

**Principles of consent, discussion and confidentiality
required of the diagnostic HIV test**

**Advisory Council on AIDS &
Scientific Committee on AIDS and STI (SCAS),
Centre for Health Protection,
Department of Health**

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Hong Kong Advisory Council on AIDS (ACA)

has the following terms of reference :

- (a) To keep under review local and international trends and development relating to HIV infection and AIDS;
- (b) To advise Government on policy relating to the prevention, care and control of HIV infection and AIDS in Hong Kong; and
- (c) To advise on the co-ordination and monitoring of programmes on the prevention of HIV infection and the provision of services to people with HIV/AIDS in Hong Kong.

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- (a) to advise the Controller of the Centre for Health Protection (CHP) on the scientific basis for the prevention, care and control of HIV/AIDS and STI in Hong Kong;
- (b) to develop recommendations and guidance regarding HIV/AIDS and STI in Hong Kong; and
- (c) to keep under review local and international development of HIV/AIDS and STI.

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Preface

These principles were jointly developed by Advisory Council on AIDS (ACA) and Scientific Committee on AIDS and STI (SCAS). Any comments and questions can be directed to the ACA/SCAS Secretariat at :

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Introduction

In Hong Kong, guidelines on consent for HIV (Human Immunodeficiency Virus) testing were previously published in 1993 for use with testing conducted for individual diagnosis.¹ Written in the era when HIV disease was highly stigmatising and without effective treatment, the guidelines positioned the HIV test as restrictive in nature and emphasised explicit informed consent.

2. In the interim, effective antiretroviral therapy, especially when started early, has transformed HIV disease from inevitable fatality to a manageable condition with markedly reduced morbidity and mortality. This success has been extended to prevention. Treatment to prevent mother-to-child transmission and occupational postexposure prophylaxis have become accepted, standard practice. Prevention programmes targeting HIV infected persons are also effective and recommended in the health care setting.²

3. These benefits, however, will not be realised unless one's HIV status is known early. For this reason, universal HIV screening is recommended and being done for such populations as antenatal women,³ patients with tuberculosis⁴ and sexually transmitted infections, and drug users attending methadone clinics.⁵ These programmes adopt an 'opt-out' approach for public health rationales and patient acceptance. This runs counter to one not uncommonly held notion that an HIV test has to be done with written consent and extensive pre- and post-test counselling.

4. Similarly, where clinical circumstances indicate the possibility of HIV, testing for HIV should not be discouraged because of the requirements of consent, discussion and confidentiality. It is therefore the intention of the Advisory Council on AIDS and the Scientific Committee on AIDS and STI to

¹ Department of Health. Guidelines on consent for HIV testing. Jan 1993. (Available at <http://www.info.gov.hk/aids/pdf/g12.pdf>. Accessed 24 May 2011)

² US CDC. Incorporating HIV Prevention into the medical care of persons living with HIV. MMWR 2003;52(RR12):1-24

³ PL Ho, KCW Chan, SSS Chiu, et al. Universal antenatal human immunodeficiency virus testing in Hong Kong: consensus statement. HK Med J 2001;7:421-7

⁴ Scientific Committee on AIDS and STI, CHP, Dept of Health. Recommendations on the management of human immunodeficiency virus and tuberculosis coinfection. July 2008. (Available at <http://www.info.gov.hk/aids/pdf/g202.pdf>. Accessed 24 May 2011)

⁵ Lee SS, Lee KCK, Wan WY, Wong KH. A urine-based approach to scale up HIV testing in drug users. AIDS 2006;20:1349-51

clarify the requirements of the HIV diagnostic test in the local context, in order to facilitate testing in the health care setting and the community. Both health care workers and personnel conducting community-based testing programmes are intended audience.

5. This document outlines the three overlapping requirements of HIV testing and describes the principles involved, with a view to helping health care services and community-testing programmes develop their own practice protocols.

- Informed consent – it is necessary for all diagnostic HIV tests. However, it does not have to be written or overly complicated. The consent is informed when a patient has balanced the benefits and harms of testing. Adequate explanation should therefore be given in this light. Certain ‘special’ situations are further discussed: the use of rapid test, consent of minors, and testing in the event of occupational exposure.
- Discussion before and after testing – it is part and parcel of informed consent. Common themes of discussion are cited for reference. However, the extent of coverage should be determined by a patient’s unique needs. The major principle is to allow ample opportunity for a patient’s concerns to be addressed.
- Confidentiality of results – given the stigmatising nature of an HIV diagnosis, confidentiality is especially important. Partner counselling and referral for HIV testing is voluntary and best done in experienced HIV clinics.

I. Informed consent

6. Diagnostic HIV testing is usually done by a screening blood test for HIV antibody, followed by a confirmatory test. However, tests using other methodologies or formats may be used with variable accuracies and are appropriate in certain circumstances. As long as the intent is to diagnose HIV infection, any test done, including CD4 cell enumeration,⁶ should be supported by informed consent.

⁶ Jansen LA. HIV exceptionalism, CD4+ cell testing, and conscientious subversion. *J Med Ethics* 2005;31:322-6

7. Pre-test informed consent respects patient autonomy, and is especially prudent considering the still stigmatising nature of an HIV diagnosis. There is no ‘standard’ format of informed consent. Rather, it should be tailored to the circumstances, the individual and the purpose of testing. In general, verbal consent suffices. The extent of documentation in a patient’s record will be governed by individual circumstances and institutional needs.

Benefits and concerns of testing

8. One usually gives or withholds consent based on the balance between the potential benefit and harm of knowing one’s HIV status. As such, it is important that information be given in such a way as to address one’s unique circumstances. Lengthy, comprehensive explanation in all aspects of the HIV test can be confusing rather than helpful.

9. An early diagnosis of HIV infection allows timely medical assessment, appropriate prophylactic measures and medical treatment. In Hong Kong, antiretroviral therapy is available. In those presenting with illness possibly related to HIV, ruling out or in the diagnosis greatly facilitates treatment and improves prognosis.

10. Awareness of one’s HIV diagnosis is also beneficial in family planning and adopting measures to prevent partner and mother-to-child transmission. Current and previous partners who may be infected or at risk could also be informed and referred for testing.

11. The stigmatising nature of HIV is a major reason why some people are reluctant to be tested. In this regard, it is helpful to explain how the result will be delivered and handled, and how confidentiality is maintained. In the health care setting, reassurance of equal access to care is important. The ramification of being HIV positive in the social context may be important to some. In Hong Kong, the law protects against discrimination of HIV infected persons in the workplace.⁷

Rapid HIV test

⁷ Disability Discrimination Ordinance. (Available at <http://www.hkllii.org/hk/legis/en/ord/487/>. Accessed 24 May 2011)

12. Rapid HIV testing provides results in minutes and can be done at the point of care. It is potentially advantageous in the following circumstances:⁸

- Late-presenting pregnant women
- Testing of source patients after occupational exposure
- Outreach settings where conventional HIV testing may not reach certain vulnerable populations, e.g. drug users, sex workers or men who have sex with men
- Settings with high rates of default

13. Most commercially available rapid tests do not test for HIV antigen and hence the window period may be longer. Being an ELISA test, a positive rapid test will also have to be confirmed by a specific test. A negative test, however, may be communicated to the patient as such, but will need to be repeated if the window period is a concern.

Minors and lack of capacity

14. Informed consent is sought from the parent or guardian when the subject is a small child or a mentally incompetent person unable to give consent on his own. However, it is necessary to ensure that consent in this context be based on the best interests of the subject, and not those of the person giving consent.

15. The capacity of a minor under 18 years of age to give consent on his own depends on his ability to understand the nature and implications of HIV testing and to weigh up options. Thorough explanation and discussion would be necessary to ensure that the minor has this capacity.

HIV testing of source after occupational exposure

16. Protection from HIV transmission in the health care setting is best provided by Standard Precautions and not by pre-exposure HIV testing.⁹ Upon occupational exposure, treatment may be prescribed according to the extent of

⁸ KCW Chan. Diagnosis of HIV infection. In Lee SS, Wu JCY, Wong KH (eds). HIV Manual 2007. (Available at <http://www.info.gov.hk/aids/pdf/g190htm/index.htm>. Accessed 24 May 2011)

⁹ Scientific Committee on AIDS and STI, Advisory Council on AIDS, CHP. Recommendations on infection control practice for HIV transmission in health care settings. Jan 2005. (Available at <http://www.info.gov.hk/aids/pdf/g139.pdf>. Accessed 24 May 2011)

exposure and the likelihood of a positive source.¹⁰ Testing of the source may offer helpful information by supporting immediate treatment if it is positive. Of note, the window period is of real concern and history may not be available or reliable to rule this out. Therefore, a negative test does not automatically rule out the need of treatment.

17. As a patient enters the doctor-patient relationship expecting medical care for himself, implied consent cannot be assumed for undergoing an HIV test after becoming the source in an occupational exposure of a health care worker. Without consent, conducting an HIV test in this circumstance may constitute interference with the patient's privacy which is protected by law.¹¹ The case is also fundamentally different from that of an incapacitated patient who will potentially benefit from improved medical care as a result of knowing his HIV status.¹²

18. Informed consent has to be obtained in this situation and is preferably obtained by another member of the care team rather than by the exposed health care worker whose identity, if possible, should not be exposed. Consent is rarely refused. If refused, the underlying reasons should be explored and addressed. For a source patient who lacks capacity to give informed consent, it is best to base management of the occupational exposure only on its extent and the likelihood of a positive source as aforementioned.

II. Discussion

Pre-test discussion

19. Full pre-test discussion may include HIV prevention, testing characteristics, treatment, and confidentiality, as summarised in Appendix. However, discussion need not be tedious. Rather, it should be individualised, interactive and non-coercive. Very often, the scope depends on testing circumstances. Provider-initiated testing based on clinical symptoms and signs should focus on treatment and prognosis. Community-based screening programme may focus on early diagnosis and care, as well as HIV prevention.

¹⁰ Scientific Committee on AIDS and STI, and Infection Control Branch, CHP, DH. Recommendations on the postexposure management and prophylaxis of needlestick injury or mucosal contact to HBV, HCV and HIV. Sep 2007 (Available at <http://www.info.gov.hk/aids/pdf/g198.pdf>. Accessed 7 Jun 2010)

¹¹ Article 14 of the Hong Kong Bill of Rights; Articles 17 and 22 of the United Nations Convention on the Rights of Persons with Disabilities

¹² Halpern SD. HIV testing without consent in critically ill patients. JAMA 2005;294:734-7

Regardless, whoever conducts the discussion should have recourse to experts if he feels inadequate in addressing all questions raised. In Hong Kong, the Government's AIDS hotline (2780 2211) is a commonly used resource in this situation.

20. Testing programmes in the health care setting may be 'opt-in', in which patients have to specifically agree to HIV testing, or 'opt-out', in which patients have to specifically disagree. As such, they may differ in the way of administration but should both abide by the same principles with the same end result: an informed decision to accept or decline the health care provider's recommendation of an HIV test.¹³ It is important that 'opt-out' testing programmes do not neglect to inform subjects that an HIV test will be done, explain the test verbally or with written materials, allow questions and refusal in private, treat patient information in confidence, and refer to experts when necessary.

Post-test discussion

21. There is no place for withholding results after an HIV test. Although delivery over the phone or by written letter may be acceptable for a negative result, it is desirable to deliver results face-to-face, especially when

- the result is positive or equivocal,
- the subject may be in the process of seroconversion and therefore need further assessment and testing
- there is mental health issue or risk of suicide, or
- specific request of such has been made.

22. Results should be explained carefully to avoid misunderstanding. Questions are answered truthfully and sympathetically. Especially for those who have tested positive, concerns about prevention, care and support should be addressed. In particular, a clear pathway for referral to an HIV specialist should have been established.

23. Partners who have shared risk with an HIV positive patient should be

¹³ WHO, UNAIDS. Guidance on provider-initiated HIV testing and counseling in health facilities. May 2007 (Available at http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2007/20070530_testing_counsellig_guidance.asp. Accessed 24 May 2011)

identified, counselled on risks of infection and referred for testing. This process of partner counselling and referral is voluntary, sensitive and is usually supervised by experienced health care providers of HIV clinics. The principles involved in the process have previously been addressed.¹⁴

III. Confidentiality

24. Information provided in a doctor-patient relationship is medically privileged.¹⁵ This is the basis for trust which makes quality care possible. By all means, a patient's HIV test result should be kept confidential. In the age of electronic medical record, heightened information security is crucial in preventing inadvertent disclosure.

25. Unless there is consent by the patient, it is inappropriate to disclose his test results to a third party other than the patient himself. In the event that the patient has lost mental capacity to comprehend such results and health care decisions based on HIV status need to be made, the guardian, if available, should be informed and guided to make decision for the best interests of the patient. In the absence of a guardian, the doctor may proceed with treatment that is necessary and beneficial to the patient.

26. In the attempt to identify at risk partners for counselling and testing, the question may also arise as to whether involuntary disclosure is necessary in order to protect a third party at risk. In this regard, general guidance is provided by the Medical Council of Hong Kong.¹⁶ Each case should also be examined carefully on its own merits and referred to the institutional ethics committee (or its equivalent) before any decision is made to breach confidentiality.

IV. Community-based testing

27. HIV test is not only done in the health care setting but also in the community. Voluntary counselling and testing that is client-initiated is well

¹⁴ Committee on Promoting Acceptance of People Living with HIV/AIDS of the Hong Kong Advisory Council on AIDS. Recommended Ethical Principles on Partner Counselling and Referral for HIV Infected Individuals in Hong Kong. Nov 2004 (Available at <http://www.info.gov.hk/aids/pdf/g135.pdf>. Accessed 24 May 2011)

¹⁵ World Medical Association. Declaration of Geneva (1948)

¹⁶ Medical Council of Hong Kong. Code of Professional Conduct, Section 1.4 'Disclosure of medical information to third parties' Jan 2009 (Available at http://www.mchk.org.hk/Code_of_Professional_Conduct_2009.pdf. Accessed 24 May 2011)

established in Hong Kong and is conducted by both governmental and non-governmental agencies. Outreach programmes that target populations at risk have also become an integral part of the local HIV prevention programme.

28. The requirements of informed consent, discussion and confidentiality apply equally to these community-based testing programmes. Furthermore, as with the health care setting, these programmes should be quality-assured.¹⁷ Personnel conducting the HIV test, however, need not be health care workers as long as they abide by its requirements. In fact, for both public and individual health reasons, broad testing in the community should be encouraged nowadays.

¹⁷ Community Forum on AIDS, Hong Kong Advisory Council on AIDS. Quality assurance guidelines on HIV voluntary counseling and testing services in outreach settings. July 2009 (Available at <http://www.info.gov.hk/aids/pdf/g211.pdf>. Accessed 24 May 2011)

Appendix

Common themes of discussion in diagnostic HIV test¹⁸

Theme	Remarks
The HIV test, its benefits and consequences	Testing characteristics such as sensitivity and specificity, the voluntary nature of testing, and the principle of confidentiality should be explained. All questions raised by the subject should be conscientiously answered. He/she should be assured that no discrimination in medical care would result.
Risk assessment and knowledge of how HIV can be prevented	These are important as a public health measure to reduce the prevalence of high-risk behaviour. Especially for those who test positive, they should be made aware of the need to inform others at risk, such as their sexual partners and those who shared their injecting equipment
Importance of obtaining test results	In the conventional two-step testing approach where subjects are seen twice (for testing and for retrieving results), a significant minority do not return. This problem may be partially addressed by the use of rapid test.
Meaning of test results	A positive rapid test result would need to be confirmed; the existence of a window period means that the subject who has exhibited risk behaviour recently should be retested later despite a negative test. Retesting is advised in about three months. For those at high risk, retesting earlier than 3 months should be considered
Referral for HIV care* and support	Referral and its mechanism shall be made known to the tested person, in the event a positive result is obtained. Referral to other medical specialists or psychologists may also be necessary.
Further information	General information source includes that provided by the Department of Health (AIDS hotline: 2780 2211; http://www.aids.gov.hk)

*As of 2011, there are three designated HIV clinics in Hong Kong

- Integrated Treatment Centre (Tel: 2117 0896), 8/F Kowloon Bay Health Centre, 9 Kai Yan St, Kowloon Bay, Kowloon
- Special Medical Clinic, Queen Elizabeth Hospital (Tel: 2958 6571), 6/F Ambulatory Care Centre, 30 Gascoigne Road, Kowloon
- Infectious Disease Special Medical Clinic (Tel: 6461 0613), 4/F, Block K, Princess Margaret Hospital, 2-10 Princess Margaret Hospital Road, Lai Chi Kok, NT

¹⁸ Adapted from: Chan KCW. Diagnosis of HIV infection. In (eds) Lee SS, Wu JCY, Wong KH. HIV Manual 2007. (Available at <http://www.info.gov.hk/aids/pdf/g190htm/index.htm>. Accessed 24 May 2011)

