World Health Organization

Delivering HIV test results

and messages for re-testing and counselling in adults

It is anticipated that the recommendations in this document will remain valid until 2012. The HIV/AIDS Department at WHO headquarters in Geneva will be responsible for initiating a review of this document and its recommendations at that time.

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Contents

Abbreviations

AIDS	acquired immune deficiency syndrome
ANC	antenatal clinic
CDC	Centers for Disease Control and Prevention
CITC	client-initiated HIV testing and counselling
HIV	human immunodeficiency virus
MSM	men who have sex with men
MTCT	mother-to-child transmission (of HIV)
PEP	post-exposure prophylaxis
PEPFAR	US President's Emergency Plan for AIDS Relief
PITC	provider-initiated HIV testing and counselling
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	voluntary counselling and testing
WHO	World Health Organization

Terminology

Acute HIV infection – Acute human immunodeficiency virus (HIV) infection is a highly infectiou phase of disease that lasts approximately two months and is characterized by nonspecific clinical symptoms. Acute HIV infection contributes disproportionately to HIV transmission because it is associated with a high level of viraemia. HIV infection may not be detected on HIV assays that employ antibody detection only. Persons who are in the phase of acute HIV infection often have flu-like symptoms, and may be more infectious than persons with chronic HIV infection.

Client-initiated HIV testing and counselling – a type of HIV testing and counselling in which persons actively seek HIV testing and counselling, often at a facility that offers these services.

Concentrated HIV epidemic – HIV has spread rapidly in a defined subpopulation, but is not well established in the general population. This type of epidemic suggests active networks of people with high-risk behaviours within the subpopulation. The future course of the epidemic is dete mined by the nature of the links between subpopulations with a high HIV prevalence and the general population. Numerical proxy: HIV prevalence is consistently over 5% in at least one defined subpopulation but is below 1% in pregnant women attending antenatal clinics.

Discordant test results – when one HIV test result in an individual is reactive and another test result using a different HIV assay in the same individual is non-reactive

Generalized HIV epidemic – HIV is firmly established in the general population. Although subpopulations at high risk may contribute disproportionately to the spread of HIV, sexual networing in the general population is sufficient to sustain the epidemic. Numerical proxy: HIV prevalence is consistently over 1% in pregnant women attending antenatal clinics.

Key populations at higher risk of HIV exposure – persons likely to be at higher risk of HIV exposure because of behavioural risk factors including people who inject drugs, and their sex partners; persons who provide sex in exchange for money, goods, drugs or other benefits (sex workers), drugs or other advantages; sex partners of HIV-infected persons; and men who have sex with men (MSM). Persons at high risk may also include heterosexual persons who have engaged in unprotected sex or have had sex with someone who has engaged in unprotected sex since thei most recent HIV test.

HIV-indeterminate status – the HIV status of an individual in whom the test results can lead to a definitive diagnosis, meaning that no clear HIV status (either HIV positive or HIV negative) can be assigned.

HIV testing algorithm – Algorithms are defined as the combination and sequence of specific assays used in HIV testing strategies.

Low-level HIV epidemic – HIV may have existed for many years, but has never spread to substatial levels in any subpopulation. Recorded infection is largely confined to individuals with higher-risk behaviour, e.g. sex workers, people who inject drugs and MSM. Numerical proxy: HIV prevalence has not consistently exceeded 5% in any defined subpopulation or 1% in pregnant women attening antenatal clinics.

Non-reactive – refers to an HIV antibody or HIV antigen/antibody test result that does not show a reaction to indicate the presence of HIV antibody and/or antigen

Partner – a person with whom an individual has had sex at least once or with whom the individual shares injecting equipment

Provider-initiated HIV testing and counselling – HIV testing and counselling that is recommended by health-care providers to persons attending health-care facilities as a standard component of medical care

Reactive – refers to an HIV antibody or HIV antigen/antibody test result that shows a reaction to indicate the presence of HIV antibody and/or antigen

Repeat testing – refers to a situation where additional testing is performed for an individual immediately following a first test during the same testing visit due to inconclusive or discordant test results; the same assays are used and, where possible, the same specimen.

Re-testing – refers to a situation where additional testing is performed for an individual after a defined period of time for explicit reasons, such as a specific incident of possible HIV exposure within the past three months, or ongoing risk of HIV exposure such as sharing injecting equipment. Re-testing is always performed on a new specimen and may or may not use the same assays (tests) as the one at the initial test visit.

Sensitivity – the probability that an HIV test will correctly identify all individuals who are infected with HIV

Seroconversion – when a sufficient quantity of HIV antibodies are produced by an individual to become detectable on a given HIV antibody and/or antigen assay

Specificity – the probability that an HIV test will correctly identify all individuals who are not infected with HIV

Trimester – three-month intervals of a woman's pregnancy. The first trimester is the period of pregnancy from the first day of the last normal menstrual period through the completion of 14 weeks gestation. The second trimester is the period of pregnancy from the beginning of the 15th through the 28th week of gestation. The third trimester is the period of pregnancy from the beginning of the 29th through the 42nd completed week of gestation.

Window period – the period of time from when a person is suspected to have been infected with HIV to when HIV antibodies can be detected by a given assay. The window period varies from person to person, and also depends on the assay used. The mean time from exposure to development of antibodies is about one month. Most people (95%) will develop detectable antibodies by 3–4 months.[1, 2]

1. Purpose and objectives of the guidance

These recommendations focus on **re-testing** for HIV. This document is intended to inform a diverse audience including HIV policy-makers, HIV testing and counselling and national AIDS programme managers, site managers, trainers and HIV testing and counselling providers. HIV testing and counselling settings in which this document can be applied are varied and include but may not be limited to: the public and private sectors, provider-initiated HIV testing and counselling (PITC) settings (i.e. any medical setting, e.g., antenatal clinic, labour and delivery room, maternal and child health clinics, tuberculosis (TB) clinics, sexually transmitted infections (STI) clinic, inpatient ward and outpatient clinics), drug treatment clinics, and community-based programmes such as client-initiated testing and counselling (CITC) facilities (sometimes referred to as VCT* centres), other CITC settings such as mobile testing sites and other outreach settings. The recommendations should serve as an additional HIV testing and counselling resource to complement the WHO/UNAIDS (2007) *Guidance on provider-initiated HIV testing and counselling in health facilities*.[3]

This guidance is intended to clarify and strengthen messages about re-testing for persons who have HIV-indeterminate or non-reactive HIV test results. However, they are not intended to replace a post-test counselling protocol, which should include appropriate prevention messages and supportive counselling, and referrals to prevention, care, treatment and support services. They also do not replace recommendations or other HIV testing guidance on initial HIV testing.3 HIV testing opportunities for persons of unknown status or persons at ongoing risk of acquiring HIV should be maximized according to standard WHO protocols.

The main objectives are:

1. to explain why it is not advisable to recommend re-testing for HIV for all populations and in all settings,

2. to clarify the specific populations and settings in which persons who have previously tested HIV negative can benefit from re-testing after a given time period,

3. to provide the timeframe for re-testing when it is indicated by population and setting, and

4. to illustrate these scenarios with messages that can be used by providers to educate individuals at the time of the HIV test.

* WHO favours the term 'client-initiated testing and counselling' in place of 'voluntary counselling and testing' or VCT. All HIV testing on public health grounds must be voluntary, whether client-initiated or provider-initiated.

It is anticipated that clarifying when re-testing is ***warranted*** and when it should be ***discouraged*** may help:

- to limit unwarranted testing and unnecessary use of personnel and resources;
- to foster early detection of HIV infection among persons at ongoing risk for HIV or among persons with a recent HIV exposure;
- to enhance earlier referral to prevention, care, treatment and support for persons newly identified as being HIV positive.

This document does not discuss re-testing for HIV-positive individuals. Persons who have had a positive HIV test result should be immediately referred to a health facility where their HIV status will be verified by testing performed on a second specimen. Other tests, such as measurement of the level of CD4+ T cells or HIV viral load may be performed to evaluate the need for antiretroviral therapy.

2. Review of the evidence

The recommendations presented in this document are based on a thorough review and examination of the evidence. A comprehensive literature review was carried out in 2008. Data were identified by searches of electronic library and HIV databases, websites of government and nongovernmental bodies, conference abstracts, as well as by examination of relevant peer-reviewed articles. Studies and other materials reported in English were reviewed. Out of over 900 studies examined, and eight WHO global, regional and country guidelines, 22 provided information relevant to this document. These included a small number of studies that examined the characteristics of HIV antibody tests, methods for identifying early HIV infection such as, individual or pooled nucleic acid amplification tests (p-NAAT), and characteristics of re-testers. Information and guidance on messages for recommending re-testing were obtained through informal discussions with managers and counsellors in HIV testing and counselling programmes from the following countries: Viet Nam, Lesotho, Kenya, Botswana, Bangladesh and Zimbabwe, as well as from the published studies cited in this document, where applicable.

Consultations were undertaken on the delivery of HIV test results and counselling messages for adults. The proposal for drafting guidance to clarify counselling messages on re-testing for HIV-negative individuals was carried forward at a meeting of HIV testing and counselling experts held at the WHO offices in Geneva in 2007. Technical HIV testing and counselling experts at this meeting discussed the content of the proposed guidance, questions to inform guidance development and potential recommendations.

An additional meeting was held in Atlanta, Georgia in April 2008 for presenting evidence from leading HIV testing and counselling and mother-to-child-transmission experts and further discussing the scope of the guidelines. The core working group also produced the first draft of the guidance at this meeting. The working group further developed the draft guidelines and presented it at the HIV Counselling and Testing Working Group of the President's Emergency Plan for AIDS Relief (PEPFAR) and implementing partners at the 2008 US PEPFAR HIV/AIDS Implementer's Meeting held in Kampala, Uganda. Feedback from this initial presentation was received and incorporated into the second draft. In August 2008, a team again presented the guidance at the 2008 International AIDS Conference in Mexico City and received further feedback.

The core working group received formal feedback from HIV testing and counselling providers in September 2008. In October 2008, the most current draft was sent to HIV testing and counselling focal persons at WHO offices in five countries who facilitated meetings to discuss the guidance with HIV testing and counselling providers in a variety of settings (e.g. provider-initiated and client-initiated sites, urban and rural sites). A facilitation guide and a feedback template, along with nine case scenarios were sent to the HIV testing and counselling focal persons. Providers were asked to apply the guidelines to the scenarios.

Other comment was sought from the HIV testing and counselling experts who were involved in the early stages of development of this guidance, but who were not in the continuous working group. In early October 2008, this guidance was sent to all participants of the April 2008 meeting for peer review. Feedback was received and incorporated into a revised version. The WHO Guidelines Review Committee approved it in January 2009. Additional input prior to publication was received from WHO technical experts in the areas of sexually transmitted infections (STI), tuberculosis (TB) and HIV/TB.

3. Need for this guidance

Global guidance on HIV testing and counselling requires regular updating from the rapid scale-up of these services in recent years, emerging data, and the introduction of highly sensitive and specific HIV testing technologies. Moreover, there has been an increase in HIV testing performed outside of traditional laboratory settings such as through community outreach (e.g. home visits through community midwives for antenatal care, or other primary health care workers, mobile van testing or other home-based testing and counselling programmes) and as a result of improvements in access to care and treatment programmes in many parts of the world.

There is a need to reduce unnecessary re-testing among persons who have previously been tested and learnt their results.[4] As HIV testing and counselling is scaled up, routinely recommending re-testing when it is not warranted will burden personnel and deplete resources.

Most persons do not require re-testing to validate an HIV-negative result. However, it is important to accurately identify persons who do require re-testing. Such persons include those whose initial test results were indeterminate, those who tested negative but are at ongoing risk for acquiring HIV (e.g. due to high-risk behaviours) and those who may be in the early stages of infection and have not yet developed a sufficient level of antibodies that can be detected by serological testing ('window period').

Since HIV testing and counselling programmes began in the mid-1980s, counsellors and health-care providers have been trained to explain the window period to all individuals. In some settings, HIV-negative persons are encouraged to return for re-testing in three months, only if they have experienced an HIV exposure risk in the previous three months. However, in many settings, all persons who are tested are recommended to return in three months whether they have experienced a risk or not. These differences in re-testing messages can lead to confusion. There are several important areas of innovation to note when clarifying re-testing messages:

1. Current HIV rapid serological assays (antibody and/or antibody/antigen detection): Given a functional quality assurance system, and adequate training of assay operators, the currently available robust and easy to use HIV tests[5] will identify nearly all persons who are truly negative; therefore, another test is not required to validate their results. Although providers may perceive re-testing as an opportunity to engage persons in prevention counselling, this wastes testing resources and places the encounter's focus on the test, rather than on discussing risk reduction strategies.[4, 6, 7, 8, 9, 10] ***Re-testing is recommended for diagnostic purposes***.

2. Acute HIV infection: Operator (tester) error is more likely to be the cause of a false-negative test result rather than a recent but undetectable infection.[11] However, recent acquisition of HIV infection, also known as ***acute HIV infection***, may also produce a false-negative test result.[11, 12] False-negative results due to acute HIV infection are more likely

to occur in high-incidence settings among persons engaging in high-risk behaviours.[13, 14, 15]

Individuals with a specific incident of HIV risk in the previous three months, or who have indeterminate status should be considered a potential case of acute HIV infection. These persons should be counselled, with an emphasis on helping the individual understand the need to engage in safe behaviours and to return for further testing. The importance of clear results must be underscored due to acute HIV infection's characteristic period of high viral load and potentially greater infectivity as compared with the chronic phase of the infection.[2, 16] The post-test counselling message should emphasize reducing the risk of HIV transmission and minimizing loss to follow-up.

Although re-testing was addressed in the *Guidance on provider-initiated HIV testing and counselling in health facilities*,[3] the challenges outlined above warrant addressing the topic in greater detail to improve the delivery and accuracy of HIV test results and messages for re-testing and counselling in adults.

The document and its recommendations reflect WHO's commitment to improve and expand HIV testing and counselling programmes, and thereby enable people to learn their HIV status. Countries should adapt current HIV testing and counselling guidance to reflect new recommendations on re-testing to improve access to HIV testing and counselling as a first step towards linking people living with HIV to HIV prevention, treatment, care and support.

4. Recommendations for re-testing

At the time of the initial test encounter, most individuals should not receive a recommendation to verify an HIV-negative result.

4.1 Situations and settings where re-testing is warranted in all epidemic types

1. *If an individual has previous or ongoing risk for HIV infection* (i.e. persons who currently inject drugs, sex workers, or men who have sex with men; having a high-risk or known HIV-positive partner; having clinical indications for re-testing such as newly acquired sexually transmitted infections [STI])

OR

2. *If an individual can identify a specific incident of HIV exposure in the three months prior to HIV testing* (i.e. history of occupational exposure, unprotected sex with a known HIV-positive person, sharing injecting equipment with a known HIV-positive person).

If an individual receiving an HIV-negative test result fits into either of the above categories, then that individual should be asked to come back for re-testing. The person should be provided with post-test counselling messages appropriate for HIV-negative persons, as per the site's standard protocol for HIV testing and counselling.

HIV-negative persons should be advised that if they have a specific incident of known or suspected HIV exposure in the future then they should return for an HIV test following that exposure. Additionally, if persons begin or resume engaging in HIV risk-related behaviours, they should be recommended to re-test at least annually. Pregnant women in a generalized epidemic setting should be recommended to re-test in her third trimester (see Specific situations). Finally, persons should be told that if they receive health-related services from other facilities, they may be advised to receive another HIV test and counselling in those settings in the future. This is done to ensure correct documentation of HIV status.

SUMMARY

Re-testing is ***recommended*** for persons with an HIV-negative test result who:

1. Have ongoing HIV risk behaviours;
2. Can identify a specific incident of HIV exposure in the past three months
3. Is a pregnant woman in a generalized epidemic setting

4.2 Specific situations

4.2.1 Based on an indeterminate HIV status

1. *Persons with discordant test results* may have acute HIV infection, especially in high-incidence settings.[13, 14] However, discordant test results are more often the result of random or systematic laboratory error, or due to the intrinsic properties of the assay. All HIV testing should be performed in accordance with the HIV test kit package insert and site-developed standard operating procedures to eliminate possible testing errors. In the rare event that the results of an HIV test are discordant, the same assays should be repeated immediately to exclude error while the individual is still at the testing site. The same testing algorithm should be used for the immediate repeat testing, and standard operating procedures should again be followed to minimize error. It may also be necessary to have a more experienced HIV testing and counselling provider at the testing site perform the repeat testing.

   If the results of the tests remain discordant, the individual should be retested **after two weeks using the same testing algorithm**. It is important to re-test after two weeks; as persons who have recently acquired HIV are likely to have detectable antibodies to HIV by then.

4.2.2 Based on population and setting

2. *Pregnant women testing HIV negative in their first or second trimesters of pregnancy in settings with generalized epidemics*: In order to prevent mother-to-child transmission (MTCT) of HIV, pregnant women should be tested **as early as possible** in each pregnancy. Women who test HIV negative in their first or second trimesters of pregnancy should be recommended to return for another HIV test in their **third trimester** of pregnancy, preferably between the 28th and 36th weeks.[17] In the event that a woman does not return for testing during her third trimester, she should be recommended to test at labour or, if that is not possible, immediately after delivery. Refer to the *Guidance on global scale-up of the prevention of mother-to-child transmission* for additional information on maternal and infant testing.[18]

3. *HIV negative persons testing in specific clinical settings (i.e. STI, TB, or outpatient clinics)*: Individuals seen for a diagnosis or treatment of STIs, for TB patients with a new potential HIV exposure or who are at higher risk of HIV exposure, outpatients with clinical conditions suggestive of HIV infection with an HIV negative test result should be re-tested after four weeks from the time they were initially tested. Individuals with STIs should be recommended to be re-tested for HIV and counselled with each new STI diagnosis.

4.2.3 Based on risk

4. ***HIV negative persons with ongoing risk behaviours***: persons who inject drugs, MSM, sex workers, persons with a known HIV-positive partner, and persons with a partner of unknown HIV status should be tested for HIV at least **annually** and provided with their respective population-appropriate risk reduction counselling.

5. ***HIV negative persons who have had a specific incident of known HIV exposure within the past three months***: Persons with known HIV exposure who test HIV negative at the first HIV testing encounter following the incident (i.e. sex with a known HIV-positive person, and/or sharing of injecting equipment with a known HIV-positive person) warrant re-testing after 4 weeks from the time of the initial test to ensure that they are truly HIV negative.

6. ***HIV negative persons who have had a specific incident of possible HIV exposure within the past 72 hours***: Baseline HIV testing and counselling should always be recommended to persons who have experienced sexual violence or an occupational exposure. This should be included as part of a post-exposure prophylaxis (PEP) service package according to national or local protocols, and is meant to establish baseline HIV status of the individual who may have been exposed. For further information about PEP, please see *Post-exposure prophylaxis to prevent HIV infection*.[19]

   Re-testing: If PEP is not available, persons with a possible HIV exposure who test HIV negative at the first HIV testing encounter following the incident (i.e. sexual violence/rape or occupational exposure) or who have an indeterminate HIV status warrant re-testing after four weeks, and if still negative, at 12 weeks to ensure that they are truly HIV negative as a result of that exposure.

   In persons who have been exposed to PEP (i.e. prescribed PEP due to sexual violence/rape or an occupational exposure), the production of antibodies to HIV may be affected and, in some cases, the time to development of a full antibody profile. For further information on when re-testing should occur in persons receiving PEP, please see *Post-exposure prophylaxis to prevent HIV infection*.[19]

SUMMARY FOR SPECIFIC SITUATIONS

Re-testing is ***recommended*** for persons who:

1. Have an indeterminate HIV status;

2. Are pregnant women in the setting of a generalized epidemic, who have tested HIV negative in the first or second trimester of pregnancy;

3. Have an STI;

4. Are outpatients with clinical findings suggestive of HIV;

5. Have continuing or ongoing risk of acquiring HIV;

6. Have specific incidents of known HIV exposure within the past three months;

7. Received an HIV-negative test result on a baseline HIV test for an incident of possible HIV exposure in the past 72 hours; in this case, and if PEP has not been initiated, re-test at 4 weeks after exposure, and if the results are still negative or discordant, the person should be re-tested again at 12 weeks after exposure.

5. Annexes

Annex 1. Re-testing for HIV-negative individuals: guidance tables

Tool 1: Tables for HIV testing and counselling managers

Use the following tables 1 and 2 to determine which persons should be recommended to return for re-testing in your setting. The tables are structured to reflect the different settings in which HIV testing and counselling may occur.

How to use these tables

1. **Select the table** that corresponds to the type of epidemic in the geographical location or facility in which you are working (Table 1: Low-level or concentrated epidemic; Table 2: Generalized epidemic). Definitions of each type of epidemic are provided in the Terminology section of this document.

   Please recall that HIV prevalence can vary widely between geographical locations and facilities within the same country. For example, one province's HIV prevalence may be much lower than the country's national HIV prevalence. Or, the HIV prevalence in an STI clinic may be much higher than that in the general population.

2. **Select the relevant setting or situation.**
   - PITC settings (i.e. any medical setting: e.g., antenatal clinic, labour and delivery room, maternal and child health clinic, TB clinic, STI clinic, inpatient ward and, outpatient clinics.
   - Other situations (i.e. individual has known HIV-positive partner, individual is at higher risk for acquiring and transmitting HIV presenting in any setting, e.g. is a sex worker, person who inject drugs, MSM, is a pregnant woman in a generalized epidemic).
   - Note that if the individual is in a high-risk category, regardless of the setting in which she or he may present, the re-testing recommendations corresponding to that individual's high-risk category should be recommended.

3. **Look across the row to find out if re-testing is required, and when.**

4. **Advise your HIV testing and counselling service providers about which groups need re-testing, and when.**

Table 1. Re-testing for HIV-negative individuals in the context of a *low-level or concentrated* epidemic

Setting	Re-testing recommended?	When to re-test?	Future re-testing recommended?
Antenatal clinic, labour and delivery room, maternal child health clinic	No	-	Yes – with each new pregnancy or if individual is in a high-risk category*
TB clinic	No	-	No – unless new potential exposure, or individual is in a high-risk category*
STI clinic	Yes	-	Yes – with each new STI or if individual is in a high-risk category*
Inpatient ward	No	-	No – unless new potential exposure or individual is in a high-risk category*
Outpatient clinic	No	-	No – unless individual is in a high-risk category*

*See situation table below for what constitutes a high-risk category.

Situation	Re-testing recommended?	When to re-test?	Future re-testing recommended?
Indeterminate HIV status	Yes	Repeat the test immediately using the same specimen and testing algorithm.	If still discordant, re-test in 2 weeks
Partner status unknown; low-risk partner	No	-	No
Partner status unknown; high-risk partner*	Yes (new patient or clients only)	4 weeks	Annually—if sexual relationship is ongoing
Known HIV-positive partner*	Yes (new patients or clients only)	4 weeks	Annually—if sexual relationship is ongoing
Sex worker, male or female*	Yes (new patients or clients only)	4 weeks	At least annually
Person who currently injects drugs*	Yes (new patients or clients only)	4 weeks	At least annually
Men who have sex with men* and transgendered individuals	Yes (new patients or clients only)	4 weeks	At least annually
Post-sexual violence/rape	Yes, if baseline HIV test was negative, or if first HIV test following the encounter was negative or status was indeterminate; see *WHO/ ILO PEP guidelines*[19]	4 and 12 weeks	No
Occupational exposure	Yes, if baseline HIV test was negative, or if first HIV test following the encounter was negative or status was indeterminate; see *WHO/ ILO PEP guidelines*[19]	4 and 12 weeks	No
Negative HIV test in past 3 months	No	-	No
No possible HIV exposure in past 3 months	No	-	No

* Denotes high-risk category

Table 2. Re-testing for HIV-negative individuals in the context of a generalized epidemic

Setting	Re-testing recommended?	When to re-test?	Future re-testing recommended?
Antenatal clinic, maternal child health clinic, labour and delivery	Yes	Third trimester; if not re-tested in third trimester, at labour and delivery or as soon as possible thereafter	Yes – with each new pregnancy
TB clinic	No	–	No, unless new potential exposure; or if individual is in a high-risk category*
STI clinic	Yes	4 weeks	Yes—with each new STI; or if individual is in a high-risk category#
Inpatient ward	No	–	No—unless new potential exposure; or if individual is in a high-risk category*
Outpatient clinic	With clinical indication of HIV infection**	4 weeks	No – unless new potential exposure; or if individual is in a high-risk category*

* Denotes high-risk category

** Depends on HIV prevalence in the clinic setting, individual's presenting complaint and individual's risk factors; to be determined by country HIV testing and counselling policies or programme manager.

Situation	Re-testing recommended?	When to re-test?	Future re-testing recommended?
Indeterminate HIV status	Yes	Repeat the test immediately using the same specimen and testing algorithm	If still discordant, retest in 2 weeks; if still discordant, refer to a higher-level health facility
Partner status unknown	Yes (new individuals only)	4 weeks	Annually—if sexual relationship is ongoing
Known positive partner	Yes (new patients or clients only)	4 weeks	Annually—if sexual relationship is ongoing
Sex worker*	Yes (new patients or clients only)	4 weeks	At least annually
Current injection drug user*	Yes (new patients or clients only)	4 weeks	At least annually
Men who have sex with men* and transgendered individuals	Yes (new patients or clients only)	4 weeks	At least annually
Post-rape	Yes, if baseline HIV test was negative, or if first HIV test following the encounter was negative or status was indeterminate; see *WHO/ILO PEP guidelines*[19]	4 and 12 weeks	No
Occupational exposure	Yes, if baseline HIV test was negative, or if first HIV test following the encounter was negative or status was indeterminate; see *WHO/ILO PEP guidelines*[19]	4 and 12 weeks	No
Negative HIV test in past 3 months	No	–	No
No possible HIV exposure in past 3 months	No	–	No

* Denotes high-risk category

** Depends on HIV prevalence in the clinic setting, individual's presenting complaint and individual's risk factors; to be determined by country HIV testing and counselling policies or programme manager.

Annex II. Counselling for re-testing

Tool 2: Counselling messages for HIV testing and counselling service providers

What do I say to an individual about re-testing?	
The individual is …	**I will say …**
An individual with **NO KNOWN specific incident of HIV exposure** in the past three months and no ongoing HIV risk behaviours	Your HIV test result is negative. This means that HIV infection has not been detected. Based on the risk information you provided, you do not have HIV infection. We recommend you only return for an HIV test if you have an HIV exposure risk in the future.
An individual with discordant HIV test results	*Upon first discordant results:* Your test results are discordant. This means that one test had a positive result, and one test had a negative result. This is rare, but it can occur. We need to repeat these same tests right now to clarify the results. A third assay may be performed to give further information that may help to give you a diagnosis. *If results are still discordant after immediate repeat testing:* Your test results are still discordant. Therefore, your HIV status cannot be determined at this time. Sometimes people with very recent HIV infection have uncertain test results like these. Please come back in two weeks so that you can be tested again. If you are in the early stages of HIV infection, the virus could infect others. Therefore, as always, please take precautions during these two weeks (use condoms, do not share injection equipment, do not donate blood).

What do I say to an individual about re-testing?	
The individual is …	I will say …
A **pregnant woman** in first or second trimester of pregnancy in a generalized epidemic setting	Your HIV test result is negative. This means that HIV infection has not been detected. It is recommended that you bring your partner in for HIV testing and counselling so that we can offer him an HIV test. Only if we know the status of both partners, we can take precautions so that you and your baby are not at risk for HIV infection before delivery. If you do not know your partner's HIV status, we recommend you practice safe sex by using condoms consistently every time you have sex with your partner. If you do become infected while you are pregnant, there is a higher likelihood that your baby could also be infected with HIV. However, if you test positive before your 36th week of pregnancy, there may still be time to give you medication to reduce the risk of HIV being transmitted to the baby before you give birth. Therefore, please come back for another HIV test between the 28th and 36th weeks of pregnancy. If you are not able to come back then, even if you test positive at the time of labour, there are measures that can be taken to reduce transmission to your baby during delivery. If at that time your HIV test should be positive, measures can be taken to reduce transmission after delivery. HIV negative women who are intending to breastfeed, should be counselled by their child's health care provider on when to be re-tested.
An individual with **continuous or ongoing risk behaviours**	Your HIV test result is negative. This means that HIV has not been detected. It is recommended that you come back for another test in four weeks. It is also recommended that you bring your partner in for HIV testing and counselling so that we can ensure that you and your partner do not have HIV. Engaging in high-risk behaviours puts you at risk for becoming infected with HIV. If it is not possible for your risks to be reduced, it is recommended that you come for an HIV test and counselling at least annually so that you will know your status.
An individual with a **specific incident of HIV exposure** in the past three months or 72 hours (e.g. sexual violence/rape or occupational exposure)	Your HIV test result is negative. This means that we were not able to detect HIV infection. However, these HIV tests are not able to detect an HIV infection that happened very recently. Based on your specific incident of HIV exposure, it is recommended that you come back in four weeks for another test. If you are in the early stages of HIV infection, it is possible that others could be infected with the virus (*review modes of HIV transmission*) Therefore, as always, please take extra precautions during these four weeks (do use condoms, do not share needles and other injecting equipment).

Annex III. Frequently asked questions

1. Are the terms 'window period' and acute HIV infection the same thing?

No. The window period refers to the time taken for a specific HIV assay to detect HIV antibodies following a newly acquired HIV infection. During acute HIV infection, antibody levels are too low to be detected by the assay or are not yet present. Acute HIV infection refers to the individual's clinical state shortly after acquiring HIV infection. Symptoms may or may not be present at this time. Acute HIV infection is a clinical stage of infection, while the 'window period' is a diagnostic time period.

2. Should re-testing be recommended for TB patients and medical inpatients?

Individuals who have TB or other serious medical conditions and test HIV negative are highly likely to be truly HIV negative and do not need re-testing to confirm their initial HIV status. People who are living with HIV often acquire TB and other opportunistic infections due to their weakened immune system; therefore, it is likely that they were infected with HIV some time back. However, persons with TB with high-risk behaviours should be re-tested according to the recommendations noted in this guidance.

3. Why should pregnant women be tested so frequently for HIV in the context of a generalized epidemic?

The most common risk factor for pregnancy is the same as that for sexual transmission of HIV: having unprotected sex. Re-testing in the third trimester closer to delivery (at or before the 36th week) minimizes the chances of undetected infection being passed on to the baby. Each new pregnancy should be treated the same way.

4. What do I do if the first test is positive (reactive) and the second test is negative (non-reactive)?

Discordant test results may be due to an error in performing the test and therefore repeating the tests immediately can usually resolve the issue. A third assay may be used to provide further information on the status of the individual. However, it is also possible that discordant test results can be due to an undetectable or a low level of antibodies as a result of an AHI. This can lead to one test being reactive (positive) but not both. It is highly likely that both assays will show reactive (and therefore positive) results within two weeks if the individual is infected with HIV.

5. Why do we have different recommendations based on the type of epidemic and/or type of setting?

The two tables given in Annex 1 distinguish between epidemic type and clinic setting as well as HIV testing scenario. In a low-level HIV epidemic, the probability of an individual who tests negative having an acute HIV infection are extremely low. However, in all types of epidemics and in settings with a higher HIV prevalence, it has been noted that high-risk groups such as sex workers, persons who inject drugs or men who have sex with men have a greater likelihood of being in the "window period", and different re-testing recommendations are warranted.

6. In high-prevalence settings, should I recommend re-testing to individuals who do not know their partner's HIV status every three months?

No, but annual testing and counselling is recommended for these persons.

7. What if the HIV assay's results are inconclusive or uncertain, such as a faint line?

Some HIV assays are designed such that any line in the test strip, no matter how faint, should be interpreted as reactive. It is important for HIV testing and counselling service providers to closely follow the HIV test kit package insert outlining the manufacturer's instructions on how to interpret the test results. If the test kit instructions do not clarify what to do with a faint test strip line, then the next step is to confirm that the test kits have not expired, that the storage conditions are optimal and that the proper testing protocol has been followed, and then test the individual again immediately with the same assay, strictly following standard operating procedures. If immediate repeat testing again leads to discordant test results, the individual or a specimen from the individual may need to be referred to another testing site (usually a laboratory) for further HIV testing.

8. Why should only new clients or patients be re-tested?

Re-testing is not recommended for persons with no known incident of exposure to HIV in the past three months or in those with no ongoing HIV risk. For persons with a recent incident of potential exposure, it may be necessary to re-test after four weeks to allow new clients/patients to be sure of their status.

9. What is the difference between a specific incident of HIV exposure and ongoing or continuing risk behaviour?

A specific incident is an isolated event such as a burst condom for someone who always uses condoms consistently. Other examples of isolated incidents are sexual violence/rape and needlestick injuries. Ongoing or continuing risk behaviour refers to behaviours that place persons at risk for acquiring HIV. One such example is the inconsistent use or non-use of condoms, or the sharing of injection equipment. Such behaviours have been found to be more likely to lead to acquiring and transmitting HIV.

10. Why should persons with continuing or ongoing risk behaviours be tested at least annually?

While testing is an important element of HIV prevention, it is only one aspect of a comprehensive package of services for preventing HIV transmission. In CITC settings, testing must include prevention counselling tailored to the needs of the individual and formulation of a risk reduction plan, particularly for persons with ongoing risk behaviours. In PITC settings, prevention counselling may be brief, but persons with ongoing risk behaviours should be referred to another HIV testing and counselling site for prevention counselling, or on-site if these services exist. Rather than more frequent re-testing, annual testing is recommended to ensure that the greatest proportion of high-risk individuals who newly acquire HIV each year learn their status and are referred to HIV care services. If an individual wishes to be tested sooner, then testing should be provided. Individuals should also be encouraged and welcome to return for continued prevention counselling as often as needed and, where available, offered effective prevention interventions. Furthermore, HIV testing and counselling programmes should refer individuals to other prevention services in the community, as appropriate.

6. Resources

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