

Strengthening health services to fight HIV/AIDS

GUIDANCE ON PROVIDER-INITIATED HIV TESTING AND COUNSELLING IN HEALTH FACILITIES





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1. INTRODUCTION

This document responds to growing need at country level for basic operational guidance on provider-initiated HIV testing and counselling in health facilities. It is intended for a wide audience including policy-makers, HIV/AIDS programme planners and coordinators, health-care providers, non-governmental organizations providing HIV/AIDS services and civil society groups.

Surveys in sub-Saharan Africa have shown that a median of just 12% of men and 10% of women had been tested for HIV and received the results. Greater knowledge of HIV status is critical to expanding access to HIV treatment, care and support in a timely manner, and offers people living with HIV an opportunity to receive information and tools to prevent HIV transmission to others. Increased access to HIV testing and counselling is essential in working towards universal access to HIV prevention, treatment, care and support as endorsed by G8 leaders in 2005 and the UN General Assembly in 2006.

WHO and UNAIDS strongly support the continued scale up of client-initiated HIV testing and counselling, but recognize the need for additional, innovative and varied approaches. Health facilities represent a key point of contact with people with HIV who are in need of HIV prevention, treatment, care and support. Evidence from both industrialized and resource-constrained settings suggests that many opportunities to diagnose and counsel individuals at health facilities are being missed and that provider-initiated HIV testing and counselling facilitates diagnosis and access to HIV-related services. Concerns about the potential coercion of patients and adverse outcomes of disclosure underscore the importance of adequate training and supervision for health care providers and the need for close monitoring and evaluation of provider-initiated HIV testing and counselling programmes.

The document recommends an "opt-out" approach to provider-initiated HIV testing and counselling in heath facilities, including simplified pre-test information, consistent with WHO policy options developed in 2003 and with the 2004 UNAIDS/WHO Policy Statement on HIV Testing. With this approach, an HIV test is recommended 1) for all patients, irrespective of epidemic setting, whose clinical presentation might result from underlying HIV infection; 2) as a standard part of medical care for all patients attending health facilities in generalized HIV epidemics; and 3) more selectively in concentrated and low-level epidemics. Individuals must specifically decline the HIV test if they do not want it to be performed. Additional discussion of the right to decline HIV testing, of the risks and benefits of HIV testing and disclosure, and about social support available may be required for groups especially vulnerable to adverse consequences upon disclosure of an HIV test result. An "opt-in" approach to informed consent may merit consideration for highly vulnerable populations.

Provider-initiated HIV testing and counselling should be accompanied by a recommended package of HIV-related prevention, treatment, care and support services described in Section 5 and implemented within the framework of a national plan to achieve universal access to antiretroviral therapy for all who need it. Simultaneous with implementation of provider-initiated HIV testing and

counselling, efforts must be made to ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harms to patients.

Adaptation of this guidance at country level will require an assessment of the local epidemiology as well as the risks and benefits of provider-initiated HIV testing and counselling, including an appraisal of available resources, prevailing standards of HIV prevention, treatment, care and support, and the adequacy of social and legal protections available. Implementation of provider-initiated HIV testing and counselling should be undertaken in consultation with key stakeholders, including civil society groups and people living with HIV/AIDS.

When recommending HIV testing and counselling, service providers should always aim to do what is in the best interests of the individual patient. This requires giving individuals sufficient information to make an informed and voluntary decision to be tested, maintaining patient confidentiality, performing post-test counselling and making referrals to appropriate services.

Endorsement of provider-initiated HIV testing and counselling by WHO and UNAIDS is not an endorsement of coercive or mandatory HIV testing. WHO and UNAIDS do not support mandatory or compulsory testing of individuals on public health grounds.

2. RECOMMENDATIONS

Guidance on provider-initiated HIV testing and counselling in this document is categorized according to the following HIV epidemic types:

1. Low-level HIV epidemics

Although HIV may have existed for many years, it has never spread to substantial levels in any sub-population. Recorded infection is largely confined to individuals with higher risk behaviour: e.g. sex workers, drug injectors, men having sex with other men. Numerical proxy: HIV prevalence has not consistently exceeded 5% in any defined sub-population.

2. Concentrated HIV epidemics

HIV has spread rapidly in a defined sub-population, but is not well-established in the general population. This epidemic state suggests active networks of risk within the sub-population. The future course of the epidemic is determined by the frequency and nature of links between highly infected sub-populations 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 in urban areas.

3. Generalized HIV epidemics

HIV is firmly established in the general population. Although sub-populations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain an epidemic independent of sub-populations at higher risk of infection. Numerical proxy: HIV prevalence is consistently over 1% in pregnant women.

· Recommendations for all epidemic types

In all types of HIV epidemics, health care providers should recommend HIV testing and counselling as part of the standard of care to:

- all adults, adolescents or children who present to health facilities with signs, symptoms
 or medical conditions that could indicate HIV infection. These include, but are not
 necessarily limited to, tuberculosis and other conditions specified in the WHO HIV clinical
 staging system.
- infants born to HIV-positive women as a routine component of the follow-up care for these children.
- children presenting with suboptimal growth or malnutrition in generalized epidemics, and under certain circumstances in other settings such as when malnourished children do not respond to appropriate nutritional therapy.
- men seeking circumcision as an HIV prevention intervention.

Recommendations for generalized epidemics

In generalized epidemics where an enabling environment is in place and adequate resources are available, including a recommended package of HIV prevention, treatment and care, health care providers should recommend HIV testing and counselling to all adults and adolescents seen in all health facilities. This applies to medical and surgical services, public and private facilities, inpatient and outpatient settings and mobile or outreach medical services.

HIV testing and counselling should be recommended by the health care provider as part of the normal standard of care provided to the patient, regardless of whether the patient shows signs and symptoms of underlying HIV infection or the patient's reason for presenting to the health facility.

Resource and capacity constraints may require a phased implementation of provider-initiated HIV testing and counselling. The following should be considered priorities for the implementation of provider-initiated HIV testing and counselling in generalized epidemic settings:

- Medical inpatient and outpatient facilities, including tuberculosis clinics.
- Antenatal, childbirth and postpartum health services.
- Health services for most-at-risk populations.
- Services for younger children (under 10 years of age).
- Surgical services.
- Services for adolescents.
- Reproductive health services, including family planning.

· Options for concentrated and low-level HIV epidemics

Health care providers should **not** recommend HIV testing and counselling to all persons attending all health facilities in settings with low-level and concentrated epidemics, since most people will have a low risk of exposure to HIV. In such settings, the priority should be to ensure that HIV testing and counselling is recommended to all adults, adolescents and children who present to health facilities with signs and symptoms suggestive of underlying HIV infection, including tuberculosis, and to children known to have been exposed perinatally to HIV.

If data show that HIV prevalence in patients with tuberculosis is very low, the recommendation of HIV testing and counselling to these patients may not remain a priority.

Decisions about whether and how to implement provider-initiated HIV testing and counselling in selected health facilities in low-level and concentrated epidemics should be guided by an assessment of the epidemiological and social context. Consideration may be given to the implementation of provider-initiated HIV testing and counselling in the following health facilities or services:

- STI services
- Health services for most-at-risk populations
- Antenatal, childbirth and postpartum services
- Tuberculosis services

3. ENABLING ENVIRONMENT

Provider-initiated HIV testing and counselling should be accompanied by a recommended package of HIV-related prevention, treatment, care and support services shown in Section 5. Although not all the services need necessarily be available in the same facility as where the HIV test is performed, they should be available through local referral. Although access to antiretroviral therapy should not be an absolute prerequisite for the implementation of provider-initiated HIV testing and counselling, there should at least be a reasonable expectation that it will become available within the framework of a national plan to achieve universal access to antiretroviral therapy for all who need it.

Antiretroviral prophylaxis and infant feeding counselling are important interventions for the prevention of mother-to-child transmission. These interventions must be available as part of the standard of care for pregnant women who are diagnosed HIV-positive through provider-initiated HIV testing and counselling.

At the same time as provider-initiated HIV testing and counselling is implemented, equal efforts must be made to ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harms to patients. This includes:

- Community preparedness and social mobilization
- · Adequate resources and infrastructure
- Health care provider training
- · Health care provider codes of conduct and methods of redress for patients
- · A strong monitoring and evaluation system.

Optimal delivery of provider-initiated HIV testing and counselling in the long term requires that laws and policies against discrimination on the basis of HIV status, risk behaviour and gender are in place, monitored and enforced. Because UNAIDS and WHO encourage voluntary disclosure of HIV status and ethical partner notification and counselling, national policies and ethical codes should also be developed to authorize partner notification in clearly defined circumstances.

Governments may also need to develop and implement clear legal and policy frameworks that stipulate 1) the specific age and/or circumstances in which minors may consent to HIV testing for themselves or for others, and 2) how the assent of and consent for adolescents should best be assessed and obtained.

4. PRE-TEST INFORMATION AND INFORMED CONSENT

Depending on local conditions, pre-test information can be provided in the form of individual information sessions or in group health information talks. Informed consent should always be given individually, in private, in the presence of a health care provider. When recommending HIV testing and counselling to a patient, the health care provider should at a minimum provide the patient with the following information:

- The reasons why HIV testing and counselling is being recommended
- The clinical and prevention benefits of HIV testing and the potential risks, such as discrimination, abandonment or violence
- The services that are available in the case of either an HIV-negative or an HIV-positive test result, including whether antiretroviral treatment is available
- The fact that the test result will be treated confidentially and will not be shared with anyone other than heath care providers directly involved in providing services to the patient
- The fact that the patient has the right to decline the test and that testing will be performed unless the patient exercises that right
- The fact that declining an HIV test will not affect the patient's access to services that do not depend upon knowledge of HIV status
- In the event of an HIV-positive test result, encouragement of disclosure to other persons who
 may be at risk of exposure to HIV
- An opportunity to ask the health care provider questions.

Patients should also be made aware of relevant laws in jurisdictions that mandate the disclosure of HIV status to sexual and/or drug injecting partners.

Verbal communication is normally adequate for the purpose of obtaining informed consent. Jurisdictions that require consent to be given in writing are encouraged to review this policy.

Some patient groups may be more susceptible to coercion to be tested and to adverse outcomes of disclosure of HIV status such as discrimination, violence, abandonment or incarceration. In such cases, providing additional information beyond the minimum requirements defined in this document may be appropriate to ensure informed consent.

Pre-test information for women who are or may become pregnant should also include:

- The risks of transmitting HIV to the infant
- Measures that can be taken to reduce mother-to-child transmission, including antiretroviral prophylaxis and infant feeding counselling
- The benefits to infants of early diagnosis of HIV.

Special considerations apply in the case of children and adolescents who are below the legal age of majority (usually 18 years of age). As minors, children cannot legally provide informed consent. However, they have the right to be involved in all decisions affecting their lives and to make their views known according to their level of development. Every attempt should be made to inform and involve the child and to obtain her/his assent. Informed consent from the child's parent or guardian is required. More detailed discussion of consent for children and adolescents is considered in Section 6.1.3.

Declining an HIV test should not result in reduced quality or denial of services that do not depend on knowledge of HIV status.

5. POST-TEST COUNSELLING

Post-test counselling is an integral component of the HIV testing process. All individuals undergoing HIV testing must be counselled when their test results are given, regardless of the test result. Counselling for those whose test result is *HIV-negative* should include the following minimum information:

- An explanation of the test result, including information about the window period for the appearance of HIV-antibodies and a recommendation to re-test in case of a recent exposure
- Basic advice on methods to prevent HIV transmission
- Provision of male and female condoms and guidance on their use.

The health care provider and the patient should then jointly assess whether the patient needs referral to more extensive post-test counselling session or additional prevention support.

In the case of individuals whose test result is HIV-positive, the health care provider should:

- Inform the patient of the result simply and clearly, and give the patient time to consider it
- Ensure that the patient understands the result
- Allow the patient to ask questions
- · Help the patient cope with emotions arising from the test result
- Discuss any immediate concerns and assist the patient to determine who in her/his social network may be available and acceptable to offer immediate support
- Describe follow-up services that are available in the health facility and in the community, with special attention to the available treatment, PMTCT, and care and support services
- Provide information on how to prevent transmission of HIV, including provision of male and female condoms and guidance on their use
- Provide information on other relevant preventive health measures such as good nutrition, use
 of co-trimoxazole and, in malarious areas, insecticide-treated bed nets
- Discuss possible disclosure of the result, when and how this may happen and to whom
- Encourage and offer referral for testing and counselling of partners and children.
- Assess the risk of violence or suicide and discuss possible steps to ensure the physical safety of patients, particularly women, who are diagnosed HIV-positive
- Arrange a specific date and time for follow-up visits or referrals for treatment, care, counselling, support and other services as appropriate (e.g. tuberculosis screening and treatment, prophylaxis for opportunistic infections, STI treatment, family planning, antenatal care, opioid substitution therapy, and access to sterile needles and syringes).

Post-test counselling for pregnant women whose test result is HIV-positive should also address the following:

- Childbirth plans
- Use of antiretroviral drugs for the patient's own health, when indicated and available, and to prevent mother-to-child transmission
- · Adequate maternal nutrition, including iron and folic acid
- Infant feeding options and support to carry out the mother's infant feeding choice
- HIV testing for the infant and the follow-up that will be necessary
- Partner testing.

6. FREQUENCY OF TESTING

Recommendations about re-testing will depend on the continued risks taken by the patient, the availability of human and financial resources and HIV incidence in the setting. Re-testing every 6-12 months may be beneficial for individuals at higher risk of HIV exposure.

HIV-negative women should be tested as early as possible in each new pregnancy. Repeat testing late in pregnancy should also be recommended to HIV-negative women in generalized epidemic settings.

7. HIV TESTING TECHNOLOGIES

The advantages of using rapid HIV tests for provider-initiated HIV testing and counselling – particularly for health facilities where laboratory services are weak – include visibility of the test and quick turn-around, increasing confidence in results and avoidance of clerical errors. Rapid HIV testing can occur outside laboratory settings, does not require specialized equipment and can be carried out in primary health facilities.

ELISA tests may be preferable in settings where large numbers of tests need to be performed, where immediate provision of test results is less important (such as for hospital inpatients) and in reference laboratories. However, ELISA tests require specialized laboratory equipment and staff.

Decisions on whether to use HIV rapid tests or ELISA for provider-initiated HIV testing and counselling should take into account factors such as the setting in which testing is proposed; cost and availability of the test kits, reagents and equipment; available staff, resources and infrastructure; the number of samples to be tested; sample collection and transport and the ability of individuals to return for results.

Virological testing, while more complex and expensive, is recommended for diagnosing HIV in children less than 18 months old.

8. PROGRAMMATIC CONSIDERATIONS

Decisions on how best to implement provider-initiated HIV testing and counselling will depend upon an assessment of the situation in a particular country, including local epidemiology; the available infrastructure, financial and human resources; the available standard of HIV prevention, treatment, care and support, and the existing social, policy and legal frameworks for protection against adverse consequences of HIV testing, such as HIV-related discrimination and violence. Where there are high levels of stigma and discrimination and/or low capacity of health care providers to implement provider-initiated HIV testing and counselling under the conditions of informed consent, confidentiality and counselling, adequate resources should be devoted to addressing these issues prior to implementation. Decisions around implementation should be made in consultation with all relevant stakeholders, including civil society groups and people living with HIV/AIDS.

9. MONITORING AND EVALUATION

Monitoring and evaluation are essential to implementation of provider-initiated HIV testing and counselling but may need to be supplemented by focused evaluations on specific aspects of programming. Regular evaluations of health care provider performance and patient satisfaction (including testing processes, pre-test information, consent process and post-test counselling) can help improve the effectiveness, acceptability and quality of HIV testing and counselling services.

1. INTRODUCTION

1.1 Background

In recent years, global commitment, action and resources to combat the HIV pandemic have increased markedly. In June 2006, the UN General Assembly endorsed the continued scale-up of HIV prevention, treatment, care and support with the goal of coming as close as possible to universal access by 2010.

Despite recent progress, at the end of 2006 an estimated 39.5 million people globally were living with HIV, and more than 4 million new HIV infections occurred in that year. Sub-Saharan Africa remains the most affected region, with 24.7 million people living with HIV (nearly two-thirds of the global burden), while epidemics in eastern Europe and Asia continue to grow¹.

Surveys in twelve high-burden countries in sub-Saharan Africa showed that a median of just 12% of men and 10% of women in the general population had been tested for HIV and received the results². The result of low coverage and uptake of HIV testing and counselling and low levels of knowledge of HIV status is that the majority of people living with HIV access HIV testing and counselling only when they already have advanced clinical disease³.

Where antiretroviral therapy is available, maximum benefit in terms of reduced morbidity and mortality is obtained when HIV is diagnosed before end-stage immunodeficiency. Even in settings where antiretroviral therapy is not yet available, interventions such as co-trimoxazole prophylaxis and antiretroviral prophylaxis for the prevention of mother-to-child transmission offer significant potential health benefits to individuals and their children. Earlier diagnosis also presents an opportunity to provide people with HIV with information and tools to prevent HIV transmission to others.

The revised Policy Statement on HIV Testing⁴ published by UNAIDS and WHO in June 2004 emphasized the importance of increased knowledge of HIV status for expanding access to HIV prevention, treatment and care. The policy statement promoted both client-initiated HIV testing and counselling (also known as Voluntary Counselling and Testing, or VCT) and provider-initiated HIV testing and counselling.

1.2 Scaling up client-initiated HIV testing and counselling

Client-initiated approaches have been the primary model for providing HIV testing and counselling. Coverage of client-initiated HIV testing and counselling services is inadequate in both high-income and resource-constrained settings. WHO and UNAIDS strongly support the continued scale up of client-initiated HIV testing and counselling.

Uptake of client-initiated HIV testing and counselling has been hampered by many of the same factors that limit uptake of other HIV-related services, including stigma and discrimination, limited access to treatment, care and health services in general, as well as gender issues. A four-country survey in Asia showed that women were more likely to seek HIV testing and

counselling because their partner was ill, representing failures of diagnosis, prevention, treatment and care⁵. Underestimation of personal risk for HIV is also a frequent obstacle to uptake of client-initiated HIV testing and counselling, especially on the part of men^{6,7,8}.

Innovative approaches that reduce practical obstacles can increase access to and uptake of client-initiated HIV testing and counselling. The advent of rapid tests has reduced the time between taking tests and obtaining results, and where HIV testing and counselling is available in settings that are convenient to clients – such as at workplaces, in mobile clinics and during night hours – uptake increases markedly. Home-based HIV testing and counselling, often conducted as part of Demographic Household Surveys but increasingly as part of prevention and treatment interventions, is also emerging as a promising approach^{9, 10,11}.

1.3. Scaling up provider-initiated HIV testing and counselling

Health facilities represent a key point of contact with people with HIV who are in need of HIV prevention, treatment, care and support. However, evidence from both industrialized and resource-constrained settings suggests that many opportunities to diagnose and counsel individuals at health facilities are being missed. In Australia, a review of records at a Canberra sexual health centre showed that more than half of HIV-positive patients with delayed diagnoses had earlier been in touch with health services, and almost all of those had at least one factor that should have prompted health care providers to consider the need for HIV testing and counselling¹². A study in Uganda showed that, among adults who were offered HIV testing at a hospital (about half of whom were subsequently found to be HIV-positive), 83% were unaware of their HIV status, even though 88% had been to a health unit in the previous six months¹³.

Provider-initiated HIV testing and counselling presents an opportunity to ensure that HIV is more systematically diagnosed in health care facilities in order to facilitate patient access to needed HIV prevention, treatment, care and support services.

In the industrialized world, a number of European countries have introduced provider-initiated HIV testing and counselling in the context of prenatal care. Provider-initiated HIV testing and counselling appears to have resulted in considerable increases in testing uptake in the United States, United Kingdom, Hong Kong, Singapore, Norway, and Canada, where the majority of clients (4/5 or more in most studies) agreed to be tested 14. Concerned by persistent late diagnoses of HIV infection and a high proportion of people with HIV who are unaware of their HIV status, and in light of evidence that people who are aware of their HIV status reduce risk behaviours 15, the United States Centers for Disease Control and Prevention issued revised guidelines in September 2006 recommending "HIV screening" for all persons aged 13-64 years attending health facilities in the United States 16.

Several low and middle-income countries have introduced provider-initiated HIV testing and counselling in a variety of settings, including Botswana, Kenya, Malawi, South Africa and Uganda^{17,18,19,20,21,22,23,24}. While data are still relatively limited, studies in prenatal care settings in

several low- and middle-income countries have shown that pregnant women were positively inclined to accept testing if they thought it could benefit their baby.

Evidence from both resource-rich and resource-poor settings indicates that the uptake of testing increases when testing is routinely discussed and offered, and where it is well-integrated into prenatal care^{25,26,27,28}. Findings from a growing number of studies in settings other than pre-natal care are also encouraging. Comparisons of data collected before and after the introduction of provider-initiated HIV testing and counselling consistently show significantly higher uptake, as documented in post-partum wards in Botswana²⁹; pediatric wards in Zambia³⁰; tuberculosis clinics³¹ as well as Ugandan pediatric wards³², maternity ward³³ and STI clinics³⁴. In Mbarara hospital in Uganda, increased uptake of HIV testing appeared to be associated with clinical benefits for patients. People diagnosed HIV-positive after provider-initiated HIV testing and counselling was introduced were at an earlier clinical stage and had higher CD4 counts than those identified beforehand, and were therefore more likely to be referred to treatment at an appropriate time³⁵.

Concerns exist that provider-initiated HIV testing and counselling could deter clients from accessing health services. Although limited, the available evidence does not support those fears. The introduction of provider-initiated HIV testing and counselling in antenatal care clinics in Botswana appears to have caused neither reduction in the use of prenatal care nor decline in the proportion of people receiving test results³⁶, and in Zimbabwe has had no negative effects on post-test counselling rates or the delivery of antiretroviral prophylaxis³⁷.

Studies have found patients to have generally positive attitudes about provider-initiated HIV testing and counselling. When hospitalized patients in the United States were asked how they would feel about an unsolicited HIV test, most had positive responses³⁸. A comparison of three models of provider-initiated HIV testing and counselling in a tuberculosis clinic in Kinshasa, Democratic Republic of the Congo, found that more than two-thirds of clients preferred "opt-out" testing where the test would be performed unless they declined, notwithstanding common perceptions that it would be difficult to decline the test³⁹.

Concerns also exist that in some settings increased knowledge and disclosure of HIV status may be accompanied by increased stigma, discrimination, abandonment and violence. In a review of 17 studies, negative consequences of disclosure, including violence, were reported in 3% to 15% of cases, with other studies reporting lower or higher frequencies^{40,41,42,43,44}, the latter in settings with high baseline domestic violence. A systematic review of partner notification in the United States found few negative consequences⁴⁵, while a study in Tanzania found that about half of respondents reported receiving support from their partner⁴⁶. Evidence from Kenya and Zambia shows that the majority of HIV-positive women reported positive outcomes with disclosure, including some who feared they would not receive support⁴⁷.

On balance, the available evidence suggests that provider-initiated HIV testing and counselling can be an important addition to the range of approaches available for scaling up HIV testing and

counselling and facilitates access to HIV treatment, prevention, care and support services. However, concerns about the potential coercion of patients and adverse outcomes of disclosure underscore the importance of adequate training and supervision for health care providers, particularly in the processes of counselling, obtaining informed consent and maintaining confidentiality of HIV test results. Close monitoring and evaluation, especially in the implementation stages, will be needed to ensure that provider-initiated HIV testing and counselling is implemented in a way that minimizes adverse outcomes and maximizes benefits for patients.

1.4 Adaptation of the guidance

The global guidance presented in this document will need to be adapted to different epidemiological and social contexts. The adaptation process will require an assessment of the risks and benefits of introducing provider-initiated HIV testing and counselling in a particular setting, including an appraisal of available resources, prevailing standards of HIV prevention, treatment, care and support and the social, legal and policy framework that is in place. In generalized epidemic settings where resources and capacity are limited, phased implementation in priority health facilities may be appropriate.

Adaptation of this guidance document and implementation of provider-initiated HIV testing and counselling should be undertaken in consultation with all key stakeholders, including civil society groups and people living with HIV/AIDS. Careful monitoring and evaluation will allow best use of available resources and help avoid negative outcomes, including stigma, discrimination, violence, breaches of confidentiality, coercion or unmet demand for treatment and other HIV services.

Endorsement of provider-initiated HIV testing and counselling by WHO and UNAIDS is not an endorsement of coercive or mandatory HIV testing. The overriding principle for health care providers should always be to do what is in the best interests of the individual patient. This requires giving individuals sufficient information to make an informed and voluntary decision to be tested, maintaining patient confidentiality, performing post-test counselling and making referrals to appropriate services.

2. OBJECTIVES

This document offers basic operational guidance on provider-initiated HIV testing and counselling in health facilities. It is intended for a wide audience, in particular policy-makers, HIV/AIDS programme planners and coordinators, health-care providers and non-governmental organizations involved in the provision of HIV/AIDS services. It does not address client-initiated HIV counselling and testing in detail, for which guidance already exists^{48,49} and which WHO and UNAIDS strongly support.

The guidance aims for synergy between medical ethics and clinical, public health and human rights objectives. These include:

- Enabling people with HIV to know their HIV status in an informed and voluntary manner; to seek and receive HIV prevention, treatment, care and support services; to prevent the transmission of HIV and to be protected from HIV-related stigma, discrimination and violence.
- · Improving treatment and prevention outcomes
- Promoting the right to autonomy, privacy and confidentiality
- · Promoting evidence-based policies and practices and an enabling environment for implementation
- Elaborating the roles and responsibilities of health care providers in ensuring access to HIV
 related testing, counselling and related interventions.

The document elaborates upon the 2004 UNAIDS/WHO Policy Statement on HIV Testing by providing the following:

- Revised terminology for provider-initiated HIV testing and counselling (Section 3)
- Guidance on the implementation of provider-initiated HIV testing and counselling in different epidemic types and for different populations including children and adolescents (Section 4)
- A description of the enabling environment, including the recommended HIV services and the social, policy and legal framework needed to support implementation (Section 5)
- A description of the processes to be followed for provider-initiated HIV testing and counselling, including minimum pre-test information, informed consent and information to be provided during post-test counselling (Section 6)
- A brief discussion on testing technologies (Section 7)
- · A brief discussion on adapting this document to national and local contexts (Section 8)
- A brief discussion on monitoring and evaluation (Section 9).

This document was developed drawing upon evidence and expert opinion presented at a consultation convened by WHO and UNAIDS in July 2006⁵⁰; public comment received from more than 150 organizations and individuals during an online consultation period between November 2006 and February 2007, and additional consultations with a wide range of individuals and organizations.

3. TERMINOLOGY

The following terminology is used in this document:

Client-initiated HIV testing and counselling (also called Voluntary Counselling and Testing, or VCT) involves individuals actively seeking HIV testing and counselling at a facility that offers these services. Client-initiated HIV testing and counselling usually emphasizes individual risk assessment and management by counsellors, addressing issues such as the desirability and implications of taking an HIV test and the development of individual risk reduction strategies. Client-initiated HIV testing and counselling is conducted in a wide variety of settings including health facilities, stand-alone facilities outside health institutions, through mobile services, in community-based settings and even in people's homes.

Provider-initiated HIV testing and counselling refers to HIV testing and counselling which is recommended by health care providers to persons attending health care facilities as a standard component of medical care. The major purpose of such testing and counselling is to enable specific clinical decisions to be made and/or specific medical services to be offered that would not be possible without knowledge of the person's HIV status.

In the case of persons presenting to health facilities with symptoms or signs of illness that could be attributable to HIV, it is a basic responsibility of heath care providers to recommend HIV testing and counselling as part of the patient's routine clinical management. This includes recommending HIV testing and counselling to tuberculosis patients and persons suspected of having tuberculosis.

Provider-initiated HIV testing and counselling also aims to identify unrecognized or unsuspected HIV infection in persons attending health facilities. Health care providers may therefore recommend HIV testing and counselling to patients in some settings even if they *do not have obvious HIV-related symptoms or signs*. Such patients may nevertheless have HIV and may benefit from knowing their HIV-positive status in order to receive specific preventive and/or therapeutic services. In such circumstances, HIV testing and counselling is recommended by the health care provider as part of a package of services provided to all patients during all clinical interactions in the health facility.

It is emphasized that, as in the case of client-initiated HIV testing and counselling, provider-initiated HIV testing and counselling is voluntary and the "three C's" – informed consent, counselling and confidentiality – must be observed.

Substantial debate has occurred about whether provider-initiated HIV testing and counselling in health facilities should employ so-called "opt-out" or "opt-in" approaches.

With "opt-in" approaches, patients must affirmatively agree to the test being performed after pretest information has been received. Informed consent is analogous to that required for special investigations or interventions in clinical settings such as liver biopsy or surgical interventions.

With "opt-out" approaches, individuals must specifically decline the HIV test after receiving pretest information if they do not want the test to be performed. This approach to informed consent is analogous to that required for common clinical investigations such as chest X-rays, blood tests and other non-invasive investigations. In most circumstances, the health care provider's recommendation will lead to the procedure being performed unless the patient declines.

Consistent with WHO policy options developed in 2003⁵¹ and with the 2004 WHO/UNAIDS Policy Statement on HIV Testing⁵², an "opt-out" approach to provider-initiated HIV testing and counselling is adopted in this document. However, the document also acknowledges that in some circumstances, such as in health facilities that serve highly vulnerable populations, "optin" approaches merit consideration. Whether patients "opt-in" or "opt-out", the end result should be the same: an informed decision by the patient to accept or decline the health care provider's recommendation of an HIV test. The terms "opt-in" and "opt-out" are generally avoided in this document in favour of "provider initiated HIV testing and counselling" which incorporates the informed right of the patient to decline the recommendation of an HIV test.

No distinction is made in this document between HIV testing and counselling that is recommended for "diagnostic" purposes (that is, for patients with HIV-related symptoms) and HIV testing and counselling that is recommended to patients who may have HIV but who are not symptomatic. Terminology such as "HIV screening", "routine offer" and "routine recommendation"⁵³, are also avoided in favour of "provider-initiated HIV testing and counselling".

Guidance in the document is formulated in terms of whether a recommendation of HIV testing and counselling should be made by the health care provider to the patient, and in what circumstances.

Provider-initiated HIV testing and counselling is neither mandatory nor compulsory. WHO and UNAIDS do not support mandatory or compulsory testing of individuals on public health grounds.

4. RECOMMENDATIONS FOR PROVIDER-INITIATED HIV TESTING AND COUNSELLING IN DIFFERENT TYPES OF HIV EPIDEMICS

Guidance on the implementation of provider-initiated HIV testing and counselling in this document is categorized according to HIV epidemic type (Box 1)⁵⁴

Box 1: Typology of HIV Epidemics

WHO and UNAIDS define different types of HIV epidemics as follows:

1. Low-level HIV epidemics

Although HIV may have existed for many years, it has never spread to significant levels in any sub-population. Recorded infection is largely confined to individuals with higher risk behaviour: e.g. sex workers, drug injectors, men having sex with other men. Numerical proxy: HIV prevalence has not consistently exceeded 5% in any defined sub-population.

2. Concentrated HIV epidemics

HIV has spread rapidly in a defined sub-population, but is not well-established in the general population. This epidemic state suggests active networks of risk within the sub-population. The future course of the epidemic is determined by the frequency and nature of links between highly infected sub-populations and the general population. Numerical proxy: HIV prevalence is consistently over 5% in at least one defined sub-population but is below 1% in pregnant women in urban areas.

3. Generalized HIV epidemics

HIV is firmly established in the general population. Although sub-populations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain an epidemic independent of sub-populations at higher risk of infection. Numerical proxy: HIV prevalence consistently over 1% in pregnant women.

4.1 Provider-initiated HIV testing and counselling in all epidemic types

4.1.1 Symptomatic patients

Presentation to a health facility with symptoms or signs of disease implies a desire for diagnosis, treatment and care. In all types of HIV epidemics, health care providers should recommend HIV testing and counselling as part of the standard of care to all adults, adolescents or children who present to health facilities with signs, symptoms or medical conditions that could indicate HIV infection. These include, but are not necessarily limited to, tuberculosis and other conditions specified in the WHO HIV clinical staging system⁵⁵. Many other common, minor complaints may also be indicative of underlying HIV infection.

Although a recommendation of HIV testing and counselling will most often be made to symptomatic patients during acute medical care, individuals with a medical condition or symptoms suggestive of HIV may also be seen in other clinical settings. Failure to recommend HIV testing and counselling to a patient with symptoms which may be HIV-related is substandard medical practice.

4.1.2 Symptomatic and HIV-exposed children

Determining the HIV status of children exposed to HIV during pregnancy, labour or breastfeeding is an important part of follow-up services in programmes for the prevention of mother-to-child HIV transmission (PMTCT). HIV testing and counselling should therefore be recommended for all HIV-exposed infants or infants born to HIV-positive women as a routine component of the follow-up care for these children.

In the first 18 months of life, methods of HIV testing that rely on the detection of the HIV virus or its products (virological testing) are required as HIV antibody testing may not reliably confirm the true HIV status of the infant. Virological methods are usually more expensive and technically demanding.

Because of the rapid progression of immunodeficiency in children and the non-specificity of clinical signs, HIV testing and counselling should also be recommended for children presenting with suboptimal growth or malnutrition in generalized epidemics, and may be considered for children under certain circumstances in other epidemic settings, such as when malnourished children do not respond to appropriate nutritional therapy.

Decisions about HIV testing for children may usefully be guided by clinical algorithms such as the one used for the Integrated Management of Childhood Illness (IMCI).⁵⁶

4.1.3 Men undergoing circumcision as an HIV prevention intervention

Studies have recently shown up to 60% efficacy of male circumcision in preventing HIV transmission from women to men. Accordingly, WHO and UNAIDS have issued a series of recommendations endorsing male circumcision as an intervention for the prevention of HIV⁵⁷. The recommendations focus primarily on the implementation of male circumcision in high-prevalence settings where circumcision rates are currently low. Consistent with these recommendations, HIV testing and counselling should be recommended to all men seeking circumcision as an HIV prevention intervention.

4.2 Provider-initiated HIV testing and counselling in generalized epidemics

4.2.1 Implementation in all health facilities

In generalized epidemics where an enabling environment is in place and adequate resources are available, including a recommended standard of HIV prevention, treatment and care (see Section 5), health care providers should recommend HIV testing and counselling to all adults and adolescents seen in all health facilities. This applies to medical and surgical services, public and private facilities, inpatient and outpatient settings and mobile or outreach medical services.

HIV testing and counselling should be recommended by the health care provider as part of the normal standard of care provided to the patient, regardless of whether the patient shows signs and symptoms of underlying HIV infection or the patient's reason for presenting to the health facility.

4.2.2 Priorities for implementation

In generalized epidemics, resource and capacity constraints may require a phased implementation of provider-initiated HIV testing and counselling, with certain health facilities or patient groups initially selected as priorities. Selection of priority health facilities or patient groups should be guided by an assessment of the local epidemiological and social context. The key steps in making such an assessment are described in Section 8

The following should be considered priorities for the implementation of provider-initiated HIV testing and counselling in generalized epidemic settings:

· Medical inpatient and outpatient facilities, including tuberculosis clinics

In generalized epidemics, hospital medical wards usually have a high concentration of patients with HIV who would benefit from diagnosis, treatment and care. Because not everyone with severe HIV-associated immunodeficiency has obvious clinical symptoms or signs of disease, HIV testing and counselling should be recommended to all patients admitted to hospitals and other inpatient facilities in generalized epidemic settings. This includes patients suspected of having, diagnosed with or being treated for tuberculosis.

Although outpatients are generally less ill than inpatients, HIV testing and counselling should also be recommended to all persons attending medical outpatient facilities in generalized epidemic settings.

· Antenatal, childbirth and postpartum health services

HIV testing and counselling as early as possible during pregnancy enables pregnant women to benefit from prevention, treatment and care and to access interventions for reducing HIV transmission to their infants.

A substantial proportion of women present to health facilities at the time of labour without having previously accessed antenatal HIV testing and counselling. Although antiretroviral prophylaxis for PMTCT is most effective when given during pregnancy, labour and in the early postpartum period, it has also been shown to be effective when started at the time of labour and/or in the infant shortly after childbirth. Therefore, HIV testing and counselling should be recommended to all women of unknown HIV status in labour or, if this is not feasible, as soon as possible after delivery⁵⁸.

If an HIV test has not previously been performed, HIV testing and counselling should also be recommended to women in the postpartum period, preferably early in this period, to enable them to receive HIV-related services for themselves and the infant, including infant feeding counselling and support⁵⁹, and diagnosis of the infant, if appropriate.

Antiretroviral prophylaxis and infant feeding counselling are important interventions for the prevention of mother-to-child HIV transmission, and must be available as part of the standard of care for pregnant women who are diagnosed HIV-positive as a result of provider-initiated HIV testing and counselling. Rapid HIV testing is also important in these settings so that interventions can be delivered in a timely manner.

It is important to ensure that women identified as HIV-negative receive any necessary, immediate support to prevent becoming infected during the course of pregnancy and the breastfeeding period, as the risk of mother-to-child transmission is high if women seroconvert during these times.

Women diagnosed HIV-positive should be encouraged to propose HIV testing and counselling to their male partners. Such testing can be done either in the health facility, for example, following counselling of the couple, or through referral of the partner to client-initiated HIV testing and counselling services.

STI services

In generalized epidemics, HIV is primarily transmitted through heterosexual sex, and the presence of a sexually transmitted infection (STI) can increase the risk of HIV acquisition or transmission. STI clinics are an important venue for increasing knowledge of HIV status among both men and women who are sexually active and increasing access to HIV prevention, treatment and care.

Accordingly, HIV testing and counselling should be recommended to all persons presenting at STI or sexual health services in generalized epidemics, or who present at other types of health services with an STI.

Patients diagnosed with an STI should be encouraged to propose HIV testing and counselling to their partners. Such testing can be done either in the health facility, for example, following counselling of the couple, or through referral of the partner to client-initiated HIV testing and counselling services.

Health services for most-at-risk populations

Specific population groups in all epidemic types are at higher risk for HIV. These may include sex workers and their clients, injecting drug users, men who have sex with men, prisoners, migrants and refugees. These populations often suffer worse health problems and have more difficulty accessing quality health services.

Strategies are needed to increase access to and uptake of HIV testing and counselling for these groups, particularly through innovative client-initiated approaches such as services delivered through mobile clinics, in other community settings, through harm reduction programmes or

through other types of outreach. Prisoners should be able to access client-initiated HIV testing and counselling at any time during incarceration without being subject to mandatory HIV testing. Efforts to expand access to client-initiated HIV testing and counselling for most-at-risk populations should include social mobilization and education initiatives to encourage people to learn their HIV status and to access services.

Because of their special health needs, populations most at-risk for HIV may be more likely to attend specific health services, such as acute care, STI or drug dependence treatment services. Consideration should therefore be given to recommending HIV testing and counselling to all patients who attend those facilities or services if this is epidemiologically appropriate and socially acceptable. Plans for provider-initiated testing and counselling in such settings should prioritize the implementation of a supportive social, policy and legal framework, as described in Section 5.2.

Populations most at-risk of HIV transmission may be more susceptible to coercion, discrimination, violence, abandonment, incarceration or other negative consequences upon disclosure of an HIV-positive test result. Health care providers will usually require special training and supervision to uphold standards of informed consent and confidentiality for these populations. Additional discussion of the right to decline HIV testing, of the risks and benefits of HIV testing and disclosure, and about social support needs may be required. An "opt-in" approach to informed consent may merit consideration for highly vulnerable populations.

Involving most-at-risk populations and their advocates in the development of HIV testing and counselling protocols and in the monitoring and evaluation of provider-initiated HIV testing and counselling programmes will help to ensure that the most appropriate and acceptable practices are followed.

Health services should also ensure that mechanisms are in place for referral to prevention, care and support services provided by community-based organizations and civil society groups⁶⁰.

Services for younger children (under 10 years of age)

In generalized epidemics, a substantial proportion of children seen at health facilities is infected with HIV. Children have a more rapid progression of HIV disease than adults and signs and symptoms of HIV-infection are often not specific⁶¹. Without access to care, at least one quarter of children with HIV die before the age of one year and most die before reaching five years of age. Antiretroviral treatment and/or interventions such as co-trimoxazole prophylaxis markedly reduce child morbidity and mortality, highlighting the importance of early paediatric HIV diagnosis.

HIV testing and counselling should therefore be recommended to all children seen in pediatric health services in generalized epidemic settings.

Special considerations will apply for obtaining informed consent in the case of children (see Section 6).

Because maternal antibodies may persist in exposed infants in the first year of life, antibody testing does not always reliably indicate the HIV status of the child. HIV testing for children less than 18 months of age is ideally undertaken using virological methods wherever possible (see Section 7).

Because parents generally accompany their children during visits to child health services, opportunities will arise to recommend HIV testing and counselling to the parents and siblings of the child, such as through family or couple counselling either in the health facility or through referral to client-initiated HIV testing and counselling services. HIV testing and counselling is especially important for mothers of HIV-infected children and for mothers who were not tested in PMTCT services.

· Surgical services

HIV testing simply for knowledge of HIV status by service providers for the purpose of "infection control" is not justified, as standard precautions should be followed for all patients regardless of their HIV status. HIV test results must not be used to deny surgery or clinical services that are otherwise indicated.

Although surgical patients generally have a lower HIV prevalence than non-surgical patients⁶², HIV testing and counselling should nevertheless be recommended to all surgical patients attending health facilities in generalized epidemic settings. As in the case of all other people accessing health facilities in generalized epidemic settings, the objective of recommending HIV testing and counselling to surgical patients is to facilitate the timely detection of HIV and to provide the best possible care and support to the patient.

HIV testing and counselling should be recommended to all men seeking circumcision as an HIV prevention intervention.

· Services for adolescents

In generalized epidemics, adolescents (10-19 years), particularly girls, are at high risk of acquiring HIV. Adolescent-provider encounters in clinical settings are an opportunity for giving information and counselling about sexual and reproductive health. It is therefore recommended that adolescent health services be considered a priority for the implementation of provider-initiated HIV testing and counselling in generalized epidemics.

Special attention should be given to issues around informed consent in adolescents (See Section 6).

· Reproductive health services, including family planning

Knowledge of HIV status may increase a woman's ability to make voluntary and informed decisions about the number, spacing and, timing of pregnancies, including the use of

contraceptive methods. It is therefore recommended that provider-initiated HIV testing and counselling be integrated into reproductive health services in generalized epidemics.

Patients diagnosed HIV-positive in these services should be encouraged to propose HIV testing and counselling to their male partners. Such testing can be done either in the health facility, for example, following counselling of the couple, or through referral of the partner to client-initiated HIV testing and counselling services.

4.3 Provider-initiated HIV testing and counselling in concentrated and low-level HIV epidemics

4.3.1 Recommendation to prioritize provider-initiated testing and counselling for symptomatic patients

Health care providers should **not** recommend HIV testing and counselling to all persons attending all health facilities in settings with low-level and concentrated epidemics, since most people will have a low risk of exposure to HIV. In such settings, the priority should be to ensure that HIV testing and counselling is recommended to all adults, adolescents and children who present to health facilities with signs and symptoms suggestive of underlying HIV infection, including tuberculosis; and to children known to have been perinatally exposed to HIV.

If data show that HIV prevalence in patients with tuberculosis is very low, the recommendation of HIV testing and counselling to these patients may not remain a priority.⁶³

4.3.2 Options for the implementation of provider-initiated HIV testing and counselling in selected health facilities

Although a country as a whole may have a low HIV prevalence, prevalence and/or risk of transmission may be higher within certain regions, among certain populations or among persons attending certain health facilities. Decisions about whether and how to implement provider-initiated HIV testing and counselling in selected health facilities in low-level and concentrated epidemics should be guided by an assessment of the epidemiological and social context. Based on that assessment, consideration may be given to the implementation of provider-initiated HIV testing and counselling in the following health facilities or services:

· STI services

The same considerations apply as in the case of generalized epidemics (see Section 4.2.2, page 24).

Health services for most-at-risk populations

The same considerations apply as in the case of generalized epidemics (see Section 4.2.2, page 24-25).

· Antenatal, childbirth and postpartum services

A number of countries with concentrated or low-level epidemics that are aiming to eliminate HIV transmission to children have implemented provider-initiated HIV testing and counselling for all pregnant women.

Other countries – particularly those with very limited resources – have not implemented PMTCT programmes and are focusing on other priorities. Decisions about whether to make provider-initiated HIV testing and counselling part of such services in low-level and concentrated epidemics need to be based on an assessment of local resources and the epidemiological and social context. Recommending HIV testing and counselling may be appropriate for pregnant women identified as being at higher risk of HIV exposure according to national or local criteria.

However, all countries should address mother-to-child transmission in national HIV/AIDS plans, even if only some elements of a comprehensive PMTCT programme can initially be included. Information about MTCT and HIV testing and counselling should also be given to pregnant women during antenatal information sessions.

Health care providers should **not** recommend HIV testing and counselling for all children in pediatric services in concentrated or low-level epidemics. HIV testing and counselling be targeted to children with symptoms, signs or conditions potentially associated with HIV, or those known to have been exposed.

4.4 Summary of recommendations

ALL EPIDEMIC SETTINGS

HIV testing and counselling should be recommended in all health facilities to:

- Adults, adolescents, or children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection, including tuberculosis*.
- HIV-exposed children or children born to HIV-positive women.
- Children with suboptimal growth or malnutrition or malnourished children, in generalized epidemics, who are not responding to appropriate nutritional therapy.
- Men seeking circumcision as an HIV prevention intervention.
- * If data show that HIV prevalence in patients with tuberculosis is very low, the recommendation of HIV testing and counselling to these patients may not remain a priority.

GENERALIZED EPIDEMIC SETTINGS

HIV testing and counselling should additionally be recommended to all patients in all health facilities, including medical and surgical services, public and private facilities, inpatient and outpatient settings and mobile or outreach medical services.

In the case of phased implementation of provider-initiated HIV testing and counselling, an approximate order of priority, depending on local conditions, may be as follows:

- · Medical inpatient and out patient facilities, including TB clinics
- · Antenatal, childbirth, and postpartum health services
- STI services
- · Services for most-at-risk populations
- · Services for children under 10 years of age
- · Services for adolescents
- Surgical services
- · Reproductive health services, including family planning

CONCENTRATED AND LOW-LEVEL EPIDEMIC SETTINGS

Implementation of provider-initiated HIV testing and counselling should additionally be considered in:

- STI services
- Services for most-at-risk populations
- · Antenatal, childbirth, and postpartum health services
- TB services

5. ENSURING AN ENABLING ENVIRONMENT

Provider-initiated HIV testing and counselling should be implemented with the objective of maximizing the health and well-being of individuals through the timely detection of HIV, prevention of HIV transmission and subsequent access to appropriate HIV prevention, treatment, care and support services. Implementation of provider-initiated HIV testing and counselling must include measures to prevent compulsory testing and unauthorized disclosure of HIV status, and potential negative outcomes of knowing one's HIV status. Potential negative outcomes include discriminatory attitudes of health care providers; financial burden associated with testing and/or unauthorized disclosure of an individual's HIV status resulting in discrimination or violence. Women may be more likely than men to experience discrimination, violence, abandonment or ostracism when their HIV status becomes known. Although a synthesis of studies on disclosure of HIV status among women in developing countries reported positive outcomes related to disclosure in most cases⁶⁴, disclosure-related violence does occur and preventive measures must be taken⁶⁵.

Positive outcomes are most likely when HIV testing and counselling is confidential and is accompanied by counselling and informed consent, staff are adequately trained, the person undergoing the test is offered or referred to appropriate follow-up services and an adequate social, policy and legal framework is in place to prevent discrimination.

5.1 Recommended HIV-related services

Provider-initiated HIV testing and counselling should be accompanied by the recommended package of HIV-related prevention, treatment, care and support services shown in Table 1. Although not all the services need necessarily be available in the same facility as where the HIV test is performed, they should be available through local referral.

Although access to antiretroviral therapy is expanding, in many settings it is not yet available. The package of care and support services described in Table 1 may nevertheless provide significant health benefits for people who are diagnosed HIV-positive. Although access to antiretroviral therapy should not be an absolute prerequisite for the implementation of provider-initiated HIV testing and counselling, there should at least be a reasonable expectation that it will become available within the framework of a national plan to achieve universal access to antiretroviral therapy for all who need it.

Antiretroviral prophylaxis and infant feeding counselling are important interventions for the prevention of mother-to-child transmission. These interventions must be available as part of the standard of care for pregnant women who are diagnosed HIV-positive through provider-initiated HIV testing and counselling.

Provision of extensive prevention services may not be feasible or required for all people who test HIV-negative in many resource-limited health facilities. However, in most cases, these can be made available through referral to community-based or other appropriate services.

Table 1: HIV-related services recommended for implementation of provider-initiated HIV testing and counselling in health facilities

· Individual or group pre-test information

• Basic prevention services for persons diagnosed HIV-negative:

- Post-test HIV prevention counselling for individuals or couples that includes information about prevention services
- Promotion and provision of male and female condoms
- Needle and syringe access and other harm reduction interventions for injecting drug users
- Post-exposure prophylaxis, where indicated

Basic prevention services for persons diagnosed HIV-positive:

- Individual post-test counselling by a trained provider that includes information about and referral to prevention, care and treatment services, as required
- Support for disclosure to partner and couples counselling
- HIV testing and counselling for partners and children
- Safer sex and risk reduction counselling with promotion and provision of male and female condoms
- Needle and syringe access and other harm reduction interventions for injecting drug users
- Interventions to prevent mother-to-child transmission for pregnant women, including antiretroviral prophylaxis
- Reproductive health services, family planning counselling and access to contraceptive methods

Basic care and support services for persons diagnosed HIV-positive:

- Education, psychosocial and peer support for management of HIV
- Periodic clinical assessment and clinical staging
- Management and treatment of common opportunistic infections
- Co-trimoxazole prophylaxis
- Tuberculosis screening and treatment when indicated; preventive therapy when appropriate
- Malaria prevention and treatment, where appropriate
- STI case management and treatment
- Palliative care and symptom management
- Advice and support on other prevention interventions, such as safe drinking water
- Nutrition advice
- Infant feeding counselling
- Antiretroviral treatment, where available

5.2 Supportive social, policy and legal framework

At the same time as provider-initiated HIV testing and counselling is implemented, equal efforts must be made to ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harms to patients.

5.2.1 Basic elements

The following elements of a social, policy and legal framework should be in place to support the implementation of provider-initiated HIV testing and counselling in health facilities:

· Community preparedness and social mobilization

Public information campaigns should be conducted to raise community awareness about HIV/AIDS; promote the rights of people living with HIV/AIDS and the benefits of knowing and disclosing one's HIV status; and provide information about the available services for HIV testing, prevention, care and support. People living with HIV/AIDS and affected communities should be involved in the formulation, implementation and monitoring of such campaigns.

· Adequate resources and infrastructure

Policy-makers and planners should anticipate the additional resources required for the implementation of provider-initiated HIV testing and counselling in health facilities, including for training, clinical infrastructure and the purchase of commodities such as HIV test kits and other clinical supplies.

WHO and UNAIDS recommend that, to the extent possible, provider-initiated HIV testing and counselling should not involve any additional costs for patients at the point of service delivery. Resources allocated to the implementation of provider-initiated HIV testing and counselling should not be diverted from other needed services, including client-initiated approaches to HIV testing and counselling.

Adequate clinical infrastructure must also be available, including adequate private consulting rooms and lockable storage for medical records. Additional resources may be needed to assist community-based organizations in providing follow-up counselling, support and other services.

· Health care provider training

A major investment required for the implementation of provider-initiated HIV testing and counselling is likely to be in the training and ongoing supervision of health care providers and administrators.

A redistribution of health worker responsibilities (task-shifting) in health facilities may help to overcome chronic staff shortages in some settings. This may entail identifying appropriately skilled

lay personnel who can receive training and remuneration to carry out HIV testing and counselling activities under the supervision of health care professionals with more specialized expertise. People living with HIV/AIDS, AIDS service organizations and other community-based organizations and civil society groups can provide an important source of skilled lay personnel. In some settings, expanding the types of health workers who are authorized to carry out HIV testing and counselling, including rapid HIV testing, may require a review of local laws and regulations.

Training programmes for personnel who will perform HIV testing and counselling in health facilities, as well as for other staff who deal with clients in health services, should be developed and implemented well in advance of the implementation of provider-initiated HIV testing and counselling. Training should be based on protocols which specifically address the following key areas:

- Ensuring an ethical process for obtaining informed consent

Guidance and ongoing supervision must be provided to health care providers on the process of obtaining informed consent. Patients must receive adequate information on which to base a personal and voluntary decision whether or not to consent to the test, and be given an explicit opportunity to decline a recommendation of HIV testing and counselling without coercion. More detailed guidance on the process of obtaining informed consent appears in Section 6.

Protecting confidentiality and privacy

Training must emphasize that health care providers have a responsibility to maintain the confidentiality of HIV test results. The fact that the patient has provided informed and voluntary consent to an HIV test, and the test result, should be documented in patient records. Clinical care can be undermined by not recording HIV results or not communicating results to other health care providers responsible for patient care.

Medical records, including test results, should only be shared with health care professionals who have a direct role in the ongoing management of the patient. These principles apply to both verbal and written communications. Patients should be offered advice on the safe-keeping of patient-held records, such as antenatal care (ANC) cards and child health cards.

Privacy must also be ensured. For example, informed consent should be sought and given in a private setting and post-test counselling for an HIV-positive patient and other communications relating to HIV status should take place away from other patients or staff not involved with that patient's care.

Medical records administrators may need to receive specific training in the appropriate handling of medical records in clinical settings where HIV testing and counselling is performed.

Avoiding stigma and discrimination in the health facility

People living with or who are suspected of having HIV frequently report mistreatment or discrimination on the part of health care providers. The implementation of provider-initiated HIV testing and counselling provides an opportunity to raise awareness about HIV/AIDS and human rights issues among health care providers and administrators and reinforce their adherence to appropriate standards of practice.

Staff interacting with patients should receive specific training and ongoing supervision to address the needs of people living with and at-risk for HIV. It should be standard practice to treat all patients decently, with respect and without discrimination on the basis of HIV status or risk behaviours, and to help patients address potential negative social consequences of HIV testing. Involving people living with HIV, members of at-risk populations and their advocates in training sessions for health care providers on these issues is strongly recommended.

Patient referral

Health care providers will require training on the referral needs of patients, their partners and family members and the services that are available locally to provide follow-up and support, including the availability of client-initiated HIV testing and counselling services.

· Codes of conduct and methods of redress

Health facilities should develop codes of conduct for health care providers and methods of redress for patients whose rights are infringed. Consideration should be given to the appointment of an independent ombudsman or patient advocate to whom breaches of HIV testing and counselling protocols and codes of conduct can be reported.

· A strong monitoring and evaluation system

A system that monitors the implementation and scale-up provider-initiated testing and counselling should be developed and implemented concurrently. This is discussed in more detail in Section 9.

5.2.2 Other measures

Although the following measures may not be prerequisites for the implementation of provider-initiated HIV testing and counselling, they should be addressed as part of national plans to scale up HIV testing and counselling and to achieve universal access to HIV prevention, treatment, care and support:

· Social and legal interventions

Optimal delivery of provider-initiated HIV testing and counselling in the long term requires that laws and policies against discrimination on the basis of HIV status, risk behaviour and gender

are in place, monitored and enforced. These include legal and social protections which enhance privacy, autonomy and gender equality. Implementing these broad social and legal protections is the responsibility of diverse stakeholders, including parliamentarians, ministries of the interior, health and justice and civil society groups67, emphasizing the need for multisectoral commitment to scaling up provider-initiated HIV testing and counselling.

· Voluntary disclosure and ethical partner notification and counselling

UNAIDS and WHO encourage voluntary disclosure of HIV status and ethical partner notification and counselling. This may require national policies and public health legislation authorizing partner notification in clearly defined circumstances, as well as the promotion of professional ethical codes among health care and social service providers. While beyond the scope of this document, these issues are comprehensively addressed in the UNAIDS/WHO publication Opening up the HIV/AIDS epidemic: Guidance on encouraging beneficial disclosure, ethical partner counselling & appropriate use of HIV case-reporting.⁶⁸

6. PROCESS AND ELEMENTS

6.1 Pre-test information and informed consent

Providers of client-initiated HIV testing and counselling typically conduct an education session and a risk assessment, with a primary focus on prevention counselling for clients both prior to and after receiving their test results.

In many health facilities, providers do not have the time to perform a detailed risk assessment. Because the objective of provider-initiated HIV testing and counselling in health facilities is the timely detection of HIV and access to health care services, pre-test information can be simplified. For example, individual risk assessment and risk reduction plans can be covered during post-test sessions, rather than in the pre-test information session, tailored to patient's HIV status.

Depending on local conditions, pre-test information can be provided in the form of individual information sessions or in group health information talks. Informed consent should always be given individually, in private, in the presence of a health care provider.

6.1.1 Minimum information for informed consent

When recommending HIV testing and counselling to a patient, the health care provider should at a minimum provide the patient with the following information:

- The reasons why HIV testing and counselling is being recommended
- The clinical and prevention benefits of testing and the potential risks, such as discrimination, abandonment or violence
- The services that are available in the case of either an HIV-negative or an HIV-positive test result, including whether antiretroviral treatment is available
- The fact that the test result will be treated confidentially and will not be shared with anyone other than heath care providers directly involved in providing services to the patient
- The fact that the patient has the right to decline the test and that testing will be performed unless the patient exercises that right
- The fact that declining an HIV test will not affect the patient's access to services that do not depend upon knowledge of HIV status
- In the event of an HIV-positive test result, encouragement of disclosure to other persons who may be at risk of exposure to HIV
- An opportunity to ask the health care provider questions.

Patients should also be made aware of relevant laws in jurisdictions that mandate the disclosure of HIV status to sexual and/or drug injecting partners.

Verbal communication is normally adequate for the purpose of obtaining informed consent. Jurisdictions that require consent to be given in writing are encouraged to review this policy.

Some patient groups, such as populations most at-risk of HIV transmission and women, may be more susceptible to coercion to be tested and to previously discussed adverse outcomes. In such cases, additional measures to ensure informed consent may be appropriate beyond the minimum requirements defined in this document. The health care provider may need to particularly emphasize the voluntary nature of the test and the patient's right to decline it. Additional discussion of the risks and benefits of HIV testing and disclosure of HIV status, and providing further information about the social support that is available to the patient, may also be appropriate.

6.1.2 Additional information for women who are or may become pregnant

In addition to the information set out in 6.1.1, pre-test information for women who are or may become pregnant should include:

- · The risks of transmitting HIV to the infant
- Measures that can be taken to reduce mother-to-child transmission, including antiretroviral prophylaxis and infant feeding counselling
- The benefits to infants of early diagnosis of HIV.

6.1.3 Special considerations for children

According to the UN Convention on the Rights of the Child, "the best interests of the child shall be a primary consideration" in all actions concerning children. This includes decision-making about medical care. As with all other patients, the purpose of HIV testing and counselling should always be to promote the best interests and optimal health outcomes for the child. HIV testing and counselling for children involve special considerations, however, and specific national policies may need to be developed.

As minors, children cannot legally provide informed consent. However, children have the right to be involved in all decisions affecting their lives and to make their views known according to their level of development. Every attempt should be made to explain to the child what is happening and to obtain her/his assent. Informed consent from the child's parent or quardian *is* required.

Where a child is extremely disadvantaged because he or she is orphaned, abandoned, undocumented, a survivor of trauma or affected by mental or intellectual disability, he or she may be at increased risk of discrimination, exploitation and unfavourable access to health care. HIV testing and counselling should be recommended for such children where the criteria of apparent HIV-related illness are satisfied, or maternal HIV-positive status is known. As with all patients, HIV testing should only be offered for the purpose of providing the child with appropriate HIV-related treatment, care and support.

Where there is no parent or legal guardian available to provide informed consent, health care providers should seek informed consent from an individual (sometimes known as a "substitute decision-maker" or "surrogate decision-maker") who has authority under the law to make a decision based on the best interests of the child.

The majority of children acquire HIV through mother-to-child transmission and a positive result in a child (serological or virological), in most instances indicates maternal infection and, possibly, paternal infection. HIV testing and counselling should therefore be recommended to parents and siblings of HIV-infected children, where possible and appropriate, in the form of couples or family HIV counselling and testing. Mothers should be specially informed that a negative test in the child does not mean that the mother is not HIV-infected⁶⁹.

Health care providers must be adequately equipped to deal with the needs of children. For example, counselling children requires skills that differ from adult and adolescent counselling, including the ability to assess maturity and use age-appropriate language.

6.1.4 Special considerations for adolescents

In most countries, the median age of sexual debut for adolescents is earlier than the age of legal majority, and many adolescents do not have independent access to HIV prevention services. With regard to sexual and reproductive information, including on family planning, the Committee on the Rights of the Child has stated in General Comment 4 (Adolescent Health and Development) that governments should ensure that adolescents have access to appropriate information regardless of their marital status and whether or not parents or guardians consent, and should remove all barriers to health services, including those relating to HIV prevention. For these reasons, WHO and UNAIDS encourage countries to provide adolescents with independent access to HIV prevention, treatment, care and support.

National and local laws may or may not stipulate precisely the age of majority for independent access to health services, or the age at which adolescents are allowed to give their own consent may vary for different procedures. For example, adolescents may be able to consent to be tested for HIV or receive condoms at a younger age than they can consent to surgical procedures. Many countries make allowances for groups of adolescents designated 'mature' or 'emancipated' minors (e.g. those who are married, pregnant, sexually active, living independently or who are themselves parents) which enable them to provide consent for themselves for some services.

Governments should develop and implement clear legal and policy frameworks that stipulate 1) the specific age and/or circumstances in which minors may consent to HIV testing for themselves or for others (as in the case of child-headed households) and 2) how the assent of and consent for adolescents should best be assessed and obtained. Efforts to expand provider-initiated HIV testing and counselling in health facilities should include training and supervision for health care providers on laws and policies governing the consent for minors to access clinical services, including when they can and cannot recommend an HIV test to an adolescent independent of the consent of the adolescent's parent or legal guardian.

Where the law does not allow a sufficiently mature adolescent to give his or her own informed consent to an HIV test, the health care provider should provide an adolescent patient with the opportunity to assent to HIV testing and counselling in private, without the presence or knowledge of his or her parents or legal guardians. The pre-test information should be adapted to the

patient's age, developmental stage and literacy level. If the adolescent provides assent, indicating that he or she understands the risks and the benefits of HIV testing and would like to receive the test, then the health care provider should seek the informed consent of the parent or legal guardian.

In some situations, a parent or legal guardian may not be available to give consent on the adolescent's behalf. The health care provider may need to assess whether an adolescent can request and consent to testing alone. The provider must always work within the framework of local or national laws and regulations and be guided by the best interests of the patient.

6.1.5 Seriously ill patients

Critically ill or unconscious patients may not be able to provide informed consent to HIV testing and counselling. In such circumstances, consent should be sought from the patient's next-of-kin, guardian or other caregiver. In the absence of such a person, health care providers should act according to the best interests of the patient concerned.

6.1.6 Follow-up where a test is declined

Declining an HIV test should not result in reduced quality or denial of services, coercive treatment or breach of confidentiality, nor should it affect a person's access to health services that do not depend on knowledge of HIV status. Individuals declining the test should be offered assistance to access either client-initiated or provider-initiated HIV testing and counselling in the future.

The patient's decision to decline the HIV test should be noted in the medical record so that, at subsequent visits to the health facility, a discussion of HIV testing and counselling can be reinitiated

6.2 Post-test counselling

Post-test counselling is an integral component of the HIV testing process. All individuals undergoing HIV testing must be counselled when their test results are given, regardless of the test result. Given that many inpatient and outpatient facilities are crowded, care should be taken to discuss results and follow-up care in a confidential manner. Results should be given to patients in person by health care providers or by trained lay personnel. Ideally, post-test counselling should be provided by the same health care provider who initiated HIV testing and counselling. Results should not be given in group settings.

It is not acceptable practice for health care providers to recommend HIV testing and counselling to patients and to subsequently withhold or fail to convey test results. Although patients can refuse to receive or accept results of any test or investigation, health care providers should make every reasonable attempt to ensure that patients receive and understand their test results in a confidential and sympathetic manner.

6.2.1 Post-test counselling for HIV-negative persons

Counselling for individuals with HIV-negative test results should include the following minimum information:

- An explanation of the test result, including information about the window period for the appearance of HIV-antibodies and a recommendation to re-test in case of a recent exposure
- Basic advice on methods to prevent HIV transmission
- Provision of male and female condoms and guidance on their use.

The health care provider and the patient should then jointly assess whether the patient needs referral to more extensive post-test counselling session or additional prevention support, for example, through community -based services.

6.2.2 Post-test counselling for HIV-positive persons

The focus of post-test counselling for people with HIV-positive test results is psychosocial support to cope with the emotional impact of the test result, facilitate access to treatment, care and prevention services, prevention of transmission and disclosure to sexual and injecting partners. Health care providers should:

- Inform the patient of the result simply and clearly, and give the patient time to consider it
- Ensure that the patient understands the result
- Allow the patient to ask questions
- Help the patient to cope with emotions arising from the test result
- Discuss any immediate concerns and assist the patient to determine who in her/his social network may be available and acceptable to offer immediate support
- Describe follow-up services that are available in the health facility and in the community, with special attention to the available treatment, PMTCT and care and support services
- Provide information on how to prevent transmission of HIV, including provision of male and female condoms and guidance on their use
- Provide information on other relevant preventive health measures such as good nutrition, use
 of co-trimoxazole and, in malarious areas, insecticide-treated bed nets
- · Discuss possible disclosure of the result, when and how this may happen and to whom
- Encourage and offer referral for testing and counselling of partners and children
- Assess the risk of violence or suicide and discuss possible steps to ensure the physical safety of patients, particularly women
- Arrange a specific date and time for follow-up visits or referrals for treatment, care, counselling, support and other services as appropriate (e.g. tuberculosis screening and treatment, prophylaxis for opportunistic infections, STI treatment, family planning, antenatal care, opioid substitution therapy, and access to sterile needles and syringes).

6.2.3 Post-test counselling for HIV-positive pregnant women

In addition to the information described in Section 6.2.2, post-test counselling for pregnant women whose test result is HIV-positive should address the following:

- Childbirth plans
- Use of antiretroviral drugs for the patient's own health, when indicated and available, and to prevent mother-to-child transmission
- · Adequate maternal nutrition, including iron and folic acid
- Infant feeding options and support to carry out the mother's infant feeding choice
- HIV testing for the infant and the follow-up that will be necessary
- · Partner testing.

6.3 Referral to other HIV services

HIV test results must be communicated with an explanation of the prevention, treatment, care and support services available to the patient. Programmes for other chronic illnesses and community-based HIV prevention, treatment, care and support services are especially important resources and it is important to establish and maintain collaborative mechanisms with them.

At a minimum, referral should include providing the patient with information about whom to contact as well as where, when and how to contact them. Patient referral works best if the health care provider makes contact in the presence of the patient and schedules an appointment, making note of the contact and the organization in the patient's file. Staff within the referral network need to routinely inform each other of changes in personnel or processes which could impact upon the referral of patients.

6.4 Frequency of testing

How often patients are re-tested will depend on the continued risks taken by the patient, the availability of human and financial resources and HIV incidence in the setting.

Re-testing every 6-12 months may be beneficial for individuals at higher risk of HIV exposure, such as persons with a history of STI, sex workers and their clients, men who have sex with men, injecting drug users and sex partners of people living with HIV. Additional research is needed in diverse settings with varying HIV epidemiology to determine the optimum interval between HIV tests for specific populations.

Risks of HIV transmission to the infant are very high if the mother acquires HIV during pregnancy or while breastfeeding. HIV-negative women should be tested as early as possible in each new pregnancy, particularly in high-prevalence settings and in the case of women who are at high risk of HIV exposure.

Repeat testing late in pregnancy should also be recommended to HIV-negative women in generalized epidemic settings.

HIV testing and counselling should generally be recommended to patients where doubt exists about the patient's prior testing history or the accuracy or veracity of prior test results.

It is important that regular HIV testing does not become a substitution for prevention behaviours. Health care providers should emphasize that people should sustain safer behaviour.

7. HIV TESTING TECHNOLOGIES

7.1 Factors to consider

The introduction of highly sensitive, specific, simple-to-use, rapid antibody tests that do not require sophisticated laboratory services, running water or electricity is an important advance. Accurate results can be available within a much shorter time than for traditional enzyme-linked immunosorbent assays (ELISA). The advantages of using rapid HIV tests for provider-initiated HIV testing and counselling – particularly for health facilities where laboratory services are weak – include visibility of the test and quick turn-around, increasing confidence in results and avoidance of clerical errors. Testing can occur outside laboratory settings, does not require specialized equipment and can be carried out in primary health facilities by appropriately trained non-laboratory personnel, including counsellors. However, trained laboratory supervisors are required for supervision and quality assurance, including quality control for testing and bio-safety. Tests selected should be of assured quality.

ELISA may be preferable in settings where large numbers of tests need to be performed, where immediate provision of test results is less important (such as for hospital inpatients) and in reference laboratories. ELISA allows large numbers of samples to be tested efficiently at one time but potential disadvantages include the necessary time to assemble enough samples to make a test run (approximately 40), the need for clerical rigour to unambiguously link individuals to test results and the reporting time of the results (half a day), which generally precludes outpatients receiving the test result at the same visit. ELISA tests are carried out using specialized laboratory equipment and therefore require certified laboratory staff to manage the test procedure, report results and maintain equipment.

Decisions on whether to use HIV rapid tests or ELISA for provider-initiated HIV testing and counselling should take into account factors such as:

- Cost and availability of the test kits, reagents and equipment
- · Available staff, resources and infrastructure
- Laboratory expertise and personnel available
- Number of samples to be tested
- · Sample collection and transport
- · The setting in which testing is proposed
- Convenience
- The ability of individuals to return for results.

Definitive diagnosis of HIV infection in children younger than 18 months requires virological tests, as the presence of maternal HIV antibodies may complicate the interpretation of positive results of HIV rapid tests or ELISA tests. Virological testing depends upon complex procedures such as HIV-DNA or HIV-RNA polymerase chain reaction (PCR), is expensive and requires highly trained

staff. WHO promotes a centralized virological testing approach where specimens are collected on filter papers which are easily transported to a central laboratory, even in tropical conditions.

7.2 Testing algorithms

HIV testing should follow recommended CDC-UNAIDS-WHO HIV testing strategies⁷⁰ and relevant national HIV testing algorithms. Testing algorithms may involve serial (also called sequential) or parallel testing. ELISA-based algorithms are almost always serial in nature, while rapid test algorithms can be either.

With **serial testing**, if the result of the first test is negative, the HIV antibody test is reported as negative. If the test result is positive, the specimen is tested with a second test using different antigens and/or platform from the first. Tests that are exactly the same but sold under different names should not be used in combination. A second positive test result is considered to indicate a true positive result in populations with an HIV prevalence of 5% or more. In low prevalence settings where false positive results are more likely, a third confirmatory test may be required. WHO and UNAIDS recommend serial testing in most settings because it is cheaper and a second test is only required when the initial test is reactive.

With **parallel testing** – recommended only when using whole blood finger stick samples rather than venous blood – two tests are carried out simultaneously using assays based on different antigens and/or platforms. Concordantly negative or positive results are considered as true negatives or positives, respectively.

When two test results (serial or parallel) show dissimilar results (one is reactive and the other non-reactive), the tests results are described as discordant. Specialist laboratory advice may be required in cases of such test discordance.

In all cases, WHO and UNAIDS recommend that HIV tests used should have a sensitivity of at least 99% and a specificity of 98%. The specific test combinations need to be evaluated in the context in which they will be used before wide-scale implementation.

8. PROGRAMMATIC CONSIDERATIONS

Decisions on how best to implement provider-initiated HIV testing and counselling will depend upon an assessment of the situation in a particular country, including local epidemiology, the available infrastructure, financial and human resources, the available standard of HIV prevention, treatment, care and support and the existing social, policy and legal frameworks for protection against HIV-related discrimination. Where there are high levels of stigma and discrimination and/ or low capacity of health care providers to implement provider-initiated HIV testing and counselling under the conditions of informed consent, confidentiality and counselling, adequate resources must be devoted to addressing these issues prior to implementation.

Decisions about whether and how to implement provider-initiated HIV testing and counselling should be made in consultation with all relevant stakeholders. The steps that may need to be taken to adapt the general recommendations in this document to national and local conditions are shown in Table 2.

Many settings with a high HIV burden face substantial human and financial constraints that limit the feasibility of implementing new health services on a large scale. As described in Section 4, it may be necessary to prioritize particular types of health facilities for the introduction of provider-initiated HIV testing and counselling, depending upon the social and epidemiological context and available resources.

Coordinated planning, training and procurement are important to help ensure synergies between provider- and client-initiated HIV testing and counselling approaches and will help to facilitate referral between different types of health services.

Table 2 Consultation and adaptation activities to implement providerinitiated HIV testing and counselling at country level

- In countries considering the implementation of provider-initiated HIV testing and counselling, the Ministry of Health should convene a national consultation to plan an implementation strategy, including adaptation of this guidance document to local conditions. Participants should include:
 - National-level programme managers for HIV, tuberculosis and other clinical services
 - Ministries of justice, welfare, interior and finance
 - Health care providers
 - Regulatory bodies and health professional associations
 - Community- and faith-based organizations, including women's organizations
 - Most-at-risk populations
 - People living with HIV/AIDS
 - · Human rights advocates
 - Private sector representatives
 - Representatives of legal and social support services.
- Existing social, legal and policy frameworks should be assessed and reviewed to
 facilitate implementation of provider-initiated HIV testing and counselling and to
 protect the rights of patients, including advocacy and communication campaigns
 and social and legal support services.
- 3. Adequate resources must be planned and available for implementation, including for testing-related commodities, health care provider training and community preparedness and social mobilization.
- 4. Operational guidelines, protocols and codes of conduct for health care providers, training tools and education materials must be developed or adapted. These should be based on HIV epidemiology, available resources, ethical and human rights principles and legal and sociocultural contexts.
- 5. For countries choosing to implement provider-initiated HIV testing and counselling in a phased manner, priority settings for initial and subsequent scale-up should be selected.
- 6. Health care providers should be identified and trained.
- 7. Provider-initiated HIV testing and counselling should be incorporated into existing supervision, quality assurance and monitoring and evaluation systems.
- 8. Civil society should be engaged in ongoing monitoring and evaluation of provider-initiated HIV testing and counselling in health facilities.
- 9. At facility level, linkages should be strengthened between services to facilitate entry into HIV-related services following HIV testing and counselling, including community-based prevention, treatment, care and support services.

9. MONITORING AND EVALUATION

Monitoring and evaluation should form an essential and ongoing part of programmes to implement provider-initiated HIV testing and counselling. National monitoring and evaluation of provider-initiated HIV testing and counselling services should allow programme managers to:

- Monitor progress in implementation, including procedures for obtaining informed consent, ensuring confidentiality and providing counselling
- Identify problems, and refine and adapt implementation strategies
- Assess the effectiveness and impact of provider-initiated testing and counselling in terms of:
 - increasing access to HIV testing and counselling, and to test results
 - increasing access to and uptake of HIV-related prevention, treatment, care and support services
 - decreased morbidity and mortality
 - increased HIV awareness and treatment literacy
 - social impact (e.g. on rates of disclosure; on stigma and discrimination; and adverse outcomes).
- · Assess cost-effectiveness and sustainability.
- Assess the quality of related laboratory services
- Assess the reasons that HIV testing and counselling is being recommended.

Monitoring and evaluation planning should aim, where possible, to utilize existing structures or mechanisms for collecting relevant indicators, rather than setting up independent systems. Standardized and simple data collection tools will enable comparability between sites and reduce burden on health care personnel. Appropriate training in data collection should be provided to health care providers and administrators.

As the amount of data in routine monitoring will always be limited, it is recommended to complement routine monitoring with focused evaluations on specific aspects of implementation. For example, quality assurance should be undertaken at the health facility level. Regular evaluations of health care provider performance and patient satisfaction (testing processes, pre-test information, consent process, post-test counselling) can help improve the effectiveness, acceptability and quality of HIV testing and counselling services.

Health facilities are encouraged to partner with non-governmental organizations and civil society groups in monitoring and evaluating provider-initiated HIV testing and counselling to ensure service quality and acceptability, including the maintenance of high ethical standards and human rights norms.

More detailed guidance on monitoring and evaluation of HIV testing and counselling, including provider-initiated HIV testing and counselling, is being developed by WHO and will be available in 2007.

APPENDIX

Additional resources

A broad selection of tools and guidance for implementing HIV testing and counselling in different settings, including provider-initiated HIV testing and counselling, may be found on the **WHO HIV Testing and Counselling Online Toolkit**. This web site is periodically updated with the latest HIV testing and counselling resources available (Web site: http://who.arvkit.net/tc/en/index.jsp:

PDF file: http://whalibdoc.who.int/publications/2005/924159327X ena.pdf).

The following documents and internet sites may also be useful resources for planning, implementing and scaling-up provider-initiated HIV testing and counselling services:

Antiretroviral therapy and clinical care

- Antiretroviral therapy for HIV infection in adults and adolescents: towards universal access recommendations for a public health approach, WHO, 2006 revision. http://www.who.int/entity/hiv/pub/guidelines/artadultguidelines.pdf
- Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: towards universal access - recommendations for a public health approach, WHO, 2006 version. http://www.who.int/hiv/pub/guidelines/pmtctguidelines2.pdf
- Antiretroviral therapy for HIV infection in infants and children: towards universal access recommendations for a public health approach, WHO, 2006.
 http://www.who.int/hiv/pub/guidelines/paediatric020907.pdf
- WHO ARV Toolkit. Website: http://www.who.int/hiv/toolkit/arv/en/index.jsp, PDF version: http://whqlibdoc.who.int/hq/2003/9241591161.pdf
- WHO Integrated management of adolescent and adult illness (IMAI) and Integrated management of childhood illness (IMCI) - various documents. Web site: http://www.who.int/hiv/pub/imai/en/

Legal and policy issues

- Policy statement on HIV testing, UNAIDS and WHO, 2004, http://data.unaids.org/una-docs/hivtestingpolicy_en.pdf
- HIV/AIDS and human rights international guidelines, UNAIDS and OHCHR, 1996. http://whqlibdoc.who.int/publications/1998/9211541301.pdf
- International guidelines on HIV/AIDS and human rights, 2006 consolidated version, UNAIDS and OHCHR.
 http://data.unaids.org/Publications/IRC-pub07/jc1252-internguidelines en.pdf
- Handbook for legislators on HIV/AIDS, law and human rights, UNAIDS and IPU, 1999 http://whqlibdoc.who.int/unaids/1999/UNAIDS 99.48E.pdf

Beneficial disclosure and partner counselling

 Opening up the HIV/AIDS epidemic: Guidance on encouraging beneficial disclosure, ethical partner counselling & appropriate use of HIV case-reporting (UNAIDS Best Practice Collection, Key Material, UNAIDS and WHO, Geneva, November 2000). http://whqlibdoc.who.int/unaids/2000/UNAIDS 00.42E.pdf

HIV testing in women and girls

- Addressing violence against women in the context of HIV testing and counselling a meeting report, WHO 2007 (forthcoming)
- Testing and Counselling for Prevention of Mother-to-Child Transmission of HIV (TC for PMTCT) Support Tools, CDC, WHO, UNICEF, USAID and PMTCT implementing partners.
 Web site: http://www.who.int/hiv/pub/vct/tc/en/index.html
- WHO Briefing Note -- HIV and Infant Feeding. Conference on Retroviruses and opportunistic infections. Los Angeles, 25-28 Feb 2007. http://www.who.int/hiv/mediacentre/Infantfeedingbriefingnote.pdf
- Sexual and reproductive health of women living with HIV/AIDS, WHO and UNFPA, 2006. http://whqlibdoc.who.int/publications/2006/924159425X eng.pdf
- Prevention of mother-to-child transmission of HIV: generic training package, WHO and CDC, 2004. Web site: http://www.cdc.gov/nchstp/od/gap/PMTCT/
- Nutrition counselling, care and support for HIV-infected women, WHO, 2004, http://whqlibdoc.who.int/publications/2004/9241592125.pdf

HIV Testing and Counselling in TB Clinical Settings

- Interim policy on collaborative TB/HIV activities WHO/HTM/TB/2004.330 (http://www.who.int/tb/publications/tbhiv interim policy/en/index.html)
- CDC and WHO tools on HIV Testing and Counselling in TB Clinical Settings 2007
 - Module One: Introduction, Background, and Rationale
 http://www.cdc.gov/nchstp/od/gap/docs/tb tools/TB%20Module%201 12.6.06.pdf
 - Module Two: Understanding the Provider-initiated and Delivered HIV Testing and Counseling Process in the Context of TB Clinical Settings http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%202_12.7.06.pdf
 - Module Three: Preparing the Provider to Perform PTC
 http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%203_12.12.06.pdf
 - Module Four: Administrative, Implementation and Standard Operating Procedures http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%204_12.13.06.pdf
 - Module Five: Clinical Considerations
 http://www.cdc.gov/nchstp/od/gap/docs/tb_tools/TB%20Module%205_12.6.06.pdf

Module Six: Demonstration Clinic
 http://www.cdc.gov/nchstp/od/qap/docs/tb tools/TB%20Module%206%20Demo 12.1.06.pdf

Most-at-risk populations

- WHO online sex work toolkit (Web site: http://who.arvkit.net/sw/en/index.jsp; PDF version: http://www.who.int/entity/hiv/pub/prev_care/sexworktoolkit.pdf)
- HIV prevention through harm reduction among injecting drug users http://www.who.int/hiv/idu/en/index.html
- Strategies for involvement of civil society in HIV testing within context of "3 by 5": Focus on marginalized communities, UNAIDS, 2004, http://data.unaids.org/Topics/Human-Rights/hr refgroup3 06 en.pdf

HIV testing and children

- Convention on the right's of the child, UN, 1989, Website: http://whqlibdoc.who.int/publications/1998/9211541301.pdf
- Convention on the right's of the child general comment No 3: HIV/AIDS and the rights of the child, UN, 2003, Website: http://whqlibdoc.who.int/publications/2002/9291730254.pdf
- Integrated Management of Childhood Illnesses (resources). Website: http://www.who.int/child-adolescent-health/publications/publMCI.htm

Testing technologies

- Training package for HIV rapid testing, CDC and WHO, 2006. http://www.phppo.cdc.gov/dls/ila/hivtraining/default.aspx
- WHO Guidelines on HIV rapid testing, WHO (to be published)
- Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach, CDC and WHO, 2005 http://www.who.int/diagnostics_laboratory/publications/HIVRapidsGuide.pdf
- Revised recommendations for the selection and use of HIV antibody tests, UNAIDS/WHO, 1997 http://www.who.int/docstore/wer/pdf/1997/wer7212.pdf
- The importance of simple/rapid assays in HIV testing, WHO/UNAIDS, 1998 http://www.who.int/docstore/wer/pdf/1998/wer7342.pdf

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- Some of these terms were proposed in earlier drafts of this document, and the term "routine offer" was used in the WHO/UNAIDS Policy Statement on HIV Testing and Counselling. The policy Statement will be updated to reflect the terminology used in this document.
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