CONTENTS

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 grow[1].

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 results[2]. 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 disease[3].

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 Testing[4] 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 care[5]. 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 counselling[12]. 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 months[13].

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 Botswana[29]; pediatric wards in Zambia[30]; tuberculosis clinics[31] as well as Ugandan pediatric wards[32], maternity ward[33] and STI clinics[34]. 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 time[35].

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 results[36], and in Zimbabwe has had no negative effects on post-test counselling rates or the delivery of antiretroviral prophylaxis[37].

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 responses[38]. 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 test[39].

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 consequences[45], while a study in Tanzania found that about half of respondents reported receiving support from their partner[46]. 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 support[47].

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 2006[50]; 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 pre-test 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 pre-test 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 2003[51] and with the 2004 WHO/UNAIDS Policy Statement on HIV Testing[52], 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, "opt-in" 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 system[55]. 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 HIV[57]. 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.