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- World Health Organization
- National AIDS Control Council
- Department of Curative and Rehabilitative Services
- National AIDS/STD Control Programme
- National Leprosy and Tuberculosis Program
- Division of Reproductive Health
- Centers for Disease Control and Prevention
- United States Agency for International Development
- University of Nairobi
- Kenya Medical Research Institute
- Kenya Medical Training College
- Kenya Medical Association
- Kenya Clinical Officers Council
- Nursing Council of Kenya
- Women Fighting AIDS in Kenya
- Elizabeth Glazer Paediatric Foundation
- Family Health International
- Christian Health Association of Kenya
HIV/AIDS has brought new and unprecedented challenges to the health system in Kenya. AIDS is the leading cause of morbidity and mortality in young adults in Kenya and has resulted in reversals in gains made in infant and early childhood mortality.

Health workers are faced with both the medical and social challenges of HIV/AIDS on a daily basis. It is estimated that up to 60% of all medical ward hospital beds in Kenya are occupied by HIV infected patients. In some parts of the country, more than half of tuberculosis patients and one-fourth of patients with sexually transmitted infections are HIV infected.

Fortunately, major strides have been made in the area of HIV care and treatment. Antiretroviral therapy (ART) is now available in Kenya. These drugs are known to prolong and improve quality of life for people living with AIDS. Opportunistic infections including TB can be treated and prevented with appropriate medical management. Safe, low-cost drugs and other interventions are available for the prevention of mother to child transmission. Similarly, treatment for HIV infected children is increasingly becoming accessible. This prevention, care and treatment, however is available only to those who know that they are infected with HIV.

Currently four out of five Kenyan adults with HIV infection do not know that they are infected. In order to provide appropriate care, HIV testing is required in many clinical settings, including for patients with diseases associated with HIV infection or conditions, such as pregnancy, where knowledge of HIV status may lead to better HIV prevention and care services. Failure to provide this testing will result in sub-standard care for HIV infected patients.

While access to care is dependent on knowledge of HIV status, HIV testing must be performed with appropriate consent and sensitivity to cultural and social issues. Results must be communicated effectively and utilized for appropriate patient management. Confidentiality must be preserved within health facilities to protect patients and their families, while at the same time providing support and encouragement to disclose results to sexual partners. HIV care and treatment must be available, and referral provided when needed, for ongoing counseling and psycho-social support.

These guidelines provide information to assist health workers in providing quality HIV testing and counseling services in clinical settings. They complement the National Guidelines for Voluntary Counseling and Testing, which are designed for HIV testing in people who are well, both in community settings and health facilities. Other Ministry of Health guidelines provide specific guidance for prevention of mother to child transmission, for antiretroviral care, for home based care, and for blood safety. This particular edition includes standards and settings for HIV testing in children and seeks to expand access to HIV testing in children. This will facilitate better identification of HIV exposed and infected children.

Together this guidance sets high standards for quality services that provide correct information to people tested, protect their rights and confidentiality, prevent further spread of HIV, and open the door for services that preserve the health and prolong the lives of those who are already infected with this virus.

The Ministry of Health is committed to meeting the targets established for the National HIV/AIDS Strategic Plan, the UNGASS and Abuja Declarations, and the WHO “3 by 5 Initiative” and providing a continuum of care for Kenyans with HIV infection. This can only be achieved if there is widespread uptake of HIV testing in health facilities and clinical settings. With the commitment and dedication of health professionals, the courage of our people, and the support of the community, we can win the war on AIDS.

Dr James Nyikal, OGW
Director of Medical Services

May, 2006
INTRODUCTION

PURPOSE OF GUIDELINES
The purpose of these guidelines is to describe the scope and define the standards of HIV testing and counseling in health care settings in Kenya. This will ensure that people have access to the highest quality in prevention and care services while protecting the rights and health of the HIV infected and uninfected.

The recent advances in testing technologies and treatment have changed the environment to such a degree that a fundamental reappraisal of HIV testing policy and practice is required. Since the purpose of HIV testing differs according to the context within which testing is performed (e.g. TB treatment or prevention, antenatal care, STD treatment), guidance is required beyond the existing guidelines for voluntary testing and counseling, which is a client-initiated service with a focus on prevention of HIV in primarily healthy populations.

POLICY STATEMENT
The Ministry of Health recognizes that HIV testing is critical for prevention of HIV infection and for access to appropriate healthcare. For individuals, knowledge of HIV status will enable them to plan their lives and protect their families. But for the health care system, HIV testing is an essential element of clinical and preventative health care services. In addition to providing access to care, the Ministry of Health also requires that an individual’s HIV test results are subject to the highest standards of confidentiality and protection.

BACKGROUND
The first case of AIDS in Kenya was recognized in 1984. Since then, the human immunodeficiency virus (HIV) has spread through the entire country. With over one million Kenyans infected with the virus and another 1.5 million who have died from this disease, AIDS has had a major socio-demographic and economic impact on the country. Life expectancy has dropped by almost twenty years since the onset of this pandemic, and more than 1 million children under the age of 15 years are orphans due to HIV/AIDS. Economic status has declined and poverty has increased. As a result HIV/AIDS in Kenya was declared a national disaster in 1999.

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Knowledge of the options for care of HIV infected individuals is, however, lower. Levels of stigma are high despite the fact that most Kenyans know a relative or friend who has HIV/AIDS or has died from this disease. The vast majority of Kenyans do not know their HIV status. The Kenya Demographic and Health Survey in 2003 showed that only 13% of women and 14% of men said they had been tested for HIV and knew their results, although approximately three-fourths of respondents never tested said they wanted to learn their status. Only one out of five who are HIV infected know their HIV status. Recent expansion of HIV services, including Voluntary Counseling and Testing (VCT) and Prevention of Mother to Child HIV Transmission (PMCT), has provided more Kenyans with the opportunity to know their HIV status. Many health facilities, however, do not yet offer these services, and many patients decline testing when it is offered to them. In addition, those who do know their HIV status may fail to disclose their HIV status to their spouse or sexual partner. Many Kenyans, therefore, are exposed to HIV unknowingly, continuing the spread of the epidemic.

BENEFITS OF HIV TESTING

Knowledge of personal HIV status offers significant benefits to those infected, particularly with the recent availability of anti-retroviral drugs that can reverse the immunological destruction from HIV and prolong and improve quality of life. The potential to interrupt ongoing transmission also provides benefits to the families and partners of those infected and thereby protects the public. Ignorance of HIV status in the health care setting can lead to sub-standard medical care.

HIV testing and counseling is a critical first step for people to know what actions they should take to prevent getting infected or transmitting HIV infection and to gain access to proper medical treatment for HIV disease and AIDS. Increased testing for screening, diagnosis and treatment will require effective communication of HIV test results by health care providers. Medical training institutions need to include testing, counseling and general communication skills as part of basic training in order that patients receive accurate results, communicated in an appropriate and sensitive manner, whenever they require these services.

GOAL /STRATEGIES

GOAL

To establish standards and guidelines for HIV testing services in clinical settings in order to provide high quality and appropriate prevention and care services for all Kenyans.

IMPLEMENTATION STRATEGIES

• Ensure that quality HIV testing services are available in health care facilities as an integral part of clinical care.
• Ensure that health workers routinely offer and appropriately recommend HIV testing for their patients.
• Ensure that patients understand the benefits of HIV testing in clinical settings and have an opportunity to decline such testing.
• Train health workers to effectively communicate results of HIV testing, to utilize results in the provision of appropriate clinical care, and to answer questions and discuss sensitive issues about sexuality, HIV and AIDS.
• Ensure the privacy of those tested through policies and records procedures that protect confidentiality of results in clinical settings while encouraging disclosure to and testing of sexual partners.
• Ensure appropriate referral of patients and access to HIV counseling and other psychosocial support services.
• Encourage all sexually active patients to know their HIV status and that of their partners for HIV prevention through provision of appropriate information about HIV in health facilities.
• Protect infants from HIV infection through routine HIV screening as a part of comprehensive maternal and child health and reproductive health care.
• Provide routine HIV screening for patients in sexually transmitted diseases clinics and other high prevalence clinical settings.
• Provide diagnostic HIV testing to patients with symptoms or signs of HIV or HIV related diseases such as tuberculosis.
• Ensure that the blood supply is adequate and safe through appropriate recruitment and selection of donors, quality screening of donated blood, and appropriate use of transfusion in clinical settings.
• Ensure that health workers are adequately trained and supervised to safely conduct HIV testing using approved test kits and algorithms and to comply with quality control procedures for accurate results.
• Establish and frequently review the technologies and algorithms for HIV testing to ensure the highest quality test results.

DEFINITIONS AND STANDARDS

1. Types of HIV testing

Six types of HIV testing are recognized:
1. Voluntary counseling and testing (VCT)
2. Routine testing and counseling
3. Diagnostic testing and counseling
4. Required testing
5. Testing for blood and tissue donation
6. Testing for medical research and surveillance

Voluntary HIV testing is initiated by a client seeking to learn his/her HIV status for the purposes of prevention of HIV infection and life planning. Testing in the VCT context is often thought of as “social” testing as the test is requested by the individual, not by a health worker, and the test results are “used” by the individual for personal life decision making.

Routine HIV testing is provided as part of a standard screening package for the delivery of specific services, such as for pregnant women receiving prevention of mother to child transmission of HIV (PMCT) services. No medical decision regarding when to order a test is required on the part of the health worker; rather, the test is provided to all patients and clients in this context, except those who specifically decline the test.

Diagnostic HIV testing is requested by health workers as part of the diagnostic work-up for patients who present with symptoms or signs that could be attributable to HIV disease. When these symptoms or signs are present, diagnostic HIV testing should be performed routinely as a basic standard of care. The main purpose of diagnostic testing is to identify HIV disease in sick adults and children so they can receive comprehensive care within health care settings. It is unacceptable for health care workers to test patients for HIV without their knowledge or without communicating test results to the patient.

Required HIV testing is performed without specific consent in certain restricted settings, such as during military recruitment, foreign travel, insurance, and specialized employment. Testing may be ordered by a court of law. In all cases of required testing, those tested shall be informed of the test and have access to the results in an appropriate setting.

Blood and tissue donations require testing for HIV and other transfusion or tissue transmissible infections. Donors should be given general information about the testing and have access to their test results.

HIV testing for medical research and surveillance is performed under specific guidelines and regulations approved by appropriate scientific and ethical review boards for these activities. With the exception of required testing mandated by a court of law, all HIV testing must be performed with informed consent, conditions for which are discussed below. Also, with the exception of testing for research and surveillance, which have their own special requirements, all persons tested for HIV must be offered their test results and receive appropriate post-test information and counseling.
2. Settings For HIV Testing

Voluntary HIV testing is offered through VCT centres that are registered and must meet standards established by the Ministry of Health. Guidelines for VCT have been published by the Ministry of Health and will be periodically updated to provide the highest standards of care. VCT centres are located in diverse settings, such as the community (e.g., with religious or non-governmental organizations), temporary sites, mobile facilities, and in health care facilities. It is not appropriate to apply guidelines for this form of self-initiated testing to the medical context where testing is initiated by the health care worker for correct diagnosis and improved medical management.

Health workers should, however, be aware of VCT services accessible to their communities and make this information available to patients in their health facilities.

Routine HIV testing is provided on a standard basis for pregnant women in antenatal, maternity, and postnatal units, for the purpose of delivery of services for the prevention of mother-to-child transmission of HIV. Guidelines for these services have been published by the Ministry of Health and will be periodically updated to provide appropriate care for pregnant women. Routine testing and counseling is also offered on a standard basis to patients attending sexually transmitted infection (STI) clinics for the purpose of comprehensive care.

Routine testing will also be provided to people who may have been exposed to HIV either through rape or in their workplace (e.g., healthcare workers). This will enable them to access care including prophylactic treatment. Occupational or nosocomial exposure to hazardous material should be reported promptly to a designated supervisor who can evaluate the exposure and make appropriate recommendations for preventive action and prophylactic care or treatment.

All infants and young children born to HIV-infected mothers and whose HIV status is not known at the time of first visit to a health facility should be offered routine testing. In situations where the infant is accompanied by their biological parents, they (parents) should also be offered routine testing.

Diagnostic HIV testing is provided by health workers as part of the diagnostic work-up of patients, in the context of provision of medical care. Within health care facilities, or in the community through registered community care programs, diagnostic HIV testing should be handled in a similar manner to other non-invasive tests necessary for reaching a diagnosis. Diagnostic HIV testing is aimed at determining the diagnosis of HIV infection in order to provide appropriate medical care.

In settings of high HIV prevalence the majority of medical and tuberculosis patients and a high proportion of paediatric patients and TB suspects may be HIV infected. It is therefore appropriate to conduct diagnostic HIV testing on all medical and paediatric patients, including those suspected of tuberculosis disease. In such settings a substantial proportion of patients presenting to surgical facilities may also be HIV infected and have conditions that are HIV related. The principles of diagnostic HIV testing should apply to surgical patients with HIV-related signs or symptoms, just like all other patients. Since health care workers should practice universal precautions to prevent exposure to HIV as well as other (known and unknown) blood-borne agents, universal pre-operative HIV testing for the “protection” of health care workers is not proper. Decisions concerning some surgical procedures (e.g., some complex orthopaedic procedures) may be influenced by the HIV status of the patient, and in such cases diagnostic HIV testing is appropriate. Failure to provide HIV testing when symptoms or signs of HIV disease are present is substandard care and is not acceptable.
3. Consent For HIV Testing

The specific content and procedures of the consent process shall be appropriate to the setting and purpose of testing. This process should guarantee individual autonomy (the right to accept or refuse a test) and access to appropriate information. In special circumstances (e.g., clinical research or surveillance), other consent procedures may be required by ethical review boards.

Since voluntary counseling and testing is self-initiated, consent is implicit in uptake of the service. Verbal consent is obtained before proceeding with testing after providing appropriate information and pre-test counseling. This includes information regarding the decision to have an HIV test, the implications and process of testing, and the importance of communication of results to sexual partners. Young people under 18 years who are married, pregnant, parents, engaged in behaviour that puts them at risk or are sex workers should be considered ‘mature minors’ who can give consent for VCT, although the counselor should make an independent assessment of the minor’s maturity to receive VCT services.

It is highly recommended that testing of minors less than 18 years who are not mature minors, especially those under 15 years, should be done with the knowledge and participation of their parents or guardians. Voluntary premarital testing of couples should be encouraged for the benefit and protection of the couple.

In routine testing and counseling, clients must be informed that HIV testing constitutes a routine part of the care provided, since specific decisions concerning prevention of transmission of HIV are based on the clients’ HIV status. Clients must be made aware that they have the option to decline HIV testing. Verbal acceptance of the routinely applied screening package constitutes informed consent for HIV testing.

Traditional practice in which patients or clients receive pre-test counseling and then decide whether to proceed with testing is an example of the “opt-in” approach, an active decision being required to take a test. With the “opt-out” approach an HIV test will be performed routinely unless it is specifically declined. In high HIV prevalence settings, the “opt-out” approach is preferable as it rapidly expands the scope of people who can access prevention and care. Training institutions should therefore introduce counseling and communication skills as part of basic training, with an emphasis on the “opt-out” approach for testing.

Diagnostic testing and counseling also uses an “opt-out” approach. Presentation with symptoms of disease to a health care facility implies a desire for diagnosis, therapy, and care. This, therefore, implies consent for diagnostic testing, including for HIV. HIV testing should not be treated differently from other non-invasive tests such as sputum or urine analysis or other blood tests. All patients must be informed that the test is being done and have the right to decline HIV testing.

Paediatric testing: In the case of patients who are in the paediatric age group (minors), written consent or documentation of verbal consent from parent or guardian is required, consistent with general requirements for consent for diagnosis and care of minors. Documentation that parents or guardians were aware of the “opt-out” option for diagnostic HIV testing is adequate. In paediatric wards with high HIV prevalence and among children with tuberculosis, universal diagnostic HIV testing is appropriate. Children should be given an age-appropriate explanation of procedures, including HIV testing, and in older children (age 8 to 15) their assent for routine and diagnostic testing is desirable.

Consent is not obtained for required testing and testing of blood or tissue donations, though subjects should be informed that an HIV test will be done and should have access to results and appropriate referral for services if needed.
4. Personnel Who May Perform HIV Testing

**Machine based tests**
Trained and qualified laboratory technicians and technologists are specifically necessary in performing laboratory machine-based HIV tests such as standard enzyme-linked immuno-sorbent assays (ELISA or EIA), polymerase chain reaction (PCR), Western Blot (WB), p24 antigen testing, or viral culture. Although these tests are part of routine laboratory work, specific personnel should be appointed to undertake these tasks, who have training in performing the tests and the care and maintenance of the equipment. This training should be widely available to laboratory professionals.

**Rapid tests**
Rapid HIV tests do not require specialized laboratory equipment. In clinical settings they may be performed by trained laboratory and non-laboratory health workers as permitted by the Director of Medical Services. These non-laboratory health workers may include nurses, midwives, clinical officers, doctors and trained counselors. As these tests may be performed on whole blood finger prick samples or other body fluids, they may be performed outside of traditional laboratory settings. When test strips are shown to the patient, it may improve patient confidence and ownership of results and also help to preserve confidentiality. Conducting such testing within outpatient clinics and inpatient wards, may improve patient flow and better integrate HIV testing as part of clinical diagnosis and patient management.

**Supervision and quality assurance**
Supervision and quality assurance for testing standards and biosafety shall be carried out by trained laboratory supervisors. Quality assurance should include proficiency testing of test sites, as well as quality control testing in central laboratories to confirm results in a sample of those tested. The goal of testing is accuracy of results so that patients receive correct information of their HIV status.

**Administration**
Practical considerations such as numbers of tests performed, facility organization, infrastructure and personnel should determine the best testing strategies in each testing context. This will determine the cadre(s) of personnel and location most appropriate to conduct HIV testing in each facility or department.

5. Laboratory Standards

Accreditation of testing sites will be based on the use of an approved testing scheme and demonstration of quality control measures.

All HIV positive antibody test results (either machine-read ELISA or rapid tests) must be confirmed with a second, different, approved antibody test or by another approved confirmatory test (Western Blot, immuno-fluorescence antibody, polymerase chain reaction, or viral culture).

Tests may be performed in parallel (two tests simultaneously) or in series.

If tests are performed serially, the first test should be the more sensitive of the two and the second should be a more specific test in accordance with WHO guidelines.

Discrepant results should be tested with a third, different test, or, if not available, patients should be told that the results are indeterminate and asked to return for repeat testing at an appropriate interval.

Patients and clients should not be told they have HIV infection without confirmed results.

HIV antibody testing may be performed in infants and young children under 18 months of age, but the presence of antibody does not confirm infection in these infants due to the possible presence of maternal antibodies. Confirmed results require specific infant diagnostic testing such as p24 antigen testing or PCR. Testing of infants should follow special algorithms established by the National Laboratory Committee. In situations where there are no PCR or P24 antigen testing, any infant or young children who are antibody positive should be treated as per National ART guidelines.

Both the individual test kits and the testing algorithms must be approved by the National Laboratory Committee of the Ministry of Health. Quality control standards, including central retesting of some specimens and proficiency testing at laboratories and health facilities shall be established by the National Laboratory Committee and implemented by the Ministry of Health.
6. Standards Of Communication of Hiv Test Results and Counselling

All testing for HIV should be followed by communication of test results with health education and counseling appropriate for the context of testing. Post-test counseling for Voluntary Counseling and Testing clients should include prevention counseling for all clients, discussion of issues of disclosure and recommendations for partner testing. HIV infected clients should be advised of risks of transmitting HIV to others and offered condoms. All HIV infected clients should be referred for ongoing support and medically assessed to determine whether antiretroviral treatment is needed.

In routine HIV testing, communication of results should focus on the implications of HIV status for reproductive health for pregnant women or the clinical context for STI or other patients. Partner or couple HIV testing should be encouraged. Emphasis is placed on post-test counseling for persons found to be HIV infected who should be advised about measures to prevent transmission of HIV to infants and sex partners, appropriate family planning advice, and referral for medical evaluation and care. Infant feeding advice should be offered in the context of a patient’s HIV status.

In diagnostic testing, the communication of results should focus on the diagnosis and management of illness. Patients (including those who have tuberculosis) must be informed that HIV testing is performed, when appropriate, on all patients along with other tests for a full diagnosis and for therapeutic planning. Emphasis is placed on post-test counseling for HIV infected persons who must be advised about long term clinical care and follow-up, including home based care, as well as prevention of HIV transmission.

In paediatric testing it is best to communicate results in a family setting. For young children, this may be done with parents or guardians separately, followed by an age-appropriate explanation of results in the presence of parents or family. Children have a right to know their HIV status; adjustment to the diagnosis and compliance with care is improved by good communication with family and health professionals. Post-test counseling will require inclusion of advice for the mother of the patient and other family members to learn their HIV status.

Testing for transfusion or tissue donation is required for prevention of transmission of the infections from donors to the recipients. Donors should be informed of the testing for these diseases either verbally or in writing and should be informed how they may learn if they have any of these diseases. Every effort should be made to inform, counsel and/or refer donors with transfusion or tissue transmissible infections for appropriate services.

In required testing, such as in the military or for insurance purposes, clients shall be informed that HIV testing is being conducted and results shall be provided upon request.

7. Confidentiality and Disclosure Of Results

As mentioned earlier, the goal of testing is access to care and prevention services. All types of testing should therefore be done in the context of referral linkages and care. It may be difficult to offer care without basic information. In clinical settings, clearly, confidential but not anonymous testing is desirable. Health workers should maintain the highest standards of confidentiality. Breach of confidentiality is professionally unacceptable, and will not be allowed.

In the Voluntary Counseling and Testing program, testing may be either anonymous or confidential. For anonymous testing, no names are recorded and results do not have a personal identifier. For confidential testing, names or other identifiers may be recorded, but confidentiality of results must be maintained.

For routine and diagnostic testing in clinical settings, results must be confidential, since anonymity would prevent the health worker from providing appropriate care. As with all medical records, HIV results must be kept confidential and shared only with those who need know to provide appropriate care for the patient.

Required test results must also be kept confidential and may not be disclosed to any organization or person without the consent of the individual or court of law.
Guidelines for HIV Testing in Clinical Settings

8. Special Considerations Concerning HIV Testing

Notification and Disclosure: Refusal to notify sexual partners of one’s positive serostatus can lead to onward transmission of HIV, and is an infringement of the right to health and life of the exposed individual. In Kenya, when a person is found to be HIV infected, in the majority of cases their spouse is still uninfected by HIV. All HIV post-test counseling should include strong efforts to persuade and support HIV infected persons to notify their sexual partners. This may be done through couple VCT where both partners learn their results together in a counseling environment or disclosure may be done in a medical setting, ideally with both partners together. In cases where, after all attempts, a properly counseled HIV infected person continues to refuse to disclose his or her status to a sexual partner, the health care provider is permitted within the law to disclose to that partner the possible exposure to HIV without the consent of the source patient. Any disclosure is best done with both concerned partners. Settings and methods of disclosure should take into account possible risks of violence and social instability. Exposed partners should be encouraged to be tested for HIV and to receive post-test counseling and referral for care if appropriate.

Law requires proper completion of death and birth certificates; truthfulness and accuracy concerning HIV/AIDS related deaths is essential in these statutory documents.

Research in Kenya is only conducted under approval by officially sanctioned Institutional Review Boards or Ethical Committees. In general, written informed consent is required for all research participation and this should include consent for HIV testing if necessary. All HIV testing must be accompanied by appropriate pre- and post-test counseling in line with policies outlined above. In general, all subjects should receive their test results, but some studies may allow informed consent for testing and for study subjects to voluntarily choose not to receive their results. This will only be acceptable if approved by all relevant official Institutional Review Boards. In clinical trials involving HIV, communication of results may be an ethical requirement for participation.

Sentinel surveillance in Kenya is based on unlinked anonymous testing of pregnant women attending antenatal clinics and of patients attending STI clinics. Blood left over from named syphilis testing is tested for HIV after being stripped of identifying information, so that results cannot be linked to a specific individual. This makes it impossible to provide the result to the individual from whom the blood was originally drawn. However, unlinked/anonymous testing should be complemented with the provision of HIV information and confidential testing and counseling whenever possible.
REFERENCES