UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

NATIONAL AIDS CONTROL PROGRAMME

GUIDELINES FOR HIV TESTING AND COUNSELLING IN CLINICAL SETTINGS

JULY 2007

FOREWORD

The HIV/AIDS epidemic continues to pose a challenge to all sectors in Tanzania. The epidemic has interacted with other underlying public health problems such as tuberculosis and thus it is now one of the top causes of morbidity and mortality in the country.

Since Tanzania declared HIV/AIDS a disaster in 1999, notable developments have been realized in the prevention, treatment, care, and support of those who are infected with and affected by the disease. In October 2004, the Government of Tanzania commenced a programme of providing the life-saving antiretroviral drugs to HIV/AIDS patients. The target is to provide treatment with antiretroviral drugs to 440,000 patients by the end of 2008. However, progress towards accomplishment of this target has been slow, partly due to inadequate identification of those eligible for treatment.

Available information estimates that only about 15% of Tanzanians know their HIV status. For many years, the client- initiated voluntary counselling and testing (VCT) has been the main model through which individuals learn their HIV status. This approach has been quite useful in reinforcing HIV prevention especially in healthy people, but falls short of capturing important groups such as patients who present to health care facilities with HIV-related conditions.

As antiretroviral drug treatment and care are now available, it has become necessary to expand the models of HIV testing and counselling. The Ministry of Health and Social Welfare has adopted the provider-initiated HIV testing and counselling in which health care practitioners will recommend HIV testing and counselling to persons attending health care facilities as part of standard of care. This kind of service will give Tanzanians the opportunity to access available prevention, treatment, care and support services.

These guidelines provides guidance to health care practitioners as they initiate HIV testing and counselling in the clinical settings. They complement the 2005 National Guidelines for VCT and other guidelines that provide specific guidance to services such as PMTCT of HIV and TB/HIV integration It is the Ministry of Health and Social Welfare's intention to merge all the guidelines related to HIV testing and counselling into one National guidelines for HIV testing and counselling in the near future.

ACKNOWLEDGEMENT

This document is one of the various guidelines developed by the Ministry of Health and Social Welfare to provide guidance towards effective implementation of comprehensive prevention, treatment, care and support programmes in HIV/AIDS.

These guidelines represent a strong collective effort from different people and organizations. The Ministry of Health and Social Welfare would like to thank all the individuals and partner organizations who were involved in the development of these guidelines. Special acknowledgement and appreciation go to the technical review team that included members from the National AIDS Control Programme (NACP), Centres for Disease Control and Prevention (CDC), Clinton Foundation HIV/AIDS Initiative (CHAI), African Medical and Research Foundation (AMREF), Japan International Cooperation Agency (JICA), World Health Organization (WHO), representatives from clinical settings representing district, regional and referral hospitals, including the Muhimbili National Hospital.

Special gratitude goes to the staff of the National AIDS Control Programme, Centres for Disease Control, World Health Organization and IntraHealth International for working tirelessly with the consultant throughout the development and finalization process of the guidelines.

Permanent Secretary
Ministry of Health and Social Welfare

Dar Es Salaam, July 2007

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Anti-Retroviral Therapy
ARVs	Anti-Retroviral Drugs
CBOs	Community Based Organizations
CTC	Care and Treatment Clinic
DMO	District Medical Officer
DNA	Deoxyribonucleic Acid
ELISA	Enzyme-Linked Immunosorbent Assay
FBOs	Faith-Based Organizations
MCH	Maternal and Child Health
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
IDUs	Intravenous Drug Users
HMIS	Health Management Information System
MOHSW	Ministry of Health and Social Welfare
MSD	Medical Stores Department
NACP	National AIDS Control Program
NGO	Non-Governmental Organization
PCR	Polymerase Chain Reaction
PEP	Post-Exposure Prophylaxis
PITC	Provider Initiated HIV Testing and Counselling
PLHA	People Living with HIV and AIDS
PMTCT	Prevention of Mother-To-Child Transmission of HIV
QA	Quality Assurance
RNA	Ribonucleic Acid
SOPs	Standard Operating Procedures
STI(s)	Sexually Transmitted Infection(s)
TB	Tuberculosis
WHO	World Health Organization
VCT	Voluntary Counselling and HIV Testing

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

The Tanzania HIV/AIDS Indicator Survey (2003-04) estimated that 7% of adults aged 15-49 years are infected with HIV. In the year 2002, the National AIDS Control Programme (NACP) estimated that 2.2 million people were living with HIV/AIDS, and about 20% of them were in need of anti retroviral drugs (ARVs).

A five-year National Care and Treatment Plan for 2003-2008 was developed and approved in October 2003. The plan advocates for care, treatment and support services to improve the quality of life for people living with HIV and AIDS (PLHA), aiming at providing ARVs to 440,000 patients in need of treatment by the end of 2008. In order to achieve this goal, access to HIV testing and counselling services must be expanded as a clinical and core intervention in the comprehensive national response to the epidemic. This includes scaling up both client-initiated voluntary counselling and testing (VCT) and provider- initiated HIV testing and counselling (PITC) services.

As part of the move towards the acceleration of HIV prevention, treatment, care and support, the Ministry of Health and Social Welfare has approved the introduction and scaling up of PITC services. These guidelines aim at providing operational guidance for PITC in clinical settings. The guidelines are national standards that must be adhered to by all institutions, organizations and individuals providing PITC services in Tanzania.

The guidelines aim at describing the actions a health worker needs to take to initiate an offer for HIV testing during encounter with persons attending healthcare facilities.

1.2 RATIONALE FOR PITC

Currently there is a global move to accelerate universal access to HIV prevention, treatment, care and support services for PLHA. This calls for urgent scaling up of HIV testing in Tanzania using different approaches so that those who need to access treatment with ARVs can do so early before they develop AIDS. This will also ensure a better quality of life for PLHAs. They will also be referred for other essential services such as PMTCT, prevention and management of opportunistic infections, care and support services.

In Tanzania, access to knowledge of one's HIV status has mainly been through VCT, whereby clients proactively seek HIV testing and counselling services. Although the VCT approach was convenient when ARVs were not available, it has some shortcomings in ensuring scaling up HIV prevention, treatment, care and support services in the country. VCT only caters for those who voluntarily seek the HIV testing and counselling services, and therefore will not be adequate in ensuring that Tanzania achieves its national prevention, treatment, care and support targets. In PITC, health care providers initiate HIV testing and counselling with individuals attending health facilities who might benefit from knowing their HIV status. Both VCT and PITC will be provided so that they complement each other in addressing prevention, treatment, care and support needs of the population.

In Tanzania an increasing number of PLHA are becoming ill and need treatment, care and support services. Therefore, the following issues need to be addressed as they form the basis for introduction and implementation of PITC as a critical step in achieving the targets for National Care and Treatment Plan for 2003 to 2008:

i. The majority of the people in the country (85%) are unaware of their HIV status
ii. More than 50% of hospital bed occupancy in urban settings is due to HIV-related illnesses.
iii. The majority of these patients are discharged without being offered HIV testing and counselling services by a health practitioner.
iv. Many people are only offered HIV testing and counselling when they present with the advanced stage of the disease which unfortunately, has high morbidity and mortality.

There are important benefits of knowledge of HIV status at the individual, community and population levels as follows:

i. At the individual level there is enhanced ability to reduce the risk of acquiring or transmitting HIV, coping with HIV status, planning for the future, accessing HIV prevention, treatment, care, and support services and protecting unborn children from acquiring HIV.
ii. At the community level, a wider knowledge of HIV status and its links to interventions can lead to a reduction in stigma and discrimination.
iii. At the population level, knowledge of HIV status trends can influence the policy environment, normalize HIV/AIDS and reduce stigma and discrimination.

To facilitate implementation of PITC services, emphasis will be placed on providing HIV test results on a same-day basis and preferably by the same health practitioner who attended that person initially. This can only be possible if more health practitioners are trained in PITC skills as stipulated in the MOHSW training guidelines.

1.3 HIV TESTING AND COUNSELLING APPROACHES IN TANZANIA

Different approaches to HIV testing and counselling exist in Tanzania as follows:

i) Client-Initiated Voluntary Counselling and Testing (VCT)
In this approach the client voluntarily makes the decision to learn his or her HIV status and seeks for counselling and testing services out of his or her own will for the purpose of prevention of HIV infection and personal life decision making. The National guidelines for VCT produced in 2005 by the MOHSW provide guidance specific for the delivery of VCT services in Tanzania.

ii) Provider-Initiated HIV Testing and Counselling (PITC)
PITC 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 will 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 health care providers to recommend HIV testing and counselling as part of a patient's routine clinical management.

PITC 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 a health facility.

It is emphasized that, as in the case of client-initiated testing and counselling, PITC is voluntary and the three C's – informed consent, counselling, and

confidentiality – must be observed. In PITC, persons retain the right to decline the HIV test without being denied any services to which they are entitled to at the health facility. HIV testing without consent may only be justified in the rare circumstances whereby a patient is unconscious and where knowledge of HIV status is necessary for purposes of optimal treatment.

Resources and capacity constraints may require a phased implementation of PITC. The following should be considered priorities for the implementation of PITC in Tanzania.

- Children and adults seeking In-patient and Out-patient services
- TB and STI patients
- Reproductive and child health services, including family planning
- Services for adolescents

iii) HIV testing for medical research and surveillance

In Tanzania this is performed according to specific guidelines and regulations approved by the appropriate scientific and ethical review boards.

iv) Mandatory HIV screening

This refers to routine screening for HIV and other blood borne viruses of all blood that is destined for transfusion or for manufacture of blood products. Routine screening of donors is required prior to any procedure involving transfer of bodily fluids or parts, such as artificial insemination, corneal grafts and organ transplant.

In addition, mandatory testing does also refer to HIV testing for immigration purposes on a mandatory basis or for pre-recruitment and periodic medical assessment of military personnel for the purposes of establishing fitness. Mandatory testing can also be ordered by court order.

Discussion of VCT, HIV testing for medical research and surveillance, HIV screening of blood, organ and semen donors, and mandatory HIV screening are outside the scope of the current guidelines for HIV testing and counselling in clinical settings.

CHAPTER 2: REQUIREMENTS FOR CONDUCTING PITC SERVICES

2.1 POLICY ENVIRONMENT FOR PITC SERVICE DELIVERY

2.1.1 National HIV and AIDS Policy

The National HIV and AIDS Policy support the provision of HIV testing and counselling services, which should be made available and accessible to everyone. It is considered a fundamental human right for every Tanzanian to know their HIV status if they so wish. However, the policy stresses that HIV testing must be carried out following informed consent.

The Government of Tanzania has the responsibility to provide managerial and financial leadership in the national and local response to the HIV and AIDS epidemic. The government allocates funds for HIV and AIDS activities every year. Government's resource constraints have been significantly alleviated by contributions from development partners, NGOs, FBOs and the private sector.

2.1.2 HIV testing and counselling as part of "Standard of Care"

The MOHSW has approved the adoption of PITC as part of the "standard of care" for all persons attending healthcare facilities. The aim is to foster early detection of HIV infection; identify and counsel persons with unrecognised HIV infection and link or refer them to existing clinical and prevention services. Unknowingly transmission of HIV will be avoided and patients will be able to benefit from existing services.

2.1.3 Multi-sectoral coordination of HIV and AIDS activities

The Government of Tanzania considers HIV/AIDS a priority development problem with devastating social and economic implications. In the year 1999, the President declared HIV/AIDS a national disaster and established the Tanzania Commission for AIDS (TACAIDS) in December 2000. The main role of TACAIDS is to spearhead a multi-sectoral response to the HIV and AIDS epidemic in Tanzania by undertaking the roles of resource mobilization, co-ordination, policy formulation and monitoring and evaluation of the national response. The policy environment is now conducive for a broad based, decentralized response that should spearhead central ministries, local governments, development partners, the private sector, voluntary organizations, non-governmental organizations (NGOs), Faith-Based Organizations (FBOs) and communities in meaningful partnerships at all levels. All public and private sectors, including the civil society have been mandated to mainstream HIV and AIDS in all their programmes, including HIV testing and counselling for their

staff or community members. At regional level the regional secretariat should spearhead the responsibility of coordination while at district level local governments should spearhead the responsibility of coordination.

2.2 COORDINATION OF PITC SERVICES

2.2.1 At the National level, the MOHSW - through the National AIDS Control Programme (NACP) – will be responsible for policy direction and coordination of PITC services. The national coordination will involve:

- Advocating for government commitment to provide resources and support for PITC
- Standardization of tools and identification of common indicators, to be integrated into the Health Management Information System (HMIS)
- Provision of standards, training guidelines and protocols for PITC
- Establishing methods for sharing lessons learnt and cross referrals with other HIV and AIDS service providers through the national HIV and AIDS services network
- Monitoring and Evaluation

2.2.2 At the regional and district levels, Regional Health Management Teams (RHMTs) and Council Health Management Teams (CHMTs) will have the following responsibilities:

- Coordinating the implementation of PITC through existing health structures
- Ensuring training of health care providers
- Supportive supervision and quality assurance for PITC
- Ensuring proper management of HMIS and PITC data.
- Ensuring incorporation of PITC activities into the comprehensive council health plans (CCHP)
- Advocating, sensitizing, and promoting PITC services at all health care facilities and community levels

CHAPTER 3: HIV INFORMATION AND COUNSELLING FOR PITC

3.1 DEFINITION OF HIV COUNSELLING IN THE PITC APPROACH

HIV counselling for PITC is a confidential dialogue between a person attending a healthcare facility and a health care practitioner aimed at enabling that person to make an informed personal decision about HIV testing in order to access treatment, care and support services. This process encompasses pre-test information and post test counselling.

3.2 PRE-TEST INFORMATION IN PITC

Preparing persons for HIV testing in a clinical setting differs from approaches used in VCT because health care practitioners have a number of clinical tasks that do not allow them to carry out extensive counselling sessions. The World Health Organization (WHO) recommends simplification of pre-test counselling in clinical care settings providing only basic information to enable that person to make an informed choice about whether or not to have an HIV test.

During the PITC pre-test information session, the provider explains to the patient:

- Clinical and prevention benefits of HIV testing
- Importance of making an informed decision about testing
- Confidentiality of the testing and results
- A description of the testing and counselling process
- Person's right to decline HIV testing

The pre-test information messages should be targeted and adapted to the situation of that person.

3.3 POST-TEST COUNSELLING IN PITC

Post-test counselling is done after the HIV test to prepare a person to receive and cope with their HIV test results. The results should be given to the individual in person by a trained health care practitioner with a full explanation of the treatment, care and support services available to the person. It is not acceptable practice for people to undergo HIV testing without the opportunity to learn their

HIV test results. Persons have the right to decline any part of the testing and counselling process, including learning their HIV test results.

It is important to uphold the person's right to confidentiality and privacy when delivering test results. Health care practitioners in clinical settings may be limited, both by time and/or by the level of their training, in their ability to counsel patients. In such cases, the health care practitioner should act as the first line counsellor, informing the person of the test result and its implications for health care, and arranging referral for more in-depth counselling and support.

During the post-test counselling session, the provider delivers the HIV test results. Health care practitioners should:

- Assess the person's readiness to receive the HIV test result
- Communicate HIV test results simply and clearly and give the patient time to consider the results
- Discuss options for partner involvement in HIV testing and counselling
- Explain how to remain negative and/or how to prevent re-infection and transmission of the virus to others, including use of condoms
- Arrange referral for additional counselling and support

Issues specific to post-test counselling for HIV-negative patients

- Highlight the window period and explain the importance to repeat the test within 3 months
- Explain the importance of joining a post-test club or a peer support group

Issues specific to post test counselling for HIV-positive patients:

- Help the person to cope with emotions arising from the test results.
- Discuss any immediate concerns and assist the patient in determining who in his/her social network may be available and acceptable to offer immediate support
- Explain to the patient about his/her referral to CTC for further management
- Arrange for referral for further counselling, care, antiretroviral treatment or support services as appropriate e.g. treatment of opportunistic infections, STI ,TB management, PMTCT, family planning, nutrition and psychosocial support as appropriate

3.4 SPECIAL CONSIDERATIONS FOR PITC SERVICES

3.4.1 Group information sessions

Group information sessions can be used prior to provision of PITC services. These sessions aim at providing information rather than counselling. They can be utilized in settings such as ANC, TB, STI, out patient, reproductive and child health, and family planning clinics. The goal of the session is to provide and discuss general information about HIV and AIDS including availability of PITC and ART services prior to individual sessions by the service provider.

3.4.2 Prevention of Mother to Child Transmission of HIV (PMTCT)

Tanzania is already implementing PITC as part of the "standard of care" in antenatal care (ANC) clinics and maternity/labour wards as part of PMTCT services. More detailed information can be found in the National PMTCT guidelines.

3.4.3 PITC for children and adolescents

HIV testing in children and adolescents will follow the national guidelines and should ensure that the child or adolescent's rights are observed according to the "Convention on the Rights of the Child". Testing children or adolescents in order to provide appropriate care can be done at any age when deemed necessary by a health care practitioner. Test results will be disclosed to children and adolescents using developmentally appropriate language when they are considered by the health care practitioner as able to understand their result.

A parent or legal guardian must consent for their child's HIV test when the child or adolescent is below the age of 16. Adolescents aged 16 and above may consent to an HIV test for themselves. Older children or adolescents who are married, pregnant, have children, or are sexually active may consent to an HIV test for themselves. When appropriate, health care practitioners should ensure that the parents or legal guardians of children or adolescents are intimately involved with all issues pertaining to the child's illness, including the disclosure process. However, it should be noted that sexually active children or adolescents who accept to be tested have the right to withhold their test results from their parents or legal guardians.

Parents and legal guardians of HIV positive children will be counselled so that they develop a better understanding of their child's circumstances and emotional needs. In addition, these parents or legal guardians should also be offered or referred for HIV testing and counselling services.

3.4.4 Caring for the carers

Providing PITC services can be stressful leading to "burn-out" among health care practitioners. Burnout is a physical, emotional, psychological and spiritual phenomenon, characterized by progressive loss of idealism, energy and purpose, and may be experienced by people working in helping professions. All PITC service providers need formal support, stress management and mentoring strategies to prevent or mitigate the effects of burnout. Service providers and their supervisors must be trained on how to identify signs of "burn out" and the measure to address them.

3.4.5 Referral and linkages

Referral for PITC services will be a two-way process that creates linkages within various units of the facility, between facilities and between the community and the facility providing the service. Also, it refers to referral to care and treatment centres. Community care and support services contribute significantly to the continuum of care through home-based and family care by volunteers.

Community-based linkages include networking with community leaders and influential people such as traditional healers, local government authorities, youth leaders, partners of PMTCT clients, peer educators, community home based care groups, and community based organizations (CBOs), FBOs, nutrition support organizations and post-test support groups or clubs. All facilities providing PITC services will map out all possible linkages in the community as a vital tool in planning, partnerships and clinical collaborations. This will contribute to strengthening the referral process and networks.

3.4.6 Post-test support

Post-test support groups or clubs are often a useful feature of HIV testing and counselling services.

i) Post-test support groups

Post-test support groups, especially PLHA support groups, should be encouraged in all communities. They should develop close links with HIV testing and counselling facilities, and make plans for cross referrals. PLHA groups will be involved in the planning and implementation of HIV testing and counselling services. They will also promote adherence to treatment with ARVs and ensure good linkages with other post-test services.

ii) Post- test clubs

These clubs are comprised of people who have undergone HIV testing and counselling regardless of their HIV status. These clubs are a forum to promote positive behaviour and messages as well as to increase knowledge and demand

for HIV testing and counselling, treatment, care and support services. Post- test club formation and participation should be promoted nationwide, even in rural areas.

3.5 QUALITY ASSURANCE OF COUNSELLING AT FACILITIES PROVIDING PITC SERVICES

Quality assurance is a way of monitoring and evaluating the quality of counselling services provided in accordance with established national guidelines, policies and standards. Approaches for assessing quality of counselling at PITC facilities will include regular training, supportive supervision, counsellor self-assessment and stress management sessions, client exit interviews to measure client satisfaction, mystery client surveys and operations research.

CHAPTER 4: HIV TESTING

4.1 HIV testing technologies

Persons who become infected with HIV produce antibodies against the virus. Likewise, HIV antigens can be found in the blood of people infected with HIV.

The following tests are available for detection of these antibodies and antigens:

4.1.1 HIV Rapid Tests

Rapid tests are recommended for PITC services because they are simple to perform, even in clinics without laboratories or specialized laboratory equipment and they provide results within 30 minutes. The results are as accurate as ELISA tests when Standard Operation Procedures (SOPs) are followed. Most rapid tests utilize whole blood, plasma or serum in running the test. Thus, venous blood or finger prick blood samples may be used. Although rapid tests are simple to perform and can be performed outside laboratory settings, staff training is required for proper performance of the test and interpretation of the test results. Efforts should be made to encourage use of capillary blood as it is simple to obtain, minimally invasive, and less frightening

4.1.2. Enzyme-Linked Immunosorbent Assay (ELISA)

ELISA was the first test to be developed to detect HIV infection. The test requires qualified staff and specialized laboratory equipment and is suitable for batch testing in laboratories where large numbers of samples are tested. The testing takes 2 to 4 hours and results are usually not available on the same day of specimen collection since a batch of samples need to be collected before running the test.

4.1.3 HIV AntigenTtests

These tests include deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) polymerase chain reaction (PCR) and p24 antigen tests. These assays are useful in the diagnosis of HIV infection in children less than 18 months of age. The tests require highly sophisticated laboratory equipment, qualified staff and dedicated space, which are currently not widely available and therefore making infant diagnosis a major challenge. Currently, infant diagnosis capacity exists at the consultants (Zonal) hospitals. Specimens for PCR will therefore be collected and transported to the nearest point where the testing capacity exists.

The utility of antibody detection tests in the diagnosis of infection in children less than 18 months is limited by the fact that antibodies to HIV are passed over from

infected mothers to their babies during pregnancy, delivery and breast-feeding and may persist in the baby's blood for up to 18 months after birth. Although the presence of antibodies in children less than 18 months does not confirm HIV infection, their presence indicate that the child has been exposed to HIV and may benefit from HIV prevention, care and support services until diagnosis is confirmed. Rapid tests or ELISA can be used to detect the antibodies in these children to determine exposure to HIV.

4.2 WINDOW PERIOD IN HIV TESTING

The 'window period' is the period from being infected with HIV to the time when the body has produced enough antibodies detectable by an HIV antibody test. This period varies but is usually between 6 weeks and 3 months. This means that a client who has just been infected may test negative because their body has not produced enough antibodies to be detected by the tests. Such a client can still transmit HIV to others. It is important to note that during this period an infected client is highly infectious hence it is crucial to emphasize preventive measures. For patients who test HIV negative and are strongly linked to risk behaviour, but may be in the window period, the health care practitioner should recommend and encourage them to undertake a repeat test after 3 months.

4.3 HIV TESTING ALGORITHM IN TANZANIA

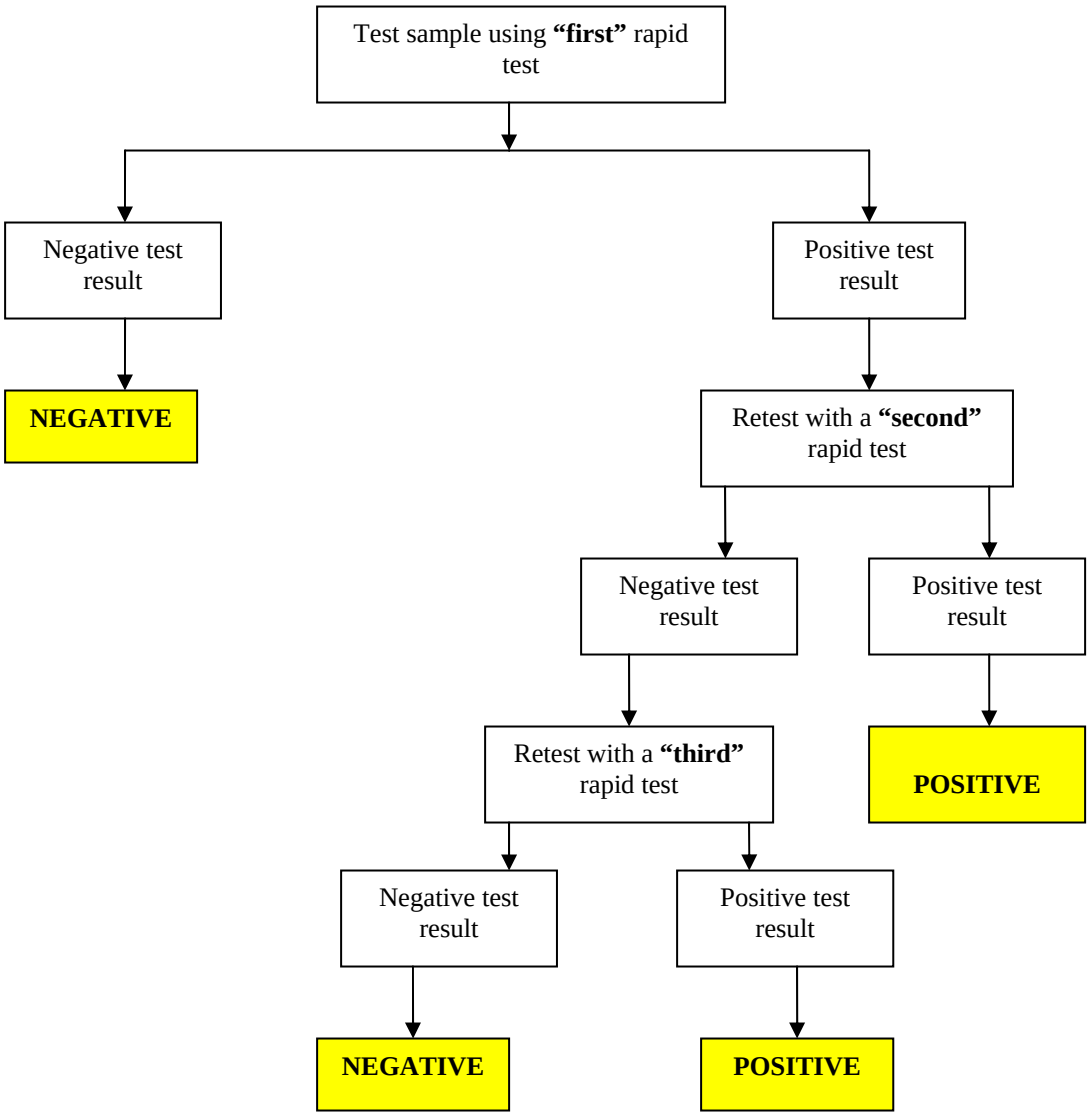
An essential requirement of all HIV testing is accuracy of the test results. HIV test kits used in the country are those that are recommended by the World Health Organization (WHO) and have been evaluated in the country before local use. A testing algorithm refers to the combination of tests and the sequence of use in HIV testing to provide maximum sensitivity and specificity. The selection of the testing algorithm is based on scientific evidence after evaluation of various HIV test kits. An HIV testing algorithm uses at least two tests to confirm positive results, which can be done either serially or in parallel.

HIV testing in Tanzania is done according the national testing algorithm and is based on the serial testing strategy recommended by WHO. This strategy is economical since a second test is required only when the initial test is positive. With 'serial testing' a blood sample is taken and tested using the "**first"** test. If the result is negative the test result is given to the client as HIV negative. If the test result is positive the blood sample is tested using a "**second"**, different HIV test. If the second test is also positive, the result is given to the client as HIV positive. If the second test is negative, (first test is positive and second test is negative), a "**third"** test (also called a **tie-breaker**) is used. The final test result of the sample is determined by the result of the tie-breaker. In a situation where

there is no tiebreaker for rapid testing, discordant samples should be referred to the laboratory for ELISA testing.

Health care practitioners will be required to follow MOHSW guidelines on which test kits to use. These guidelines will be updated periodically, and will be disseminated to all facilities providing HIV testing services including PITC.

Figure 1: National HIV Rapid Testing Algorithm



4.4 PERFORMANCE OF RAPID HIV TESTS BY NON-LABORATORY HEALTH CARE PRACTITIONERS

It is desirable that individuals trained in health laboratory practice conduct HIV testing where possible. However, in order to support the expansion of HIV testing and in particular PITC services in Tanzania, the relevant legislation is being reviewed to allow non-laboratory health care practitioners to perform rapid HIV testing after appropriate training. Laboratory practitioners will be responsible for providing oversight for HIV testing in facilities providing PITC services.

4.5 QUALITY ASSURANCE AND SAFETY AT THE HIV TESTING SITE

4.5.1 Quality assurance

Quality assurance (QA) is defined as the overall program that ensures that the final HIV test results reported are correct. A false result may irrevocably damage the reputation of the PITC service and the consequences to the client may result in social, psychological and stigmatisation problems.

Two levels of Quality Assurance should be recognized.

a) Internal Quality Assessment (IQA)

IQA involves some of the following:

- Good laboratory practices with set standards for performing HIV testing
- Systems for management of HIV test results
- Tracking records on available test kits, batch numbers and expiry dates
- Periodic inclusion of previously characterized samples in order to identify problems with competency of the personnel performing the HIV tests, and also identifying problems with new lots of test kits.

b) External Quality Assessment (EQA)

This involves objective assessment of a test site's operations and performance by an external agency or personnel. Laboratory practitioners have a vital role to play in the supervision of activities at the HIV rapid testing sites. EQA involves some of the following:

i) Proficiency Testing

All facilities providing HIV testing and counselling services should receive HIV proficiency samples from the reference or consultant hospital

laboratories at least twice a year. All facilities failing the proficiency tests need to receive additional technical supervision and support.

ii) On-site Evaluation:
This involves periodic site visits to assess practices at the HIV testing sites. The supervision role should be undertaken by the laboratory practitioners in charge of the health facility and district or regional laboratory technicians. On-site assessment will also be done by the Consultant hospital and National Reference Laboratories when deemed necessary. In order to make the assessment objective, a standardised on-site evaluation checklist will be used during the supervision.

4.5.2 INFECTION PREVENTION AND CONTROL DURING HIV TESTING

Strict infection prevention and control measures as provided by the MOHSW guidelines must be observed. These include:

- Every person (patient/clients or staff) being potentially infectious and susceptible to infection.
- Use appropriate hand hygiene techniques including; routine hand washing, hand antisepsis, antiseptic hand rub and surgical hand scrub
- Wear personal protective gear as necessary which may include: boots, aprons, gowns, gloves, face masks, protective eyewear and caps
- Appropriately handle sharps
- Conduct environmental cleaning regularly
- Safely dispose of infectious waste materials to protect those who handle them and prevent injury or spread to the community
- Process instruments by decontamination, cleaning, and either sterilization or high-level disinfection following recommended procedures

CHAPTER 5: ETHICAL AND LEGAL CONSIDERATIONS

5.1 HUMAN RIGHTS

The most basic human right principle requires that every person has a right to know his or her HIV status. In Tanzania PITC services are provided in an environment where human rights are observed and respected.

The human rights principles most relevant to PITC, and which every service provider and patient should ensure that they are observed include:

- The right to informed consent before a medical procedure is carried out
- The right to information for making choices about one's health and well being.
- The right to education
- The right to privacy
- The right to non-discrimination, equal protection and equality before the law
- The right to marry and found a family
- The right to the highest attainable standard of physical and mental health

In Tanzania, all health care practitioners are bound by ethical principles to do all that is necessary and available to provide the best possible care and follow-up to any person. Therefore an HIV test must be provided when consented to, or indicated in accordance with the "3Cs" principles of confidentiality, counselling and informed consent which includes voluntarism. Timely referral for follow up, medical care and psychological support must be ensured.

5.2 STIGMA AND DISCRIMINATION

In the context of HIV and AIDS, stigma and discrimination refer to actions taken against individuals solely on the basis of their HIV status. PITC is an approach aimed at scaling up HIV testing and counselling services in clinical settings so that more people will know their HIV status. It has been shown that programmes that allow more people to know their HIV status may reduce stigma and discrimination and foster normalization of HIV testing.

5.3 INFORMED CONSENT

The term "informed consent" refers to a person being given an opportunity to consider the benefits and potential implications associated with having access to information regarding their HIV sero-status, an understanding of the testing procedure, and then making the decision to be tested for HIV. A person should be able to consider the implications of a negative or positive HIV test result on their personal and professional lives.

The actual process of obtaining informed consent can be adapted to suit the different settings under which PITC services will be implemented. Although the process of obtaining informed consent will vary according to different settings, all patients should receive sufficient information and should be helped to reach an adequate understanding of what is involved. The three crucial elements in obtaining truly informed consent of HIV testing are providing pre-test information on the purpose of testing; treatment and support available; and ensuring the person's understanding of these messages and respecting the person's's autonomy. Only when these elements are in place will patients be able to make a fully informed decision on whether or not to be tested. Documentation of informed consent must be consistent with that of other non-invasive medical investigations. Therefore, verbal consent for PITC is adequate, and therefore written consent will not be required in clinical settings.

5.4 LEGAL ISSUES RELATING TO INFORMED CONSENT

5.4.1 Minimum Age for HIV Testing

PITC of children and adolescents below 16 years of age shall be carried out with the consent of parents or legal guardians, and when the health care practitioner has determined and is satisfied that testing is in the best interest of the child. Adolescents aged 16 years and above may consent for PITC themselves. Also adolescents who are married, have children, or are sexually active shall be categorised as "mature minors" and permitted unrestricted access to PITC services irrespective of their age.

5.4.2 PITC for Children

The welfare of the child must be the primary concern when considering testing a child for HIV. Counselling should be provided to both the child and the parent or guardian and consent for testing must be obtained from the parent or guardian. In the event where the parents or legal guardians refuse to consent and there is obvious clinical evidence suggestive of HIV infection in the child, the health care practitioner should proceed to test the child, give the results to parents or legal guardians, and seek the support of the department of social welfare.

In PMTCT programmes, HIV testing for babies who have been exposed to HIV must be routinely recommended through the parents or legal guardians according to the National Guidelines on PMTCT Services.

5.4.3 Testing of Mentally Challenged Persons

The welfare of persons who are mentally challenged should be the primary concern of health care practitioners when PITC services are to be provided. The service can be provided after obtaining consent from the parent or legal guardian in deserving cases, and only if it is in the best interest of the patient.

PITC services must not be provided to clients who cannot give true informed consent for HIV testing because they are under the influence of alcohol or illicit drugs. The service should be withheld until they have recovered.

5.5 CONFIDENTIALITY

Confidentiality is one of the guiding principles for provision of HIV testing and counselling services and must be protected. HIV test results shall be confidential, provided only to the person who has been tested. Disclosure of the results to a third person shall only be done with a written consent from the person tested. Any health care practitioner who breaches confidentiality acts contrary to the professional code of conduct and may be subjected to legal action.

5.5.1 Confidential record keeping

All medical records, including those with HIV-related information, must be managed in accordance with the stipulated standards of confidentiality in the health care facility. Only persons with a direct role in the management of the patient should have access to these records.

5.5.2 Shared confidentiality

Shared confidentiality is when a person utilizing a PITC service wishes to involve significant others in the HIV testing and counselling process, including receiving the HIV test result. In clinical settings, shared confidentiality shall involve also the patient and relevant health care practitioners directly involved in providing care. Shared confidentiality can also apply to the disclosure of information from an individual to family member and friends. Health care practitioners should educate persons on the importance of disclosure of their HIV status and encourage them to do so.

5.6 WRITTEN RESULTS

Health facilities providing PITC services should record HIV test results in all medical records. HIV testing result certificates should not be provided to any person because this may compromise confidentiality, and may lead to misuse of the results.

When an HIV positive patient is being referred, the referral documents must state all essential information, including the HIV test result. The procedure of referral and continuity of care must be clearly laid down for those who are HIV positive. The health care practitioner must ensure that the person understands the referral process and the importance of keeping personal medical records and presenting these at the referral site.

5.7 PARTNER NOTIFICATION

All persons, both HIV positive and HIV negative, should be encouraged to inform their partner(s) about their HIV test results. HIV positive persons that are reluctant or fearful to disclose their results must be referred for additional, on-going more in-depth counselling to help them inform their partner(s). In the interest of public health, a health care practitioner may inform the partner(s) of the HIV test results in the presence of the person tested.

Inability to disclose positive test results to a partner can result in the onward transmission of HIV. Therefore, in the few cases in which a properly counseled HIV-positive person refuses to disclose to a partner, the health care provider should be able to counsel and inform the respective partner, without the consent of the source person, provided there has been an ethical weighing of the potential harm involved, and appropriate steps have been taken.

5.8 OCCUPATIONAL EXPOSURE

Health care practitioners who become accidentally exposed to HIV in the course of providing care should follow appropriate steps as described in the MOH infection prevention guidelines and should have access to PEP and be appropriately supported by the employer. It is the responsibility of each employer to ensure that PEP services are available and appropriately used at the workplace.

6. SUPPLY CHAIN MANAGEMENT

6.1 Supplies Required for PITC

The quantity and type of supplies will depend on the volume of clients /patients and services offered at the health facility. Some of the critical supplies include the following:

- HIV test kits
- Medical consumables, such as needles and syringes or lancets, swabs, spirit, disinfectants, including sodium hypochloride (5% Chlorine)
- Gloves and all other medical supplies, including those for universal precautions
- Drugs for Post Exposure Prophylaxis [PEP]
- Sharps disposal containers / safety boxes
- Contaminated waste disposal containers
- Dust bins
- Registers for record keeping
- Condoms - both male and female
- Penile and pelvic models for demonstration of condom use
- Adequate information material/IEC/BCC materials
- Waste disposal management requirements such as incinerators, pit , buckets

6.2 PROCUREMENT

6.1.1 Procurement of test kits and related commodities

All test kits and related commodities for the public sector are procured centrally through the Medical Stores Department (MSD). All other health facilities should only procure test kits recommended by the MOHSW and according to the national testing algorithm.

An annual demand forecast for the tests will be made collaboratively by NACP and the Diagnostic Unit of the MOHSW. The forecasting and quantification will be based on consumption data from health facilities, district reports and requisition and reporting data collated centrally in order to ensure sufficient stocks of kits and other supplies.

6.1.2 Ordering and distribution of test kits and related commodities

Ordering of HIV kits and other testing supplies from health facilities will be done through the District Medical Officer. District orders will be sent to MSD for procurement according to the agreed mode of operations regarding ordering of laboratory reagents and supplies. Health facilities should bear in mind the lead period between ordering and delivery of supplies from MSD. Health facilities are strongly recommended to send orders for their supplies early enough to avoid stock out of supplies for PITC services. Based on consumption data all responsible persons at the health facility and district level need to ensure that HIV test kits and supplies are never out of stock by ordering their requirements in advance.

Upon receipt of HIV test kits and other testing supplies from MSD, it is recommended that the DMO expedite delivery of the supplies to health facilities providing PITC services

6.1.3 Commodity management

Every health facility providing HIV testing services must ensure that the kits and other commodities are stored properly and used before their expiry date. For proper storage of HIV test kits and supplies, refer to manufacturers recommended storage conditions in HIV test kits insert and Standard Operational Procedures (SOP)s. There should be proper stock quantification and forecasting, stock monitoring and inventory control system.

7. SUPERVISION, MONITORING, AND EVALUATION

The implementation and scaling-up of PITC services should be monitored and evaluated for coverage, quality, funding and overall performance of services. Data from PITC services will be collected through the National HIV Counselling and Testing Monitoring System. All levels of health services involved in PITC should be able to analyze and use the collected data in order to improve the service.

7.1 DATA MANAGEMENT

The following are some of the points that guide management of HIV Testing and counselling data in Tanzania

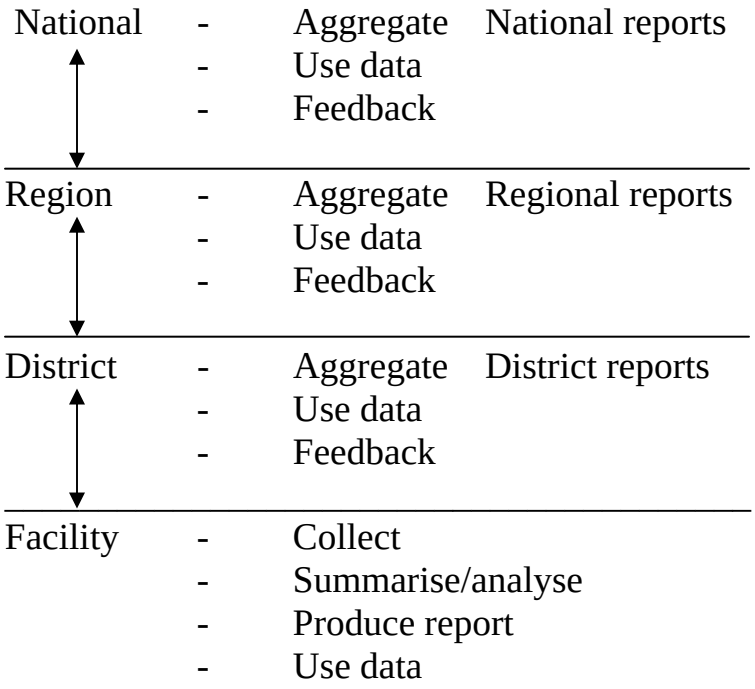
- All HIV testing and counselling service providers will use standard data collection and coding system.
- Data entry, tabulation, transfer, analysis and reporting will fit into the existing Health Management Information System.
- Feedback on the compiled national PITC information shall flow from National level through the same level to the point of origin

7.2 COMPONENTS OF THE MONITORING SYSTEM

- Site/facility register located at all service delivery sites
- Site/facility monthly summary form
- District level monthly summary form
- Regional level monthly summary form
- National database

7.3 DATA FLOW

- Facilities will aggregate, analyze, and report data to the district on a monthly basis
- Districts will aggregate, analyze and report facility activity on a monthly basis
- Regions will aggregate, analyze and report district activity on a monthly basis
- NACP will aggregate, analyze and report regional activity on a monthly basis



7.4 SUPPORTIVE SUPERVISION

- There will be a standard supportive supervision guide in use
- Feedback to the site based on monthly reports will be a key activity during a supportive supervision visit
- PITC supervisors will be trained at all levels from the facility, district, region and national. This training should include the interpretation and use of PITC data.
- There will be regular supervision
    - Facility supervision to be carried out monthly
    - District and regional supervision to be carried out quarterly

7.5 M&E OPERATIONAL PLAN FOR PITC

A protocol for collecting, analyzing, verifying and reporting PITC data will be available for all sites implementing PITC

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