, by whom the tests are administered, and the means and timing of the delivery of test results.
- Time demands on GPs.

In testing sites such as sexual health centers and specialist HIV centers pre test counseling may be provided by trained counselors. In the majority of HIV tests however, this activity will be carried out by the doctor and in some cases, the nurse administering the test. In these situations time constraints and lack of training may result in the intended outcomes of pre test counseling not being achieved.

AFAO advocates that the current HIV Testing Guidelines be updated to include the following "Assessment of Understanding" in the section relating to pre test counseling/discussion.

AFAO believes that a step-by-step guide to the pre HIV discussion will be of assistance to practitioners of various disciplines in administering tests in a range of settings. AFAO recommends that the following, or similar, guide be included in the revised HIV Testing Policy.

### Pre HIV Test Discussion

#### **Step 1. Assessment of understanding of HIV/AIDS, modes of infection, outcomes of infection.**

##### Possible Actions.

Provide information.  
Move to step 2

#### **Step 2. Assessment of personal risk factors.**

- Activities, (timing, is PEP indicated)
- HIV sero-status of partner/s
- Possible co factors (other STIs)

##### Possible Actions.

Advise patient of assessment of risk and indicated need for testing.  
Desirability of undertaking course of PEP.  
Provision of information on avoiding risk in the future.  
Move to step 3.

#### **Step 3. Assessment of possible infection.**

- Physical symptoms.
- Sero-conversion illness.

##### Possible Actions.

Referral to a medical practitioner for a physical examination.  
Provide alternative diagnosis of symptoms.  
Move to step 4.

Step 4. Assessment of understanding of the ramifications of a positive test result.

#### **Possible Actions**

Explore treatment options.  
Discuss impact on relationships, lifestyle, sexual and injecting drug use practice etc.

**Step 5. Definite answer to the question.** “ Given what we’ve just discussed do you want to proceed with a test for HIV?”

### **Possible Actions**

Administer test or refer to medical staff to administer test.  
Provide written information on HIV, risk avoidance etc.

## **4. Combined antibody/antigen testing**

Combined testing for HIV refers to testing designed to locate and evaluate both HIV antibodies and particular viral antigens.

Antigen testing can identify HIV infection, on average, 4-5 days prior to the recognition of antibodies in a HIV antibody test. Combined antibody/antigen tests provide a more accurate indicator of HIV infection.

A significant benefit to combined antibody/antigen testing is the reduction of the ‘window period’ where antibodies to HIV infection may not have formed and where, in the absence of an antigen test, HIV will not be detected.

In situations where HIV sero-status is used as an element for the negotiation of unprotected sex within relationships, more accurate testing results confirmed within a shorter period of time will, AFAO believes, lead to a reduction in HIV infections.

Combined testing is currently used by all Government funded pathology laboratories when undertaking confirmatory testing.

AFAO believes that a standard protocol of HIV serology testing, incorporating both antibody and antigen testing should be implemented in all testing facilities in both public and privately administered laboratories.

## **5. Rapid Testing**

Rapid testing technology has improved considerably since 1998 when the ANCARD/IGCARD HIV Testing Policy was formulated.

At the current time rapid testing technologies have improved to the point where their specificity is equivalent to (or even higher than) currently used HIV testing. Their sensitivity is on the whole still slightly lower (but very close to) currently used HIV tests.

Given proper administration, a HIV negative result from rapid testing will be dependable whereas confirmatory testing must be done on any positive result, as is the case with conventional HIV testing.

Important potential issues regarding introduction of Rapid Testing include:

- i) *The need for rapid confirmatory testing.*  
Given that a positive screening test result will be given to a patient who will have to wait for a confirmatory result, it is important that confirmatory testing be done as quickly as possible.
- ii) *The appropriate settings to introduce rapid HIV testing.*  
In low prevalence settings, most positive screening results would be false positive results. Rapid HIV testing in high prevalence settings produces an

outcome very similar to current testing technologies. Therefore it may be less appropriate for rapid HIV testing to be introduced at the point of care for low prevalence settings.

- iii) *The impact on epidemiological data.*  
Because all HIV-positive tests would still require confirmation then collection of these data should not be affected. However, it would be harder to collect and/or estimate the number of HIV-negative test results.
- iv) *The technical and training issues associated with any introduction of rapid HIV tests.*  
Given the wider number of health care professionals who will be administering tests there will be a need for appropriate training in relation to how to administer the test and appropriate counselling protocols.

AFAO believes that Australians will benefit from the application of rapid testing for HIV. The use of rapid testing should be limited to point of care settings (that is, in medical settings). These settings must demonstrate appropriate quality assurances, meet data collection requirements, and be able to meet the guiding principles outlined in the HIV testing Policy.

After consideration of the opportunities and implications of rapid testing, and the experiences of rapid testing in other countries, AFAO believes that the introduction of a 'two tiered' system would be the most efficacious for the implementation of this technology in Australia.

This system would be comprised of a combination of rapid and conventional testing being offered upon indication, through assessment utilising an established criteria, in appropriate public clinic situations and through private practices.

This implementation of rapid testing would necessitate the development of criteria and guidelines to assist practitioners to decide what form of HIV test would be appropriate in a given situation. These criteria would incorporate an assessment of the level of risk and HIV prevalence. AFAO recommends the development of such guidelines and criteria.

## **6. Home Testing**

Home HIV testing is sometimes confused with rapid HIV testing. While home HIV testing often utilises rapid HIV testing technologies it is by definition administered in the home or some other non health care setting, by a non health professional who is often the person being tested.

Two types of HIV tests for home use are available and in use in some other countries. Examination of home-based testing issues should differentiate between:

- Test kits that produce results which are available to the user at the time of testing. These tests have been approved in approximately 30 countries.
- Test kits that operate as a home based specimen collection system where the specimen is then forwarded to a pathology lab for analysis and results returned to the user.

At present home HIV testing technology, whilst being available in the US and some other countries, has not been licensed by the Therapeutic Goods Administration (TGA) for production in or importation into Australia.

AFAO does not support licensing by the TGA of either type of home HIV test kit in Australia based on the following concerns:

- The elimination of a process of ensuring pre test understanding of HIV, the test, and possible results for the person undertaking the test.
- The possibility that, with a lack of understanding of the 'window period' for infection, negative test results will be utilized to facilitate the negotiation of unprotected sex amongst individuals.
- The possible mis-utilisation by elements in the Australian sex industry of home testing technology in order to facilitate unsafe practices.
- The separation of a possibly incorrect positive test result from a process of confirmatory re-testing.
- The creation of a situation whereby the recipient of a positive test result is removed from a clinical situation where information and advice regarding treatments, support and practices to prevent transmission of HIV are available.
- The undermining of the necessary epidemiological process of notification and surveillance of HIV infections across Australia.
- For type B test kits, the unreliability of samples provided by at least 10% of kits used in the USA, raises concerns regarding the ease of use and reliability of these kits.

## **7. Antenatal screening**

AFAO does not support across the board screening for HIV of all pregnant women within Australia.

Such a measure would be ineffective in meeting both the needs of the individual and the community in addressing HIV.

AFAO believes that a thorough 'at risk' history taking and where indicated an offer of HIV testing to pregnant women, rather than a comprehensive screening of all expectant mothers is a more effective way to address mother to child transmission.

AFAO recommends that the following should be included in the antenatal testing section of a reviewed National HIV testing document:

- Discussion of HIV and other tests should only then take place if indicated by a risk assessment.
- An appropriate assessment of understanding should be carried out and explicit consent received before proceeding with any testing.
- A plan for recommended support, care and treatment must be in place at the time that a positive result is delivered to a patient.
- Effective assessment of risk factors for HIV and other serious blood borne conditions should be included in the training provided to medical practitioners and obstetric nurses and counselors.

The funding costs associated with general screening of pregnant women for HIV with little epidemiological data to support it, and the high probability of such testing being carried out without informed consent, and without adequate processes in place to safeguard the well being of the women being tested, indicate to AFAO that such screening would be inappropriate and ineffective.

## **8. Informed Consent and antenatal testing.**

AFAO maintains a clear position on the necessity of obtaining informed consent prior to all HIV testing.

One particular area of HIV testing where it is reported that informed consent is frequently not being obtained is that of the testing of pregnant women.

Traditionally it has been customary for a doctor at this time to take blood and order a number of "routine" tests. It has become the practice of many doctors to also order tests for HIV antibodies as part of this routine.

It is important to differentiate between routine tests for conditions which carry very little impact, for example iron deficiency, and those with potentially more drastic outcomes such as testing for HIV infection.

The above listed process of HIV Testing Assessment of Understanding should be followed in all situations where testing is proposed including that of antenatal testing.

Where no discernible risk of HIV infection is assessed and the patient has not expressed any concern regarding HIV infection, HIV testing would be a waste of public health resources and possibly produce unnecessary anxiety for the pregnant woman.

In previous cases reported to AFAO, the emotional/psychological and social impact of a positive HIV diagnosis on women who had not realised they were even being tested has been considerable. Without the benefit of pre test risk assessment, discussion or counseling the trauma of a positive diagnosis is magnified dramatically. Were routine screening to become accepted practice it is likely that measures such as risk assessment, and pre test counseling would often be overlooked and such instances of disastrous "surprise diagnosis" would become more frequent.

## **9. HIV testing and the Australian sex industry**

AFAO maintains its established position that easy access to free and non-judgmental sexual health testing and treatment, provided and promoted in appropriate modes and locations, has been a key factor in the prevention of the spread of HIV through the Australian sex industry.

AFAO reasserts the following points in relation to HIV testing and the Australian Sex Industry.

- That HIV testing for sex workers must be voluntary.
- That the results of a sex worker's HIV test are confidential and remain the sole property of the sex worker concerned.
- That a sex worker who receives a positive result to a HIV test is entitled to the same support, care, treatment and protection under the law as other individuals.
- That sex industry owner/operators must never promote their employees as being HIV, AIDS or disease free.

As previously stated, AFAO does not support the licensing of home testing in Australia. One of the reasons for this is that home testing may be misused by owners/operators in the sex industry.

This may occur in the following ways:

- Sex workers receiving negative results to HIV home testing kits may be presented by owners/operators to potential customers as being 'HIV free', discounting the reality of the window period for infection.
- Sex industry customers may be offered home testing as a way for owner/operators to pressure workers to provide unsafe sexual services, again discounting the window period and the risk of infection for the worker.

## **10. Funding**

AFAO recommends that HIV testing and sexual health screening be funded under the long consultation schedule of Medicare fees to enable appropriate protocols to be followed (see 1.4)

Medicare coverage of the long consultation fees and pathology costs associated with breast cancer examinations and Pap smear testing offer a precedent to be adopted in this situation.

AFAO further recommends that in the interest of maintaining the confidentiality of the individual being tested there must continue to be no link between the coding of samples for testing and the Medicare identification number utilised by both the pathology laboratory and Medicare system.

AFAO  
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