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FOREWORD

The HIV epidemic in Malawi has affected every sector of the society to such an extent that it has been declared the single greatest challenge facing the nation today. Despite the country's success in raising awareness in almost every corner of society, the number of new infections remains unacceptably high.

To address this challenge, The Malawi National Strategic Plan for HIV and AIDS (2015–2020) has endorsed the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 Treatment Targets by 2020: for epidemic control by 2030, Malawi will by 2020 ensure that 90% of all people living with HIV know their status, 90% of all people with diagnosed HIV infection receive sustained antiretroviral therapy (ART), and 90% of all people receiving ART will have viral suppression.

HIV testing services (HTS) are the gateway to HIV care and treatment and are therefore the cornerstone to attaining the 90-90-90 targets. As Malawi strives to achieve universal access to ART, especially with the implementation of test and start, HIV testing services (HTS) represent an even greater opportunity for ART scale-up. Because of this, the newly revised HTS guidelines emphasize both increasing access and improving quality of HTS, ensuring all those tested receive the correct result.

These guidelines replace the previous “HIV Testing and Counseling Guidelines” (3rd edition, 2009); they describe and define basic minimum requirements for establishing, providing, and monitoring HIV testing services in Malawi. They are intended to assist health managers, clinical service providers, and HTS providers in developing and expanding HTS for people at risk of HIV infection as well as those requiring treatment, care and support.

HIV testing services remains integral in supporting efforts to reduce stigma and discrimination and promote openness in discussing issues of HIV and AIDS. As a coordinating institution for biomedical response to HIV, the Ministry of Health will continue to undertake its stewardship role through provision of guidelines to support service delivery. It is imperative that these guidelines are effectively translated into practice. I urge all health workers to constantly and vigorously promote HIV testing services to all clients within their care.

DR. MCPHAIL MAGWIRA,

SECRETARY FOR HEALTH

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ACRONYMS

AMC	Average Monthly Consumption
ANC	Antenatal care
ART	Antiretroviral therapy
CBHTS	Community-based HIV testing services
CBO	Community Based Organization
CDC	U.S. Centers for Disease Control and Prevention
DAR	Daily activity register
DBS	Dry blood spot
DHMT	District Health Management Team
DHO	District Health Office
EID	Early infant HIV Diagnosis
EQA	External quality assurance
FBO	Faith based Organizations
FRS	Family referral slip
GF CN	Global Fund Concept Note
HMIS	Health Management Information System
HTS	HIV testing services
HTSS	Health Technical Support Services
I-TECH	International Training and Education Centre for Health
JCE	Junior Certificate of Education
MDHS	Malawi Demographic Health Survey
M&E	Monitoring and evaluation
MOH	Ministry of Health
MOS	Months of Stock
MSCE	Malawi School Certificate of Education
NAC	National AIDS Commission
NGO	Nongovernmental organization
NHRL	National HIV Reference Laboratory
NRU	Nutritional Rehabilitation Unit
NSP	National Strategic Plan for HIV and AIDS Prevention
OPD	Out Patient Department
PEP	Post-exposure prophylaxis
PITC	Provider-initiated testing and counseling
PLHIV	People living with HIV
PMPB	Pharmacy, Medicines and Poisons Board
PMTCT	Prevention of mother-to-child transmission
PSHD	Presumed Severe HIV Disease
PT	Proficiency testing
QC	Quality control

RDT	Rapid Diagnostic Test
STI	Sexually transmitted infection
TOT	Training of Trainers
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	Voluntary Counseling and Testing

DEFINITION OF TERMS

Confirmatory HIV test: A test conducted to improve diagnostic accuracy and rule out errors before enrollment into the antiretroviral therapy/prevention of mother-to-child transmission program.

Discordant couple: A couple in which one partner is HIV positive and the other is HIV negative.

Early infant diagnosis: Testing of infants to determine their HIV status, given that HIV can be acquired in utero (during pregnancy), intra-partum (during delivery), postpartum (through breastfeeding), or via parental exposure.

HIV self-testing: A process in which an individual who wants to know his or her HIV status collects a specimen, performs a test, and interprets the result by him- or herself, often in private.

HIV status: A reference to reports of being HIV positive, HIV negative, or HIV inconclusive.

HIV testing services: The full range of services that should be provided together with HIV testing—counseling (pretest information and posttest counseling); linkage to appropriate HIV prevention, treatment, and care services and other clinical and support services; and coordination with laboratory services to support quality assurance and the delivery of correct results.

Index testing: A focused approach to HIV testing in which the household and family members (including children) of people diagnosed with HIV are offered HIV testing services; also referred to as index case HIV testing.

Integration: The collocation and sharing of services and resources across different disease areas. In the context of HIV, this may include the provision of HIV testing, prevention, treatment, and care services alongside other health services, such as treatment for TB, treatment for sexually transmitted infections, antenatal care, family planning services, and screening and care for other conditions, including non-communicable diseases.

Key populations: Defined groups who, due to specific higher-risk behaviors, are at increased risk for HIV irrespective of the epidemic type or local context. These guidelines refer to the following groups as key populations: men who have sex with men and sex workers.

Mature minor: Any child younger than 13 years of age who is married, pregnant, or is sexually active.

Pretest information: A dialogue and the provision of accurate information by a trained provider or health worker before an HIV test is performed.

Priority populations: Those groups who are at risk and vulnerable for poor health outcomes and for whom public health interventions would have the greatest impact.

Quality assurance: A part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality control: A process used to test and monitor performance of a test. It may monitor the entire test system or only one aspect of it.

Repeat testing: A situation wherein additional testing is performed for an individual immediately following initial test results, within the same testing visit, using the same tests, and where possible, using the same specimen.

Retesting: When individuals are tested again after a defined period of time (a period wherein transmission risk exists).

Seroconversion: The time when an individual first produces a quantity of HIV antibodies sufficient to be detectable on a given HIV serological assay.

Testing algorithm: The combination and sequence of specific assays used within HIV testing strategies.

Window period: The period between HIV infection and the detection of HIV-1/2 antibodies using serological tests.

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CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

Malawi has a generalized HIV epidemic with a national HIV prevalence rate estimated at 10.6% among adults aged 15 to 49 years (MDHS, 2010)¹. There is marked variation in gender, age, socio-economic characteristics and geographic location. In the 15-49 years age group, HIV prevalence is higher among women (13%) than men (9%). The regional HIV prevalence varies from 15% in the south to 8% in the center to 7% in the north (MDHS 2010) and corresponds to locations with higher population densities. Urban areas continue to have higher prevalence at 17%, compared to 9% in rural areas (MDHS 2010).

Based on epidemiological modeling, the national HIV incidence rate was estimated at 0.41% among people aged 15 to 49 years in 2014, a decline from 0.74% in 2009. The 2013 Modes of Transmission (MOT)² Study estimated that 67% of new HIV infections occur among heterosexual relationships. 52% of all new infections were estimated to be among females and 36% of these were adolescent/young women (15-24 years). Young women and girls may be more vulnerable to HIV infection due to lower socioeconomic status, high prevalence of sexual and gender-based violence. (GF CN, 2014)³.

The national HIV Testing Services (HTS) program has scaled up from 70 static sites in 2002 to 847 static sites in 2015. The number of tests performed annually has increased from approximately 150,000 in 2000 to more than 2 million in 2015 including repeat testers (HTS program reports). The rapid expansion of the prevention of mother-to-child transmission (PMTCT) program under Option B+, which started in 2011, required the availability of HIV testing in all antenatal care (ANC) and maternity service delivery points in the country.

1.2 POLICY CONTEXT

The Government of Malawi has been steadily scaling up HIV prevention, treatment, care, and support efforts for more than three decades in line with international commitments and standards. The Department of HIV and AIDS in the Ministry of Health (MOH) has a responsibility to oversee HTS in Malawi, a critical component of the national HIV response.

Malawi's HTS program is guided by the ambitious goals outlined in the Malawi National Strategic Plan for HIV and AIDS (NSP) (2015–2020)⁴, which aims to meet the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 Treatment Targets by 2020. By the end of 2020, Malawi has committed to have diagnosed 90% of all people living with HIV, started and retained 90% of those diagnosed on antiretroviral therapy (ART), and achieved viral suppression for 90% of clients on ART.

1.3 GOALS, PURPOSE, AND RATIONALE

1.3.1 GOALS

The overall goals for Malawi's HTS are as follows:

- Increase access to HIV testing services and identify people with HIV early through the provision of quality services for individuals, couples, and families.
 - Effectively link individuals and their families to appropriate HIV treatment, care, and support, as well as HIV prevention services, based on their status.
 - Support the scale-up of high-impact interventions to reduce HIV transmission and HIV-related morbidity and mortality.
-

1.3.2. PURPOSE

These guidelines offer basic guidance on operations of HTS in Malawi to ensure the delivery of standardized, high quality HTS and expand access to testing. The target audience for these guidelines is health policymakers; HIV and AIDS program planners and coordinators; health care providers in public and private sectors, including faith based organizations (FBOs) such as the Christian Health Association of Malawi (CHAM); Non-Governmental Organizations (NGOs) and Community-Based Organizations (CBOs) involved or intending to be involved in the provision of HTS. The guidelines do not offer specific technical knowledge, skills, and techniques of HTS, as these are documented in various standardized HIV testing and counseling training curricula and other available HIV and AIDS literature.

1.3.3 RATIONALE

Since 2009, when the last guidelines were revised, a number of global policy changes and opportunities in the response to the fight against HIV and AIDS have emerged. Significant progress has been made in the delivery of HIV testing and counseling alongside other efficacious HIV prevention, care, treatment, and program-strengthening interventions. The national HTS program has massively scaled up to all districts, at both community and facility levels. In August 2012, MOH, with support from the United States Centre for Disease Control and Prevention (CDC), evaluated Malawi's HIV testing and counseling program to assess implementation and the quality of service delivery. The United Nations Children's Fund (UNICEF) also conducted an evaluation on access to HTS by young people in five districts. These assessments highlighted the need to improve the quality of HTS by updating national guidelines; strengthening national HTS trainings; and retraining all HTS providers using the revised HTS training curriculum.

This revised HTS guidelines are therefore aim at addressing issues noted in these assessments, as well as aligning HTS with changing policies and emerging issues in HIV & AIDS programs at both the international and national levels, as highlighted in the 2015-2020 NSP.

Summary of Key Points

- Malawi's HTS program is guided by the ambitious goals outlined in the 2015–2020 NSP, which aim to meet the UNAIDS 90-90-90 Treatment Targets by 2020
- The national HTS program refocuses to meet the goal of having 90% of people living with HIV know their status by 2020 and ensuring successful linkages to HIV prevention, care, and treatment services

CHAPTER 2: HTS DELIVERY APPROACHES

HTS is available through a wide range of approaches, both in facilities and in the community, to increase access and coverage in Malawi.

2.1 FACILITY-BASED APPROACHES

The two most widely accessed types of facility-based HTS approaches are Provider Initiated Testing and Counseling (PITC) and Voluntary Counseling and Testing (VCT) with subsequent referrals and linkages to prevention, care, and treatment, services.

2.1.1 PITC

PITC is the routine offer of HTS to anyone accessing services at a health facility, and is one of the most effective models for identifying HIV positive clients. In PITC, HTS are streamlined and focus on the provision of pretest information and an accurate test result.

PITC must be prioritized in all high-yield settings, namely, the following:

- Adult and pediatric inpatient wards
- Nutritional rehabilitation units (NRU)
- Antenatal care (ANC)
- Maternity (labor and postnatal wards)
- TB clinics, Sexually Transmitted Infection (STI) clinics, and other Out Patient Departments (OPD)

All patients/clients accessing PITC must consent for testing; PITC is neither mandatory testing nor compulsory, and those being offered should be informed of their right to decline.

2.1.2 VOLUNTARY COUNSELING AND TESTING

VCT occurs when the client voluntarily makes a decision to learn his or her HIV status and seeks HTS at a site providing the service. VCT should include pretest and posttest counseling. Verbal informed consent should always be sought from the client before testing. VCT should be widely promoted through community sensitization and health education both within the facility and at the community level.

2.2 COMMUNITY-BASED HTS

Community-based HTS (CBHTS) can be conducted in various modes including campaign, home-based, door-to-door, workplace, mobile, outreach, and school/educational institution modes. These guidelines recommend strategic and targeted CBHTS to ensure appropriately high yield with a specific focus on priority and high-prevalence geographical areas; or key and priority populations with higher risk behaviors or access challenges. Target groups include sex workers, men who have sex with men, prisoners and other people in closed settings, orphans and vulnerable children, young women aged 15 to 24 years, fisher folks, and estate workers. CBHTS could also be used to target high-risk male populations who normally would neither access VCT or PITC.

Partners implementing any CBHTS should comply with the quality of HIV testing, supply chain, and reporting requirements noted in these guidelines. They should consult the MOH Department of HIV and AIDS for guidance before implementation. Refer to Appendix 1 for detailed guidance on mobile and outreach clinics.

2.3 OTHER HTS APPROACHES

Other approaches implemented in Malawi include index testing, mandatory testing, HIV surveillance and research, and HIV self-testing. They should also be provided with the necessary referrals to HIV prevention, care, treatment, and other support services.

2.3.1 INDEX TESTING

Index testing, also referred to as index case HIV testing, is a focused type of HTS in which sexual partners as well as household and family members, including children and adolescents, of people diagnosed with HIV are offered HTS. This type of HTS can be offered using either facility-based HTS or CBHTS approaches with the index client being issued family referral slips (FRSs) for their partners and family members, or clients accessing HTS as a result of disclosure from the index.

2.3.2 MANDATORY TESTING

Mandatory HIV testing may be ordered by a court of law. Clients must be informed that their results will be shared with the court of law officials. Under the mandatory HIV testing model, services must be confidential and performed with adequate counseling. Persons receiving HIV tests in these settings should be informed of the tests, and all guiding principles for HTS must be adhered to.

All clients donating tissue, blood, and blood products are screened for HIV and other blood-borne infections. All clients donating should be provided with pretest information including benefits of knowing their HIV status and be given an opportunity for posttest counseling.

2.3.3 HIV SURVEILLANCE AND RESEARCH

All surveillance systems and other research studies must use the same approved national testing algorithm for HIV diagnosis to avoid discrepant results and ensure that HIV test results are given to an individual. HTS quality assurance measures should always be adhered to during surveillance and research. The relevant ethics review boards must approve HIV testing protocols for research purposes in health care and non-health care settings prior to implementation.

2.3.4 HIV SELF-TESTING

HIV Self-testing (HIVST) is a process whereby a person who wants to know his or her HIV status collects a specimen, performs a rapid test and interprets the test result in private. In Malawi, HIVST is currently only implemented at operational study sites, therefore, HTS providers are not required to give out test kits to clients for HIVST until a policy decision is made.

An HIV self-test result does not constitute a confirmed diagnosis. A certified HTS provider must confirm self-test results in accordance with the national HIV testing algorithm.

“Supervised” self-testing involves support from a health worker or volunteer before or after individuals test themselves for HIV; may include a demonstration of how to use the test, pre- or post-test counselling and referrals to additional services.

“Unsupervised” self-testing refers to independent or open access to HIV self-testing; support may or may not be indirectly provided, based on the user’s initiative, such as telephone hotlines, leaflets, referral information, support groups, legal aid and HIV treatment, care and prevention services.

Summary of Key Points

- HTS in Malawi will focus on intensifying PITC to all clients and emphasizing index testing.
- PITC must be prioritized in all high-yield settings, namely, the following:
 - Adult and pediatric inpatient wards
 - NRUs
 - ANC and labor wards
 - TB clinics, STI clinics, and OPDs
- Community based testing should be strategic and targeted, to ensure appropriately high yield.
- Partners implementing any CBHTS should comply with the quality of HIV testing, supply chain, and reporting requirements noted in these guidelines.
- Index testing is a focused type of HTS in which sexual partners as well as household and family members (including children and adolescents) of people diagnosed with HIV are offered HTS.
- HIV self-test result does not constitute a confirmed diagnosis.

CHAPTER 3: GUIDING PRINCIPLES FOR HIV TESTING SERVICES

The guiding principles for HTS in Malawi revolve around human rights, ensuring the prioritization of the client's best interest. All models of HTS should adhere to WHO's five Cs:

- **Consent:** The HTS provider must obtain verbal informed consent. Clients should be informed of the process for HTS and their right to decline testing. Any client older than 13 years can give consent.
 - If a patient is unconscious or unable to give consent, such consent can be given by the spouse, next-of-kin or health care provider in cases where there is no guardian.
 - Mature minors younger than 13 years can consent for HTS, if this is determined by the health worker to be in the best interest of the child.
- **Confidentiality:** HTS must be confidential. HIV status can only be disclosed with the client's consent. Under the following circumstances, HIV status can be disclosed:
 - To other health workers if relevant to the clinical management of clients, i.e. shared confidentiality
 - If required legally
 - If this is in the best interest of a child
- **Counseling:** Appropriate and high-quality pretest information and posttest counseling must accompany HTS. Supportive supervision and mentoring should be conducted regularly to ensure the provision of high-quality counseling.
- **Correct test results:** Quality assurance mechanisms to ensure provision of correct results, aligned with the guidelines from the National HIV Reference Laboratory (NHRL), includes proficiency testing, external quality controls and supportive supervision
- **Connections:** Effective linkage and referrals should be made to appropriate services including prevention, care and treatment services. Newly identified HIV positive clients should be reviewed clinically to determine eligibility according to the national guidelines and for early ART initiation.

Summary of Key Points

- All models of HTS should adhere to WHO's five Cs: consent, confidentiality, counseling, correct test results, and connections to prevention, care and treatment services.

CHAPTER 4: OPERATIONAL PROCEDURES FOR HTS

4.1 FORMS OF COUNSELING IN HTS

4.1.1 INDIVIDUAL COUNSELING

Individual counseling involves counseling of an individual by a counselor on HIV testing and HIV and AIDS prevention, treatment, care, and support.

4.1.2 COUPLE COUNSELING

Couples should be offered HTS together with support for mutual disclosure. Couple counseling should be encouraged for couples:

- Attending ANC, STI, and other care services
- Who have not tested together previously, or are planning for marriage, pregnancy or choosing family planning methods
- Who are discordant or where one partner is known to be HIV positive

In cases wherein a couple has discordant first test results, the HTS provider should conduct a second test only for the partner who tested positive and not the one who tested negative.

4.1.3 SPECIAL CONSIDERATION

Family Counseling

A family unit may be counseled together in one counseling session. This should be voluntary. Every family member should be given an opportunity to make an informed decision and consent to test and to disclose. The clients' wishes should be respected whether they choose to receive their results together or individually.

Children and Adolescents

Disclosure of HIV status to a child should be regarded as a process that is guided by the developmental age of the child and should not be a one-counseling-session event. Specific details about disclosure of HIV status to children are provided in the HTS participant handbook.

4.2 THE GENERAL HTS PROTOCOL

The HTS protocol involves three components:

1. Pretest counseling
2. HIV testing
3. Posttest counseling

4.2.1 PRETEST COUNSELING

The pretest counseling session provides basic information about HIV and HTS. This may be provided to individuals, couples, or a group of people who are about to receive HIV tests. A trained counselor or health worker should conduct pretest counseling. HTS should be free of coercion. The client has the right to refuse to be tested. Declining testing will not affect the client's access to HIV-related services or general medical care. The client should be provided an opportunity to ask the provider questions. Clear and concise information should be provided about:

- The importance of early HIV diagnosis
- The HIV testing process
- The window period
- HIV risks and risk reduction
- The meaning of an HIV-positive and an HIV-negative diagnosis
- Linkage to other relevant services: enrollment in HIV care for clients with an HIV-positive test result, and preventive services for those with an HIV-negative result
- The potential for incorrect results if a person already on ART is tested
- Confidentiality
- Disclosure
- Partner and/or family testing

Special Consideration for PITC – Pretest Information

In PITC settings, giving **pretest information** is the preferred choice, rather than pretest counseling. In this case, the provider only gives the client relevant information on benefits and why he/she needs to be tested for HIV. For example, at the TB clinic, you inform patients about the high co-infection rates and the fact that HIV infection significantly increases risk for TB infection, and how dual management of TB and HIV gives a better outcome for TB treatment. In this case, issues of risk and risk reduction etc. are discussed during posttest counseling, making pretest information sessions very short and not time consuming to the HTS provider.

Special Consideration for Pregnant and Postpartum Women

Pretest information or health education for women who are or may become pregnant or who are postpartum should also include:

- The importance of early HIV diagnosis for mothers and infants
- The risk of transmitting HIV to the infant
- The importance of ART for the mother's health and in preventing transmission to the baby
- Counseling on infant feeding practices to reduce the risk of HIV transmission
- Partner and/or family testing

4.2.2 HIV TESTING

HTS providers are trained to provide a whole blood rapid test in one comprehensive session. The testing should be done according to the nationally approved HTS algorithm (refer to Appendix 3).

4.2.2.1 CONFIRMATORY HIV TEST

- All patients need a confirmatory HIV antibody test to rule out any possibility of mix-up of test results or fraudulent access to ART:
 - Before starting ART
 - Patients who received confirmatory testing at pre-ART enrolment (before 2016) do not need another confirmatory test when starting ART.
 - All children under 24 months who start ART need a confirmatory DNA Polymerase Chain Reaction (DNA-PCR) using a new DBS sample. This can be collected on the day of starting ART
- Do not delay ART initiation if HIV test kits are not available for the confirmatory test, but do confirmatory test at the next scheduled visit as soon as testing is available.

RAPID DIAGNOSTIC TEST (RDT): A confirmatory HIV test with a second specimen is to be conducted on HIV-positive clients before they are initiated on ART to rule out potential misdiagnosis. Confirmatory HIV test should be conducted by a different HTS provider; however, it can be conducted at the ART clinic if there is an HTS room. The first and the second rapid tests are done in parallel for confirmatory tests.

Protocols for quality assurance (QA) and quality control (QC) should be followed.

DNA-PCR: For children tested HIV positive with DNA-PCR, a second DBS sample will be collected before starting ART. If the second sample confirms the positivity, then there is no need to retest. In cases where the confirmatory result is negative, the infant should remain on ART and another DBS sample (3rd sample) should be collected and sent to the PCR laboratory. If the confirmatory DNA-PCR test result is not returned within 3 months (sample lost, error in results) then another DBS sample should be collected.

4.2.2.2 REPEAT TESTING

Additional testing is performed for an individual immediately following a first test during the same testing visit due to discordant test results; the same assays and where possible the same specimen are used.

4.2.2.3 RETESTING

Retesting refers to testing after a defined period of time for an individual who previously tested negative or had inconclusive results. Retesting is always performed on a new specimen (blood).

Table 1: Schedule of HIV testing in children: Choice of type of test, interpretation of results and follow-up management (Malawi Clinical HIV Guidelines, 2016, version 4) ⁵

Age (months)	Test	Schedule	Result	Interpretation	Action
Under 12	DNA-PCR (if available)	First opportunity from age 6 weeks	Negative	Not infected, but at risk of infection if breastfeeding	Continue HCC. Do rapid test at age 12 months.
			Positive	HIV infected	Start ART. Confirmatory DNA-PCR at ART initiation.
	Rapid antibody	Immediately if signs of PSHD identified OR If mother's HIV status cannot be ascertained	Negative	Not infected, but at risk of infection if breastfeeding	Treat condition. Continue HCC. Repeat rapid test at age 12 and 24 months.
			Positive	Possibly HIV infected if no PSHD symptoms Likely AIDS if symptoms for PSHD	Enrol in HCC. Do DNA-PCR at first opportunity. Start ART. Confirmatory DNA-PCR at ART initiation.
12 to 23	Rapid antibody	From age 12 months OR If mother's HIV status cannot be ascertained	Negative	Not infected, but at risk of infection if breastfeeding	Continue HCC, repeat rapid test at age 24 m.
			Positive	HIV Infected	Start ART. Confirmatory DNA-PCR at ART initiation.
24 and above	Rapid antibody	From age 24 months but ensure that BF stopped at least 6wks ago	Negative	Not infected	Discharge child from HCC.
			Positive	HIV Infected	Start ART. Confirmatory (parallel) rapid test at ART initiation.

Table 2: Schedule for general retesting conditions

Condition/Circumstance	Time Frame for Retesting
Persons with indeterminate/inconclusive HIV test results	Retest after 4 weeks
Pregnant women with negative HIV test result in ANC	Retest in maternity (labor or postnatal before discharge)
Symptomatic patients with sexually transmitted infections and high risk	Retest after 4 weeks and in every new episode of sexually transmitted infection
HIV-negative persons with ongoing risk behavior	Retest every 12 months
HIV-negative persons who have had a specific incident of known HIV exposure within the past 3 months	Retest after 4 weeks
HIV-negative persons who have had a specific incident of possible HIV exposure within the past 72 hours	Retest after 4 weeks

4.2.3 POSTTEST COUNSELING

Posttest counseling is an integral component of the HIV testing process. All individuals undergoing HIV testing must be counseled when their test results are given to them, regardless of the test results. Posttest counseling should be provided based on the outcome of the test results.

Clear and concise information should be provided about:

- HIV risks and risk reduction
- The meaning of an HIV-positive and an HIV-negative diagnosis
- Linkage to other relevant services: HIV treatment, care and support, as well as HIV prevention services, based on their status.
- Disclosure

4.3 REFERRAL AND FOLLOW-UP

The goal of comprehensive care is health, social, and emotional well-being for people living with HIV and AIDS. All HTS providers should have a directory of available HIV and AIDS services in the vicinity to which they will refer clients and patients. These referral points include community-based care and support groups as well as health facilities.

For referral to be effective and standardized in both VCT and PITC, HTS providers should have standard name-based referral forms (refer to Appendix 4).

In addition to referrals from the HTS site to other preventive or treatment sites, HTS providers have a critical role in strengthening index testing. Any client tested for HIV who has a sexual partner with unknown HIV status should be given a Family Referral Slip (FRS), regardless of the client's HIV test result. All HIV-positive parents should be given FRS for all children and sexual partners with unknown status. Index patient testing is a critical strategy to reach the first 90 in the 90-90-90 targets, and the issuance of FRS should be reinforced in all HTS sites.

Antenatal and postnatal services are of particular importance; to leverage the very high testing coverage among women, FRS should be given to all pregnant and/or breastfeeding women, and they should be encouraged to bring their partners for HIV testing; if they are diagnosed HIV positive, mothers should also be given FRS for all their children.

For a successful FRS strategy, community sensitization should be strengthened to address the issue of disclosure and acceptance of HIV status.

4.4 QUALITY ASSURANCE FOR HIV COUNSELING

Quality assurance includes all systems for monitoring and evaluating the quality of HTS in accordance with national guidelines.

All HTS providers should adhere to the following:

- Follow nationally prescribed standards of practice for performing HIV tests
- Assess each newly opened batch of HIV rapid test kits for validity and reliability
- Manage commodities and supplies to ensure uninterrupted services, avoid reaching expiration dates and secure storage
- Maintain complete documentation in national registers, Monitoring and Evaluation (M&E) tools and logbooks
- Comply with infection control procedures
- Ensure appropriate storage requirements for test kits and blood samples

The number of clients to be seen by each counselor at any HTS site must be within the range of what is practically possible when all standard HTS protocols are followed and is also dependent on whether individual pretest counseling or group pretest education sessions are conducted.

HTS supervisors should routinely conduct the following at each HTS site:

- Quarterly supportive supervision using standard tools to ensure that the basic minimum standards are complied with
- Quarterly client exit interview
- Quarterly sit-in observation sessions using appropriate counseling checklist tools and with the

client's consent. Each observation session must be followed by constructive feedback.

- Remediation (corrective measures with clear action plan) based on supervision reports, sit-in observations, data analysis and exit interview findings
- Quarterly HTS provider meetings with documentation of minutes.

4.4.1 HTS PROVIDERS' LOGBOOK

All certified and practicing HTS providers will be provided logbooks with personal identification information. Logbooks are quality assurance and quality improvement tools in which observed counseling supervision and performance in proficiency panel testing amongst others will be recorded for the purpose of improving the performance of HTS providers. Counselors should make sure that all logbooks are updated and stored at their practicing sites. When a counselor has not updated his or her logbook for two consecutive quarters, it is assumed that he or she is not practicing. After supervision, he or she will not be allowed to practice until undergoing a proficiency test.

Summary of Key Points

- In cases wherein a couple has discordant first test results, the HTS provider should conduct a second test only for the partner who tested positive and not for the partner who tested negative.
- Pretest information for pregnant or postpartum women should include risk of transmitting HIV to infant, benefits of early HIV diagnosis/treatment, counseling on HIV risk-mitigation, infant feeding practices, and encouragement of partner testing.
- Index patient testing is a critical strategy to reach the first 90 in the 90-90-90 targets, and the issuance of FRS should be reinforced in all HTS sites. Of particular importance, FRS should be given to all pregnant and/or breastfeeding mothers, and they should be encouraged to bring their partners for HIV testing; if they are diagnosed HIV positive, mothers should also be given FRS for all their children.
- For a successful FRS strategy, community sensitization should be strengthened to address the issue of disclosure and acceptance of HIV status.
- To maintain high-quality counseling services, all HTS providers must adhere to all existing HIV counseling protocols, and ensure their logbooks are updated.

CHAPTER 5: HIV TESTING PROCEDURES AND STANDARDS

5.1 BASIC LABORATORY PRACTICES

Provision of HTS should follow standards and requirements that are consistent with those of MOH. These include the following:

- Test kits and supplies must be stored securely
- The consumption of test kits should be closely monitored and documented
- Storage area temperatures should be within the range recommended by the manufacturer
- The first-expired, first-out policy for test kits should be enforced
- Adherence to both internal and external quality control practices

5.1.1 CHARACTERISTICS OF HIV RAPID TEST KITS

Only HIV rapid test kits evaluated and approved by MOH should be used for HTS. This should include new batches and donated kits.

5.2 TESTING ALGORITHMS FOR MALAWI

HIV testing algorithms outline the sequence in which tests should be performed. The selection of test kits must be based on MOH-approved protocols and standards, which are available at National HIV Reference Laboratory (NHRL).

- HTS providers should be aware that testing algorithms might change as new testing technologies are approved for use.
- District Health leadership must adhere to the national approved protocols accordingly.
- All HTS facilities in Malawi are required to follow the serial testing algorithm as recommended by MOH. The algorithm was adopted after thorough analysis and research (refer to Appendix 3).

Serial Testing

All clients should be tested first using a whole blood HIV rapid test

- If the 1st test is non-reactive, the results are reported as “HIV negative”.
- If the 1st test is reactive, conduct a 2nd HIV test with a different rapid test kit.
 - If the 2nd HIV test is reactive, the results are reported as “HIV positive”.
 - If the 2nd HIV test is non-reactive, the results are reported as “Discordant”.

Parallel Testing

Clients with a discordant result should be retested in parallel using the first and second tests.

- If the results remain discordant, report as discordant and repeat the parallel test after four weeks.

- If the results remain discordant after four weeks, report as discordant. Collect a dry blood spot (DBS) sample as soon as possible and send to the central laboratory for confirmation with DNA-PCR diagnosis.

5.2.1 WHO SHOULD PERFORM WHOLE BLOOD HIV RAPID TESTS

Medical and nonmedical staff who have been adequately trained and certified by the national HIV program as HTS providers should perform whole blood HIV rapid tests; all other tests (non-rapid) should be sent to district laboratories or central laboratories. Laboratory technicians should ensure quality of testing at the HTS sites.

5.3 HIV TESTING FOR CHILDREN

Children of HIV-positive parents are a priority group for HIV testing. HTS for children is separated into the following age groups:

- Infants younger than 12 months
- Children 12 to 23 months
- Children 24 months and above

These distinctions are necessary because the testing algorithms may depend on a child's age. The age-specific algorithms are outlined in sub-sections 5.3.1 to 5.3.3.

5.3.1 INFANTS YOUNGER THAN 12 MONTHS OF AGE

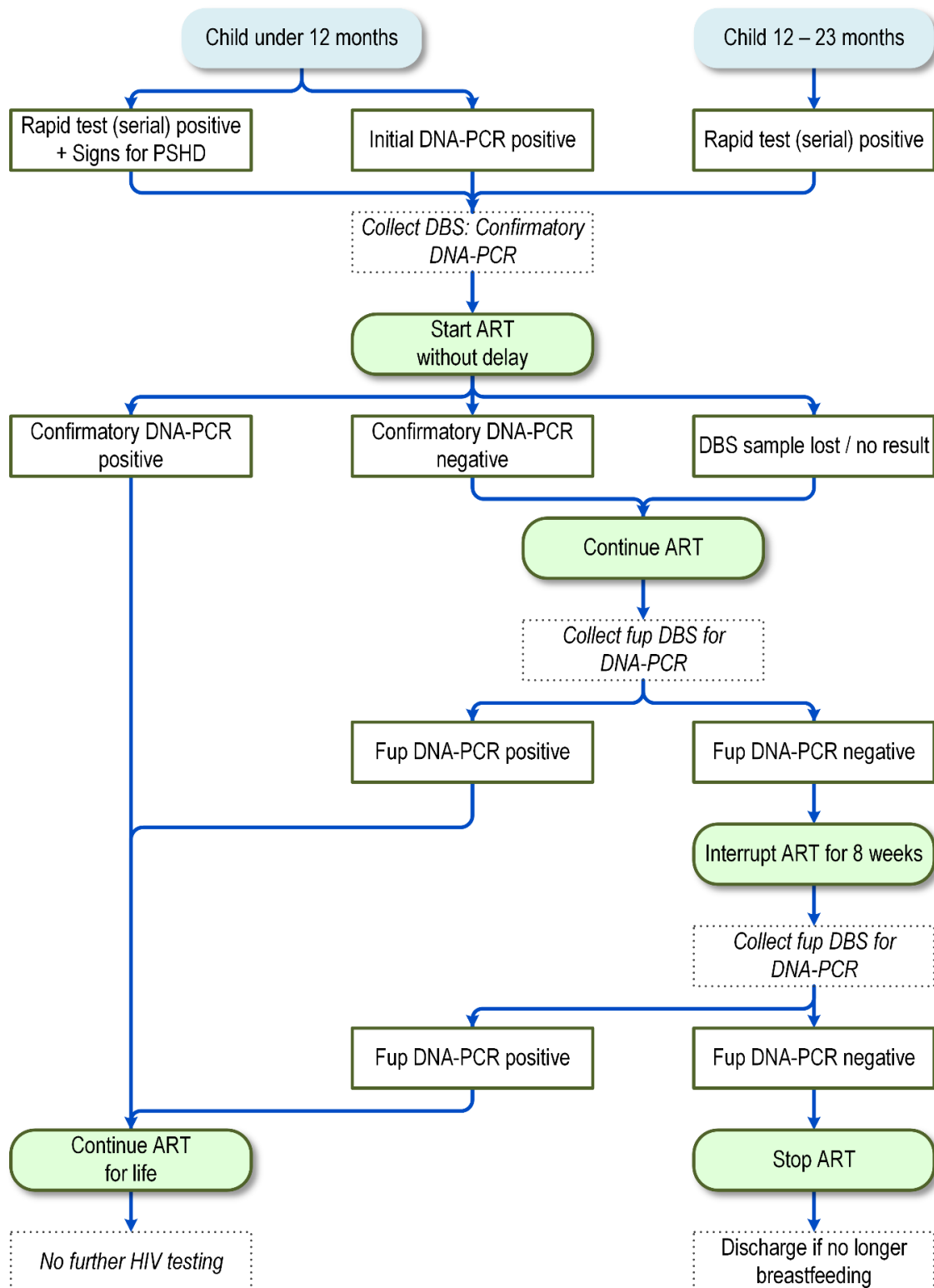
- All HIV exposed infants (HEI) should be tested for HIV at six weeks after birth or at the earliest opportunity thereafter using DNA-PCR. The sample should be collected at a health facility and sent to the nearest testing laboratory.
- If the DNA-PCR result is positive, collect a second DBS for re-testing. This should be done before starting ART. ART should be started based on the first HIV positive test result (refer section 4.2.2.1 and figure 3 below).
- If the confirmatory DNA-PCR test result is not returned within 3 months (sample lost, error in results) then another DBS sample should be collected.
- An infant with unknown HIV exposure presenting with Presumed Severe HIV Disease (PSHD) should be tested using approved HIV rapid tests. If the result is positive, the infant should be started on ART and a DNA-PCR should be performed immediately (refer section 4.2.2.1 and figure 3 below).

5.3.2 CHILDREN 12 TO 23 MONTHS

- All exposed children (if unknown HIV status or previously negative but still breastfeeding) should be tested at 12 and 24 months or at first contact with the health facility using the approved HIV rapid tests.
 - A negative test does not completely exclude HIV infection unless the child stopped breastfeeding six weeks before the test.

- All sick children with unknown HIV status should be tested using HIV rapid test.
- All children to be started on ART under the age of 2 years need a confirmatory DNA-PCR.
- Collect the DBS sample on the day of initiation.
- Don't delay ART initiation - don't wait for results of the confirmatory PCR result before starting ART.

Figure 3: Summary of HIV testing for children under 24 months (Malawi Clinical HIV Guidelines, 2016, version 4)⁵



5.3.3 CHILDREN 24 MONTHS AND ABOVE

- All children 24 months and older should be tested as adults.
- All sick children with unknown HIV status should be tested using HIV rapid test.

Using a positive parent as an index case is one of the most effective ways of finding these kids.

5.4 QUALITY ASSURANCE FOR WHOLE BLOOD ANTIBODY RAPID TESTING

NHRL will mandate the Quality Assurance Reference Laboratory technicians to provide on-site QC and quality assurance for staff performing HIV testing. The emphasis is on supervision, proficiency testing (PT), and QC testing using known samples from reference laboratories. Feedback on PT should be provided to the HTS sites in written format and must be kept on file.

5.4.1 POST MARKETING EVALUATION

For every batch of test kits imported into the country, a sample will be taken for testing with a known panel for quality check. Once a consignment of kits is distributed to the various testing sites, the HTS provider counselors would be required to run QC on every newly opened box of kits in addition to the routine schedule of QC and to record results appropriately.

5.4.2 DBS RETESTING FOR EXTERNAL QUALITY ASSURANCE

Every 20th sample will be collected from HTS sites using DBS samples in the following situations or circumstances:

- When a new site is opened
- As a QC measure for retesting at the NHRL

In addition to the above scenarios, HTS sites will be assessed twice a year, where a DBS sample will be collected from every 20th client from randomly selected HTS sites for testing at the national level, to ensure adherence to quality assurance standards.

5.4.3 QC

At a minimum, QC should be done once a week, if rapid test kits are exposed to conditions outside the range of stability, when a new HTS provider is performing testing, a new test kit lot is opened or shipment of test kits is received. Results of QC shall be documented on the appropriate section of the HTS register and HTS supervisor shall countersign to verify the results.

5.4.4 PROFICIENCY TESTING (PT) PANEL

- The PT panels will be administered every six months to all practicing HTS providers.
- The performance of each provider will be recorded in the individual logbook, and each provider shall receive timely feedback from NHRL in writing within two weeks.
- District HTS supervisors and zone lab supervisors will need to take corrective action on service

providers who score less than 100%.

- Lab supervision is required at least once every quarter; those who score less than 100% in two consecutive proficiency tests must immediately stop testing until they are retrained.

Note: For purposes of consistency, only NHRL is mandated to provide QC and PT samples.

5.4.5 SUPERVISION

District supervisors will carry out site supervision at least every month using nationally approved supervision tools; in addition, the national supervision team will supervise HTS sites every quarter. Reinforcement of internal supervision should be done during the external supervision visits. It is the role of the supervisors to make sure changes in protocols and any new related development are communicated to the providers. They must make sure that all necessary supplies and commodities are available to ensure quality results. NHRL will conduct quarterly spot checks on HTS sites and share written reports with District Health management teams (DHMTs) and stakeholders.

5.5 SAFETY

Universal precautions on infection prevention, such as hand washing and proper waste disposal, must be adhered to as recommended by MOH. All sites must display safety job aides provided by MOH. HTS providers also should be knowledgeable about the availability and access to post exposure prophylaxis.

Summary of Key Points

- Only HIV rapid test kits evaluated and approved by MOH should be used for HTS
- Index testing is critical for the identification of children, especially those above 2yrs of age.
- All children under 2 years starting ART must have DBS sample taken at the point of ART initiation for confirmation of HIV positive status using DNA-PCR. They should be initiated while waiting for the confirmatory test results
- Lab supervision is required at least once every quarter; HTS providers who score less than 100% in two consecutive proficiency tests must immediately stop testing until they are retrained.
- For consistency purposes, only NHRL is mandated to provide QC and PT samples.
- All providers should perform QCs according to the protocols stipulated in this document.

CHAPTER 6: GUIDANCE FOR THE ESTABLISHMENT OF HIV TESTING SERVICES

6.1 AUTHORIZATION

Any site or provider wishing to offer HTS should be approved officially in writing and registered with the District Health Office (DHO). Application forms to establish HTS services should be obtained from respective DHOs.

The DHO will deregister HTS facilities that do not comply with any of the MOH minimum standards (refer to Appendix 2), including the following:

1. No trained HTS provider is available.
2. The facility does not participate in HTS external quality assurance (EQA) for one year.

The DHO will also stop an HTS provider from providing HTS if he or she does not comply with standards as stipulated by MOH. These include the HTS provider's

1. Not providing HTS for a period of one year,
2. Not complying with ethical and human rights when providing HTS,
3. Not performing PT for a period of one year, and
4. Performing HTS while under the influence of alcohol or illicit drugs (an act of misconduct under Malawi civil service regulations).

6.2 LOCATION OF HTS

Locations of HTS should be selected in collaboration with DHO, considering factors such as

- High HIV prevalence and transmission areas,
- Population density of 10,000 people for urban area or 8 km radius from another HTS static site,
- Hard-to-reach geographical access, and
- Potential for linkages to a network of providers/facilities for essential prevention, treatment, care, and support services.

6.3 INFRASTRUCTURE

Organizations and facilities offering HTS should ensure adequate infrastructure and offer services in an environment that guarantees privacy, confidentiality, and reasonable comfort.

A minimum package for static sites includes:

- Adequate reception or waiting area;
- Minimum of one designated well lit HTS room that ensures privacy and has at least three chairs, a

surface area for testing, and a worktable for paperwork;

- Hand-washing facility with running water and soap;
- Lockable file system or lockable drawers;
- Secure storage facilities for reagents and consumables; and
- Appropriate waste disposal system for infectious and noninfectious materials, including sharp containers.

6.4 HTS EQUIPMENT AND SUPPLIES

Equipment and supplies necessary to operate HTS include

- Laboratory supplies and other consumables;
- Printed HTS-related protocols, standard operating procedures, and job aids that are well displayed or bound in booklet form;
- Male and female condoms, including vaginal and penile models for both male and female condom demonstrations;
- Standardized HTS data collection, monitoring and evaluation (M&E) and reporting tools;
- First aid kits; and
- Soap for hand washing.

An inventory and ordering system should be in place to ensure adequate supplies, including an HTS daily activity register (DAR).

6.5 INFORMATION EDUCATION AND COMMUNICATION MATERIALS

It is recommended that all HTS sites provide information, education, and communication materials that should include key HIV and AIDS messages and available services. These can be sourced from the Health Education Unit and the National AIDS Commission through respective DHOs. MOH should develop and print information, education, and communication materials and job aides with support from partners.

6.6 HUMAN RESOURCES

Each HTS site should have a minimum of two HTS trained, certified, and practicing staff. It is recommended that refresher trainings be provided to all practicing HTS providers (including trainers and supervisors) every two years and from time to time based on need and changes in the guidelines. District HTS coordinators and HTS supervisors should also provide scheduled mentoring and supportive supervision activities to all HTS providers within their districts.

Summary of Key Points

- Any site or provider wishing to offer HTS should:
 - Obtain application forms to establish HTS from respective DHOs.
 - Be officially approved in writing and registered with DHO
 - Have adequate infrastructure, supplies, infection prevention and control measures, and at least two trained HTS providers

CHAPTER 7: HTS IMPLEMENTATION STRUCTURES

7.1 POLICYMAKING AND IMPLEMENTATION

The policymaking of HTS will take into account ongoing reforms in the country. In view of the complexity of the HIV and AIDS epidemic, policymaking and implementation of the guidelines will be subject to reviews from time to time to address emerging issues.

7.2 SERVICE IMPLEMENTATION STRUCTURE

7.2.1 DEPARTMENT OF HIV AND AIDS

The Department of HIV and AIDS (DHA) in MOH has responsibility for the overall coordination of HTS in Malawi and is responsible for implementing HTS policy. This department serves as the primary point of contact for all national HTS-related issues. The DHA coordinates and monitors the implementation of national plans and policies for testing and counseling. This department also coordinates the development, approval, dissemination, and periodic review of the national HTS guidelines.

The DHA and the Department of Planning and Policy Development will have primary responsibility for coordination of M&E activities, collection and analysis of data, as well as writing and dissemination of reports. The three units will ensure adequate and updated information systems and service provider adherence to standardized reporting systems, including maintenance of a reliable reference base for research and development on HTS issues.

7.2.2 NATIONAL AIDS COMMISSION

The National AIDS Commission provides overall leadership and coordinates the national multi-sectorial response to HIV and AIDS in Malawi. The National AIDS Commission as the overall coordinating body will ensure that HTS programming by partners is clearly defined and guided by HIV and AIDS policy and the national strategic frameworks. It will also ensure that the HTS program is evidence based and focuses on achieving high yield, gender sensitivity and anchored in a human rights framework.

7.2.3 NATIONAL HIV REFERENCE LABORATORY

National Health Reference Laboratory (NHRL) has been mandated by MOH to coordinate all issues relating to quality assurance and assessment in HIV testing. In addition to implementing the EQA program, it is responsible for evaluating new HIV rapid test kits, making recommendations to MOH before the test kits can be used in the country, and conducting post market surveillance of HIV rapid test kits in Malawi.

7.2.4 ZONAL HEALTH OFFICE

The Zonal Health Office monitors and supervises HTS to ensure quality HTS provision in its zone.

7.3 DISTRICT HTS COORDINATION ARRANGEMENTS

DHO is responsible for the overall coordination of the implementation of HIV and AIDS health-sector interventions at the district level. For HTS, this would include the following:

- Authorization for establishing new HTS sites
- Appraisal and supervision of both facility HTS and CBHTS, including deregistration where standards are not met
- Development and implementation of an overall district HTS strategy within the context of the District Implementation Plan

DHO will serve as a member of the District AIDS Coordinating Committee of the local councils and will appoint a district HTS coordinator within DHO to coordinate all HTS activities in the district.

7.3.1 DISTRICT HTS COORDINATOR

The District HTS Coordinator reports to DHO and is responsible for coordinating HTS in the district, in conjunction with DHO and DHMT. A practicing HTS provider trained in both counseling and testing who has been certified by MOH and has served for a minimum of one year may be appointed a District HTS Coordinator and be a member of the extended DHMT.

He or she will:

- Ensure adequate commodities, supplies, and personnel for HTS in the district
- Set up district capacity-building programs in consultation with DHMT and MOH headquarters
- Develop and coordinate networks of providers and hold quarterly meetings involving HTS stakeholders at the district level
- In consultation with DHMT, identify and recommend HTS supervisors for training;
- Compile and submit quarterly reports to DHO with copies to the District AIDS Coordinator, the Department of HIV and AIDS, the Health Management Information System (HMIS), and the Zonal Health Office;
- Manage district HTS administrative issues in consultation with DHMT, the HTS supervisors, and HTS site staff.

7.4 HTS IMPLEMENTING STAFF

7.4.1 DISTRICT HTS SUPERVISOR

Each district will have one or more HTS supervisors serving under the leadership of the district HTS coordinator. The HTS supervisor is responsible for overall supervision and M&E for a maximum of 20 HTS sites in the district or parts of the district as assigned by the District HTS Coordinator. He or she will compile monthly HTS reports and submit them to the District HTS Coordinator. The HTS supervisor must be trained in HTS provision and supervision. Attributes of the HTS Supervisor to effectively supervise and support experienced HTS staff include, but not limited to, counseling, support, supervision, administrative, management, and interpersonal skills. Only counselors who have actively served as HTS providers for at least one year will be trained as HTS supervisors.

7.4.2 THE DISTRICT LABORATORY SUPERVISOR

The district laboratory supervisor (in-charge) must have quality assurance supervisory knowledge and skills, should have completed the whole blood rapid test training, and should be certified by MOH. His or her responsibilities include the following:

1. Providing QC testing samples
2. Monitoring site performance in whole blood rapid testing, QC testing and giving feedback
3. Providing samples for PT or panel testing and giving feedback to providers
4. Coordinating DBS sample collection and transmission to the testing laboratory and giving feedback on validation testing to sites

7.4.3 HTS MASTER TRAINERS

HTS master trainers provide recognized HTS Training of Trainers (TOT) using the approved national HTS TOT curriculum coordinated by the DHA. They also provide oversight during HTS trainings for both providers and supervisors and HTS supportive supervision at the national level. HTS master trainers should have experience in conducting HTS trainings and demonstrate above average skills in training methodology, mentorship, and supervision of HTS. Incumbents should be well trained and experienced in their areas of expertise (laboratory and counseling).

7.4.4 DISTRICT HTS TRAINERS

HTS trainers provide recognized training using the approved national HTS training curriculum coordinated by the district HTS coordinator and supervisors in conjunction with MOH's HIV and AIDS Department. HTS trainers should be practicing HTS providers with experience in counseling and performance of whole blood rapid test and should be available to conduct training when required. Incumbents should have a minimum of a Malawi School Certificate of Education (MSCE). Individual organizations, government departments, or

ministries in conjunction with the DHA will select them. They can be health or non-health personnel who have successfully completed the TOT course for HTS training certified by MOH.

Responsibilities include the following:

- Conducting HTS training using the nationally approved training curriculum
- Screening participants in HTS training using the approved criteria in the HTS training manuals
- Advising the districts about requirements for HTS trainings
- Writing reports documenting training to the DHA through the district HTS coordinator, including full names of participants and their institutional affiliations
- Planning and conducting refresher courses in collaboration with the DHA, using the DHA's approved curriculum

7.4.5 HTS SITE SUPERVISOR

Each HTS site should have an HTS site supervisor. Where applicable, the site supervisor is responsible for counseling, supervision of HTS staff, and HTS on site. The supervisor is also responsible for coordinating all HTS in all testing units, including its community-based activities if any, and reports to either the health facility in-charge or the manager at stand-alone sites. Activities include HTS provision, supervision of HTS staff, and ensuring M&E tools are filled.

7.4.6 HTS SERVICE PROVIDER

An HTS provider must have successfully completed the nationally recognized HTS training course, must be certified by the DHA before practicing, and should provide services consistent with these guidelines. A newly certified HTS provider should be paired with an experienced provider for a minimum of three months.

His or her responsibilities include the following:

- Conducting posttest counseling using the standard protocols outlined in these guidelines
- Ensuring effective client referral and linkage to other services
- Collecting data, keeping records, and writing reports
- Attending regular support supervision meetings

Roles and responsibilities as stipulated here should be developed into position descriptions for staff and volunteers. These should be written and communicated to all HTS providers during their orientation. Management of the HTS site also must define working hours.

Selection Criteria for Those Who Should Be Trained as HTS Providers

For medically trained providers, the following minimum qualifications are recommended:

- Have a certificate in any medical discipline, that is, nurse, clinical officer, medical assistant, dental therapist, and environmental health officer/assistant
- Have at least one year's experience working in Malawi
- Be age 18 or older
- Must be in reasonably good health and in a clear state of mind
- Be motivated to provide HTS in a clinical setting, with an intention to practice after training (this course is not appropriate for providers who intend to recommend testing to patients)
- Able to read and write English and preferably fluent in the local language
- Have no criminal record
- Have adequate vision or wear corrective lenses

For nonmedical providers, the following minimum qualifications are recommended:

- Be an MSCE holder
- Have at least one year's experience working in Malawi
- Be age 18 or older
- Must be in reasonably good health and in a clear state of mind
- Be motivated, enthusiastic, and sensitive and have a genuine desire to help others
- Be able to read and write English
- Have no criminal record
- Be familiar with the language, culture, and religious beliefs of the community with which he or she is to work
- Be recruited by an HIV implementing organization, with the objective of providing HTS at the end of the training
- Be affiliated with an HIV organization social or support group, with the objective of providing HTS at the end of the training
- Have adequate vision or wear corrective lenses

7.4.7 HIV DIAGNOSTIC ASSISTANTS

HIV diagnostic assistants are a cadre with the following roles and responsibilities:

- Perform rapid HIV and syphilis testing and counseling in all priority PITC settings
- Collect DBS blood samples for early infant diagnosis, viral load, discordant results, and EQA
- Track HIV sample transportation and coordinate patient follow-up and return test results
- Comply with routine quality assurance measures for HIV and syphilis rapid testing including being available for regular HTS/ART/PMTCT supervision and mentorship sessions
- Ensure effective HTS, early infant HIV diagnosis (EID), viral load, and syphilis client referral and linkage to other services

- Collect data, keep appropriate records, and write HIV and syphilis diagnostic services reports
- Ensure availability of adequate HTS, EID, viral load, and syphilis testing commodities and supplies in the testing room
- Ensure effective delivery of HTS in line with required standards
- Maintain effective communication/collaboration with supervisors and other health care providers
- Ensure adherence to the duty roster to avoid interruption of services

Minimum qualifications for HIV diagnostic assistants are the following:

- Be an MSCE holder
- Meet all standard requirements for initial HTS training as indicated in the HTS guidelines
or
- Be a certified HTS provider holding a Junior Certificate of Education (JCE)
- Successful completion of skills-intensive training or initial comprehensive HTS training

7.4.8 ROLES OF PEOPLE LIVING WITH HIV IN HTS

In Malawi, people living with HIV should be involved in all areas of the comprehensive HIV and AIDS response, including prevention, treatment, care, support, impact mitigation, and policy development. People living with HIV who meet the minimum criteria mentioned previously in section 7.4 should be included in HTS training and service provision.

7.4.9 USE OF VOLUNTEER COUNSELORS IN HTS

Trained HTS providers can offer services at approved HTS sites on a voluntary basis. However, the use of volunteers may affect the sustainability of services, especially in the public sector. All volunteer HTS providers should be allocated to sites where they will be practicing. Careful consideration should be given to long-term incentives and benefits for volunteer HTS.

7.4.10 HTS SUPPORT STAFF

HTS support staff positions can include receptionist, data entry clerk, driver, messenger, and watchman. The eligibility criteria can be set by managers of HTS sites. The managers of these support staff should ensure that all support staff understand the nature of services being provided by the site and that support staff have received orientation in HTS including ethical requirements.

7.5 TRAINING AND PROFESSIONAL ADVANCEMENT

Appropriate training and certification of staff are critical to the provision of quality HTS. The DHA, will approve various HTS training curricula, coordinate and monitor the quality of trainings, and serve as the certifying authority in the training of HTS providers. The training courses currently approved are the following:

- *HTS Providers Training.* This is the standard generic and certified HTS training required for all HTS providers. It is the absolute minimum training requirement for all providers of HTS. It is currently a four-week course consisting of three weeks of classroom sessions and one week of supervised, observed practice at a recognized site. Full-time attendance and passing of all assessments and examinations lead to certification by MOH.
- *HTS Supervision Training Course.* This is an MOH-approved five-day training course in supervision of HTS. The minimum entry criterion is one year's HTS experience.
- *HTS TOT Course.* This is a two-week MOH-approved TOT course in HTS. Trainees will be certified on successful completion of the TOT training, which should be followed by at least one co-facilitation of one four-week HTS generic training course with an experienced trainer. The minimum entry criterion for TOT is one year's HTS experience.

CHAPTER 8: HIV TEST KITS SUPPLY CHAIN SYSTEM

HIV test kits are critical commodities to the success of the HTS program. A regular and reliable supply of rapid diagnostic tests for HIV is critical to effective HTS provision in the country. HIV test kits commodity management is integrated with other HIV commodities. Refer to Appendix 5 illustration of the HIV commodity stock management cycle. HIV commodities are delivered to all health facilities every two months.

8.2 QUANTIFICATION AND PROCUREMENT PLANNING

- MOH coordinates the quantification, procurement planning, and procurement of HIV test kits.
- The Department of HIV and AIDS works with Health Technical Support Services (HTSS) to coordinate the quantification based on assumptions generated from programmatic strategies. Quantification results are documented in the annual quantification report.
- All NGOs must contact MOH DHA before procurement of HIV test kits to minimize wastage that may arise from parallel procurement systems.
- MOH will be responsible for coordinating procurement-planning activities to ensure optimal utilization of resources allocated for HIV test kits at the national level.

8.3 WAREHOUSING AND INVENTORY MANAGEMENT

- Central-level warehouse management is conducted in line with MOH's National Drug Policy. Storage services are currently outsourced given the storage capacity constraints at the central level.
- A forced inventory management system is used where a maximum-minimum of 9:6 months of stock is maintained at the central level and 4:2 at the health facility level (see Table 2).
- Given the limited shelf life for test kits, staggered deliveries are scheduled within the pipeline to make up the maximum stock level of 9 months.

Table 4. Inventory Management System Structure

Pipeline Level	Maximum Months of Stock	Minimum Months of Stock
Health Facilities	4	2
Central Level	9	6

8.4 DISTRIBUTION OF HIV TEST KITS

- HIV test kits are delivered every two months from a central warehouse directly to ART/PMTCT sites based on a top-up basis. Supplies to stand-alone HTS sites are delivered to their respective DHO pharmacies.
- Distribution lists for all facilities are calculated based on the testing statistics reported as consumption data in the DAR, district targets for special testing events and stock reports collected during quarterly HIV program supervision.
- The distribution list is shared with the DHO/District Management Officer/HTS coordinators and relevant stakeholders every two months. A request to be added to the mailing list should be channeled through hivdeptlogistics@gmail.com or the toll-free number Airtel 59191; TNM 6882.
- All implementing partners are required to seek prior approval from the director of the DHA before implementation of HTS at the district level.
- The HTS coordinator supervises all HTS sites within the district, reviews the distribution list, and monitors use of Rapid Diagnostic Tests (RDTs) at the health facilities.

8.5 RECEIVING HIV TESTING SUPPLIES AT THE HEALTH FACILITY

- Inspect the entire consignment in the presence of a witness designated by DHMT/facility in-charge; physically count all tests kits delivered, and check expiry dates.
- Indicate the verified quantity received into the respective box on the delivery note. Write 0 (zero) for any items not received – don't leave any boxes empty.
- Facility in-charge should sign, date, and stamp the delivery note to confirm receipt of the items as indicated.

8.6 STORAGE AT THE HEALTH FACILITY LEVEL

- All items received should be kept in a secure storage area (clean, dry, cool, and off the floor).
- Enter the quantity and date of receipts on stock cards.
- Arrange items by expiry date to make it easy to follow the first-expired, first-out (FEFO) principle.

8.7 DOCUMENTATION FOR TEST KIT TRANSACTIONS

- Stock cards must be updated when effecting stock movements from the pharmacy/drug store to the dispensing area.
- Requisition and Issue Vouchers should be used when making requisitions from the pharmacy/drug store.
- DAR is used to track consumption and stock on hand data at each testing point.
- Keep a separate DAR at all places where HTS is done.
- Use separate pages for the different types of tests (Determine, Uni-Gold).
- Test kits used for clients must match entries in the HTS register.
- DARs include sets of three carbonated sheets: keep the white sheet at the facility; send the blue sheet to DHO; retain the pink/yellow sheet for collection by HIV Logistics (MOH).

- Fill out the monthly summary on the HTS report by adding numbers from all DARs used at the facility.

8.8 STOCK MANAGEMENT AT THE TESTING SITE AND COMMODITY TRACKING

- Conduct a monthly physical stock count for all test kits (in store and at all testing points), and update stock cards.
- Calculate average monthly consumption (AMC) and months of stock (MOS) for all HIV test kits after doing the monthly physical count:

units used in last A months

stock on hand

A

- Call HIV Logistics as soon as possible if shortage, excess, or expiry is noted.
- HIV Logistics will send a unique authorization code or disposal code where applicable by SMS or phone.
- Fill out a Registration Form for Relocation or Disposal of HIV Commodities for each adjustment.

8.9 QC OF TEST KITS

- Quality assurance policy must be complied with to ensure that test kits are validated before distribution to user points.
- The Pharmacy Medicines and Poisons Board (PMPB) and MOH Community Health Science Unit must be notified on receipt of HIV test kits to enable them conduct QC testing for the same.

Summary of Key Points

- Uninterrupted availability of Rapid Diagnostic Test Kits is critical to the success of the HTS Program
- MOH will be responsible for coordinating procurement-planning activities to ensure optimal utilization of resources allocated for HIV tests at the national level.
- All HIV RDTs delivered to the district and health facilities must be accounted for using MOH approved registers and logistics forms

CHAPTER 9: HMIS

HTS will be monitored by MOH within the context of the Essential Health Package. Core data collection and reporting at HTS sites should be done using the approved MOH M&E tools to measure and report the indicators specified in HMIS.

9.1 HTS MONITORING TOOLS

All HTS sites should at a minimum use approved MOH data collection and reporting tools. MOH M&E tools should not be altered. Institutions implementing HTS requiring additional data should seek authorization from the director of the Department of HIV and AIDS. Any additional data collected should be shared with DHO for effective management of HTS.

Given the sensitivity of HTS data, it is also important that there is a clear rationale for any additional data collected; the protection of clients' privacy and confidentiality is of paramount importance. Additional HTS data collected for research purposes should receive ethical clearance from the Ethical Review Boards and the Department of HIV and AIDS.

9.1.1 HTS REGISTER

All HIV testing sites are required to record every client who receives HIV testing and counseling—regardless of the context in which the service is provided (e.g., ANC, STI, door to door)—in the standardized national HTS register.

9.1.2 DAILY ACTIVITY REGISTER (DAR)

All HIV testing service points within HTS sites are required to track test kits consumption. An up-to-date record of test kits balances, receipts, losses, and utility is to be kept in every HTS point using DAR.

9.1.3 HTS MONTHLY SITE REPORT

Each facility is required to report monthly to DHO. Reporting should be done from all HTS registers that shall be in use at the respective facility using a standard reporting form. Accurate data aggregation is facilitated by the page summaries in the registers.

For internal use and targeted surveillance activities, sites may maintain more detailed client data in compliance with requirements for clients' confidentiality. Sites conducting outreach activities will maintain a dedicated register and report monthly to the mother facility for onward transmission to DHO. However, for mobile services, the mother site will dedicate one register to be used at all places visited for mobile HTS services.

HTS data from sites should be submitted to DHO through the district HTS coordinator. In turn, district-level reports will be submitted to the national-level coordinators. These data should be summarized in the HTS monthly reporting forms.

9.2 DATA ANALYSIS, REPORTING, AND FEEDBACK MECHANISMS

Data should be used for the purposes of understanding HTS demand and utilization and improving management of HTS. MOH will design and update feedback mechanisms to ensure that each level of services and management is adequately informed regarding HTS.

Personnel involved in data entry, data analysis, and data publication should be trained on the specific requirements of their roles. They should understand the linkage between the work of the different levels and its effect on quality data, information, policy, and strategy implementation. The HMIS office should ensure appropriate human resource development in case there is a change of system, software package, or personnel. Evaluation of HTS will be done according to the national M&E framework.

9.3 PUBLICATION OF HTS DATA

MOH will produce quarterly and annual service statistic reports and HMIS bulletins that include HTS. These publications will ensure easy accessibility of HTS data by all stakeholders and researchers. Published data will be disaggregated and will include data on care, referral, and other social issues related to HTS.

Summary of Key Points

- All HTS sites should use approved MOH data collection and reporting tools.
- All HIV testing sites are required to record every client who receives HIV testing and counseling.

REFERENCES

1. Malawi Demographic HIV Survey (MDHS), 2010
2. Malawi Prevention Response and Modes of Transmission Analysis: Distribution of new HIV infections in Malawi for 2013: Recommendations for prevention strategies
3. Global Fund Concept note (GF,CN), 2014
4. Malawi National Strategic Plan (NSP), 2015-2020
5. Malawi Clinical HIV Guidelines, 2016, Version 4

Outreach Model

Outreach HIV testing services (HTS) involves regular non-full-time service provision at designated health centers or community sites using staff from another static or mother site. These health centers or community-based sites often do not have adequate staff and other resources to implement static full-time service throughout the week. A plan is then arranged with a mother HTS site that has adequate resources to provide regular part-time HTS, for example, one or two days a week or one or two days in a fortnight.

Mobile Model

Mobile HTS is commonly implemented through a “mobile unit” van or other suitable vehicle with tents and moveable furniture that can easily be constructed into counseling rooms. The mobile unit and HTS providers move into the designated place in the community and provide services in accordance with a predetermined plan.

Approval

Institutions or agencies planning to provide mobile or outreach HTS must submit a proposal to the District Health Office (DHO). The decision to implement mobile or outreach HTS must be approved through the District Health management team. Reports should be submitted—if noncompliant, authorization approval can be reversed.

Proposal

Submit a proposal to DHO outlining the model of HTS you want to implement and where, how, and when you intend to provide the services. In cases of outreach, include a memorandum of understanding with the head of the facility where you would want to provide the services. In cases of mobile HTS, the proposal should include permission obtained from Technical Advisors and other traditional leaders of the community in which you will provide the mobile services.

Requirements before the Provision of HTS

1. Involve the community in the planning, and obtain permission from TAs and other traditional authorities.
2. Inform key stakeholders, community-based organizations, nongovernmental organizations, faith-based organizations, and posttest health and social support services.
3. Ensure referral networks will be operational.
4. Ensure that the community is mobilized and sensitized.
5. Provide dates and times when HTS will be provided. Use flyers, pamphlets, community radios, and so forth to inform the community.

6. Visit the place or premises to ensure suitability for HTS provision.
7. Ensure that supplies of test kits and other medical and nonmedical consumables will be adequate.

Provision of the Service

1. Provide services in compliance with HTS guidelines:
 - a. Counseling space that guarantees privacy
 - b. Requirements for lab, including running water
 - c. Waste disposal
 - d. All requirements for implementing partner available
 - e. Reliable transport for counselors serving in outreach sites
 - f. Standard data collection tools available
 - g. Standard HTS protocols available
 - h. Post-exposure prophylaxis starter pack available
 - i. Quality assurance to follow national guidance
2. Ensure provision of adequate counselors to meet unexpected high demand.
3. Arrange for suitable overnight accommodation and subsistence for all personnel involved in the mobile service.
4. Ensure periodic administration of quality assurance in compliance with standard protocols.
5. Ensure that monitoring and evaluation is done through standard approved methodology.
6. Provide necessary feedback to DHO on how the service is getting on.

HIV Testing Services, Minimum Standards Checklist

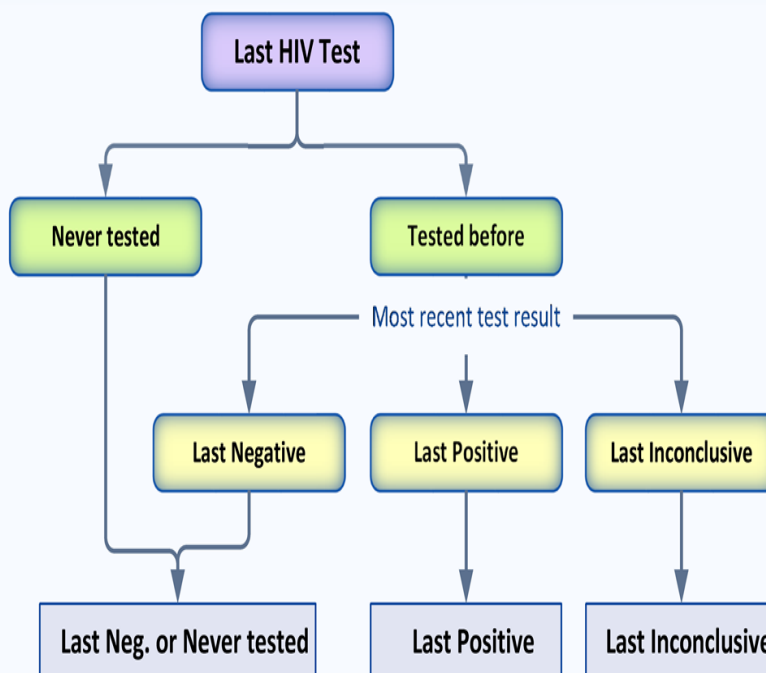
Human resources		
1.	The site should have at least two certified counselors.	
2.	Identify a site focal person who will be in charge for the HIV testing services (HTS) site.	
Policy, standards, and guidelines		
1.	National HTS guidelines available and in use at the site	
2.	HTS protocol booklet available	
3.	HTS standard operating procedures and Job aides on display	
4.	Safety protocol on display (infection prevention, waste management, post-exposure prophylaxis including hand washing)	
5.	An updated logbook for each HTS provider at the site	
6.	Incident report booklet (refer to Appendix 6)	
Assess infrastructure of the main counseling unit		
1.	Waiting area	Clean and adequate sitting area
		Information, education, and communication materials available
2.	Counseling room	Clean, tidy, spacious, well lit, and ventilated
		Working timer
		Calendar
		Wall thermometer with a recording chart
		At least three chairs and one table, separate testing surface
		Lockable cabinet for records (HTS provider access only)
		Door tags (counseling in progress/please enter)
		Penis model available
		Male condoms freely available
		Female condoms freely available

	Information, education, and communication materials available
Safety	
1.	Running water and soap available
2.	Sharps container available
3.	Two separate bins for contaminated waste and non-contaminated waste available
4.	Functional pit/incinerator for safe disposal
5.	Disposable gloves available
6.	Cotton wool available
7.	Methylated spirit available
8.	Antiseptic/decontamination solution available
9.	Antiseptic solution made up according to standard operating procedures
Quality assurance for HIV testing	
Internal Quality Assurance	
1.	Availability of quality control materials (dry tube specimen with known positive and negative samples)
2.	Performance of quality control and proper recording of results
3.	Monthly review of internal quality assurance by HTS supervisor
External Quality Assurance	
4.	Performance of proficiency testing every six months
5.	Feedback on proficiency testing results obtained/received from Reference Laboratory on time
6.	Availability of filter papers for dried blood spots on the site
7.	Availability of Zip-lock bags, desiccant packs, and glycine papers on the site
8.	Collection of dried blood spot specimens at the site
Quality assurance for counseling	
1.	Blank Ministry of Health session observation checklist available

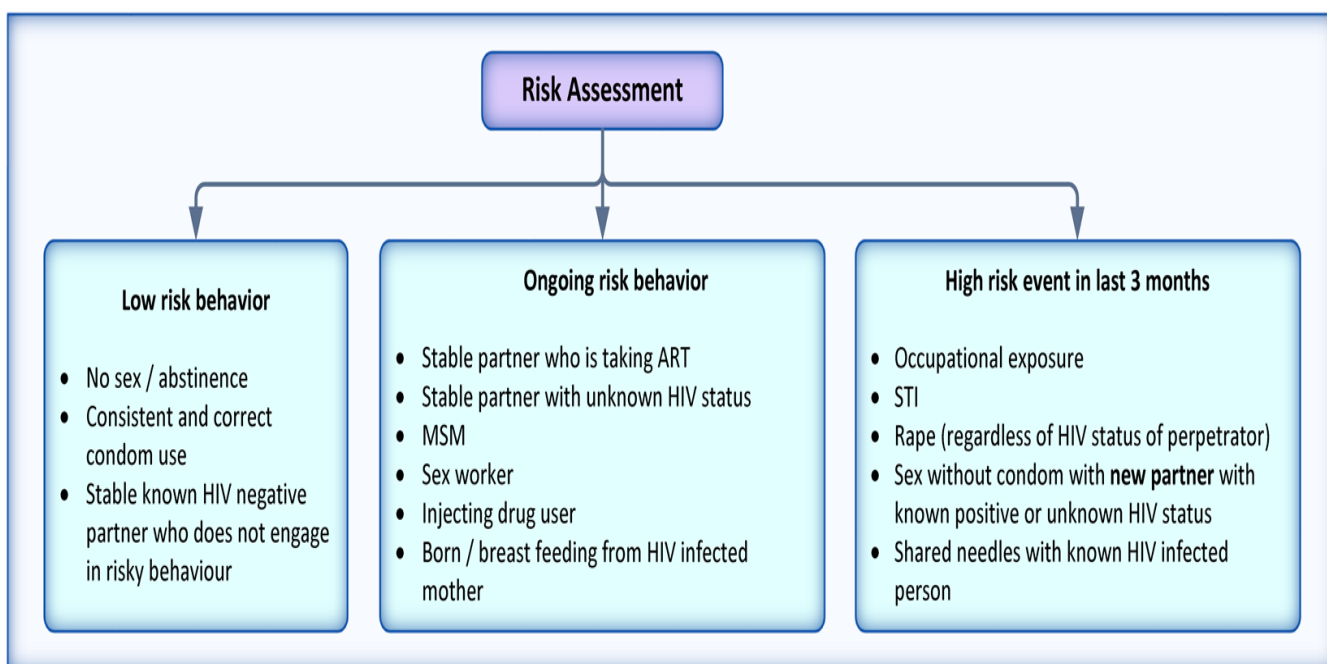
2.	Number of counselors have participated in sit-in session observations in the last quarter
3.	Counselor meeting conducted during the last quarter
4.	Minutes for HTS quarterly meetings
Monitoring and evaluation tools	
1.	National HTS register available and properly filled out
2.	HTS daily activity register available and properly filled out
3.	HTS monthly report form available and properly filled out
4.	Family referral slips available and constantly used
HIV test kit management	
1.	HIV test kits kept in pharmacy/drug store
2.	Proper storage (safe, off the floor, dry, cool, arranged by expiry date and lot number, appropriate temperature)
3.	Use of standard stock card for HIV test kits
4.	Adherence to issuing procedures (first expiry, first out)

APPENDIX 3. MALAWI SERIAL HIV RAPID TESTING ALGORITHMS

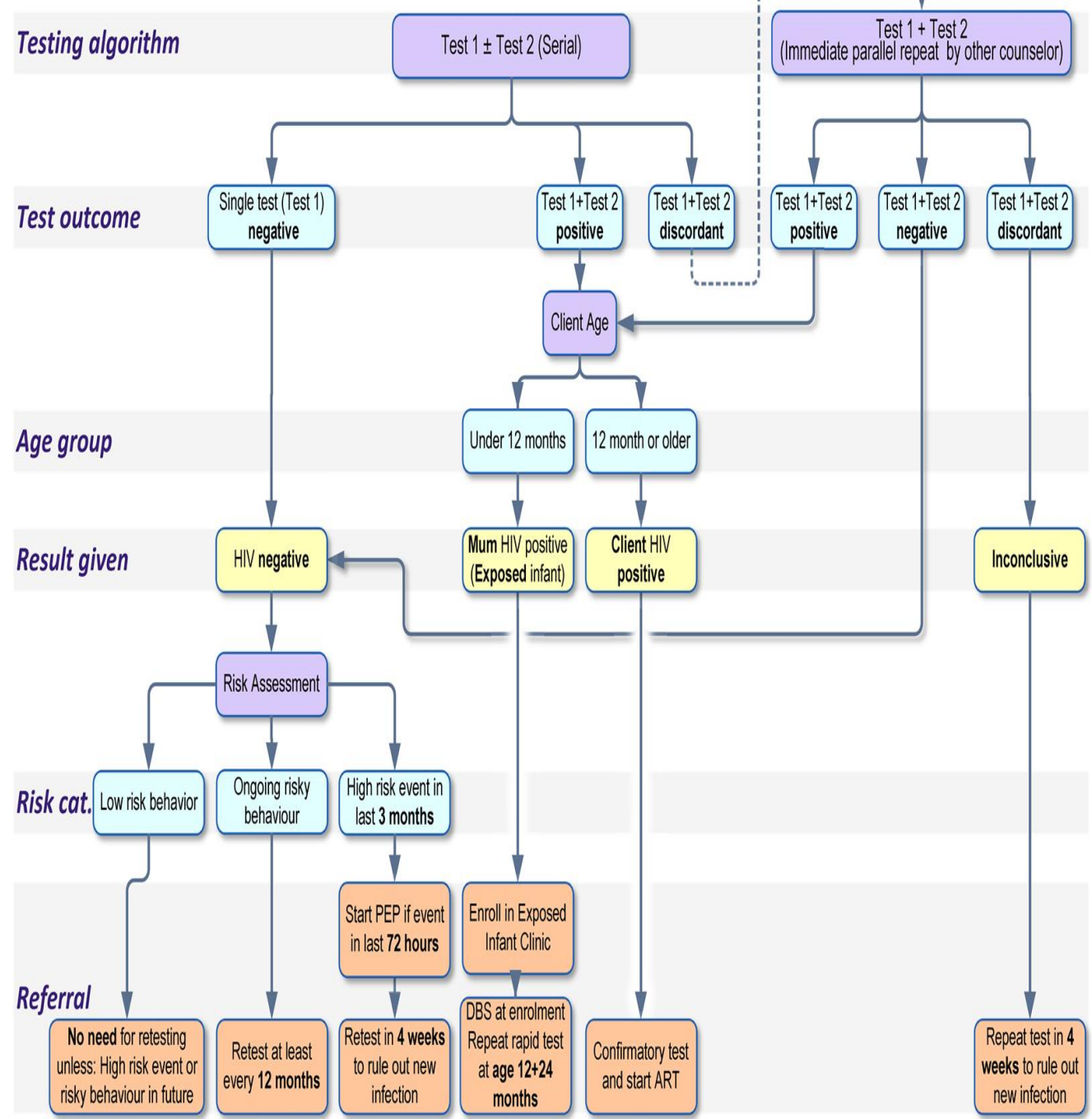
- Has the client ever been tested for HIV?
- If yes, what was the most recent result?
- Documented results are preferred, but reported results are acceptable.

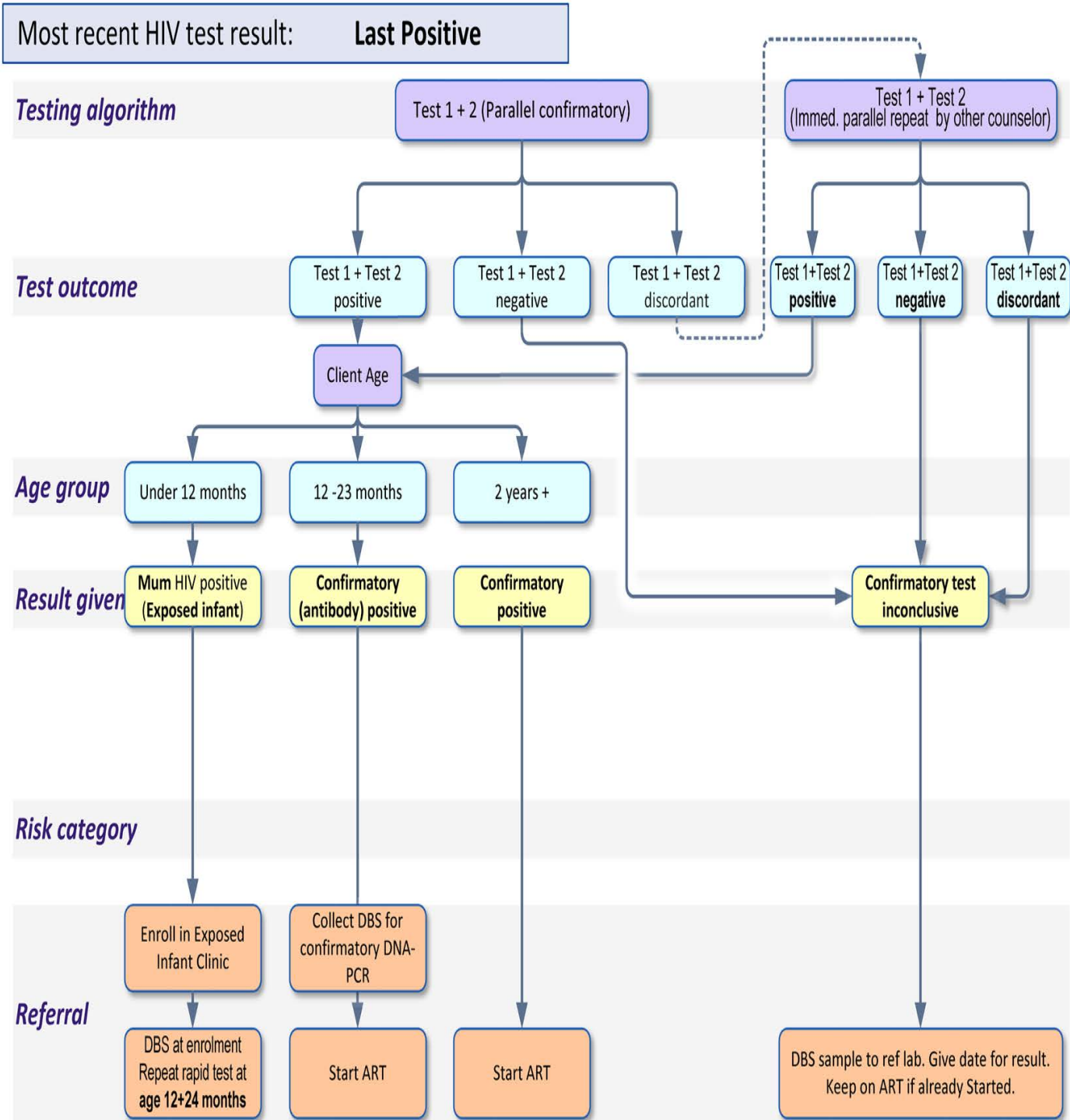


Follow Flow chart for:



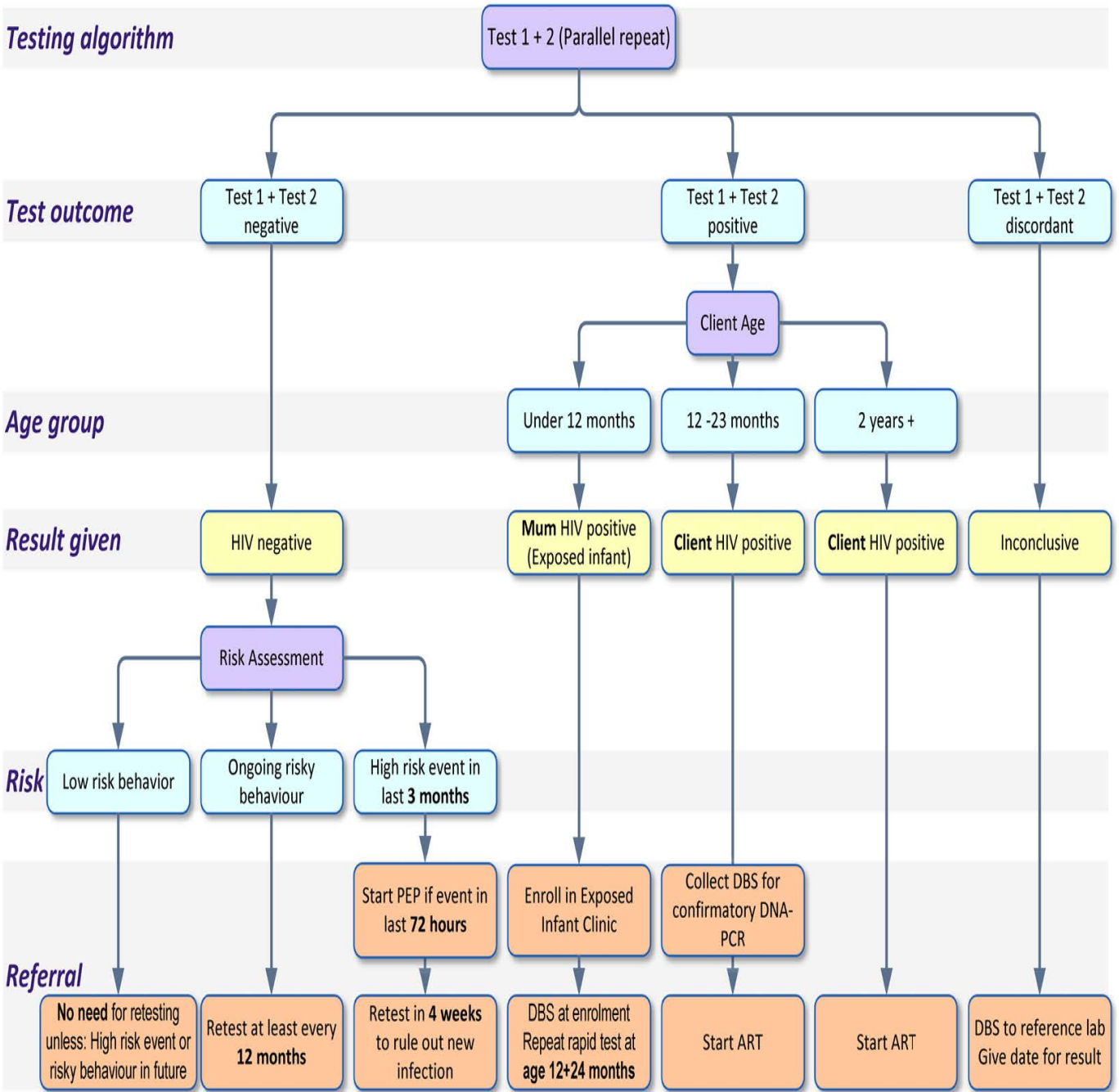
Most recent HIV test result: **Last Negative or Never tested**





Most recent HIV test result: **Last Inconclusive**

Testing algorithm



APPENDIX 4. STANDARD REFERRAL FORM

FROM HTS SITE TO OTHER SERVICES

Date: _____

Client name : _____

Client phone number: _____

Age: _____ Sex: _____

Current residence: _____

Referred from (health facility/section): _____

Referred to (health facility/section): _____

HIV test result: _____

<i>(Tick all that apply)</i>	List of services
	ART/PMTCT Clinic
	STI
	TB
	Family Planning
	PLHIV Support Groups
	Home-based Care
	Social Welfare
	Posttest Clubs
	Other, Specify:

HTS provider ID and Signature: _____

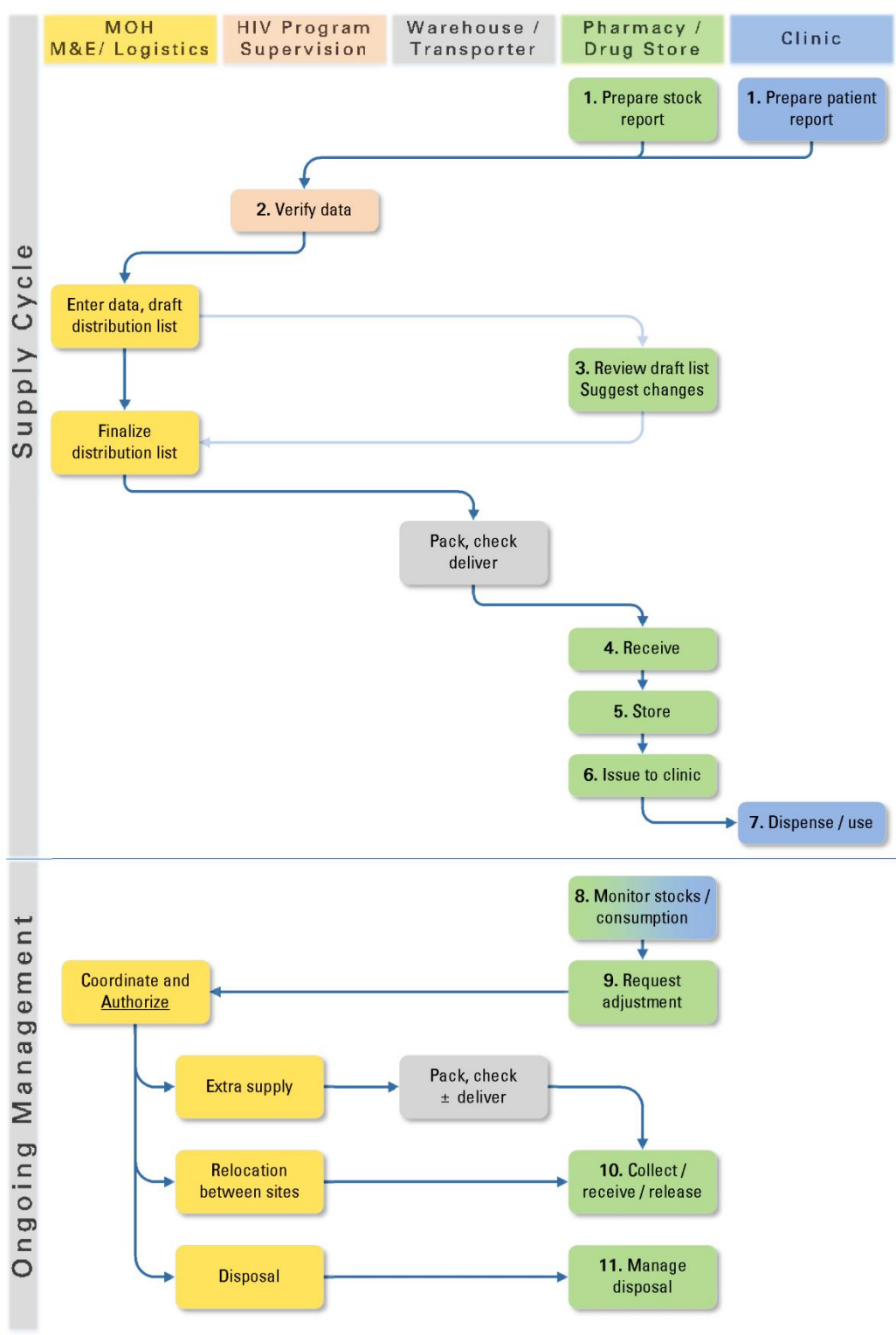
Receiving Facility: _____

Client enrolled on (Date) _____

Client enrolled by _____ *Signature* _____

Remarks _____

APPENDIX 5. HIV COMMODITY STOCK MANAGEMENT CYCLE



APPENDIX 6: HTS INCIDENT REPORT FORM



HTS INCIDENT REPORT FORM

Date of Incident:		Time of incident:	
Location of incident :			
Reporting person details <ul style="list-style-type: none"> • Name: • Provider ID: • Contact information: • Signature: 			
Type of incident (explain in details)			
How did the incident occur			
Action taken to resolve the incident			
Supervisor informed about the incident	Yes	No	
If supervisor informed what action has been done	Signature of supervisor		
Follow up plan			

APPENDIX 7: ETHICS AND CODE OF CONDUCT FOR HTS PROVIDERS

A code of ethics outlines the fundamental values of HTS provision. HTS providers should understand these values so as to maintain a professional relationship with their clients.

The standards followed by HTS providers serve to safeguard integrity, impartiality and respect, with regard to both parties.

The following is an outline of the main features of an ethical code of conduct for HTS providers.

Ethical Code of Conduct for HTS Providers

General Principles

Competence

- HTS Providers:
 - Are responsible for their own physical safety, effectiveness, competence and conduct, thereby avoiding any compromise of the profession.
 - Must ensure that they have received the required skills and techniques in HTS. training
 - Should regularly monitor their competence through supervision or consultative support, and by seeking the views of their clients and other HTS providers.
 - Must recognize their boundaries and limitations of competence, and provide services, skills and techniques for which they are qualified by training and practice.
 - Must refrain from any claim that they possess qualifications or expertise that they do not;
 - Must make appropriate referrals to others with expertise that they do not possess; and
 - Must refrain from making exaggerated claims about the effectiveness of the intervention offered by their services in relation to HIV prevention and care.

Consent

- HTS providers must obtain their clients' consent to engage in the counselling and/or HIV testing process. Unless sanctioned by legal authorities on criminal or mental health grounds, HTS is to be voluntarily undertaken by clients, and should take place in a private and confidential setting.
- It is the provider's responsibility to inform clients about the nature and duration of counselling and testing process.
- All people taking an HIV test must give informed consent prior to being tested. This consent must be obtained or provided in the counselling relationship.
- HTS providers are expected to ensure that clients have adequately understood all of the issues involved in HIV testing and counselling before giving informed consent for HIV testing.
- HTS providers must recognize the rights of those whose ability to give valid consent to HIV testing may be diminished because of age, learning disabilities or mental illness.
- HTS providers must recognize the right of clients to withdraw their consent at any time, even after their blood has been taken for HIV testing.

Confidentiality

- HTS providers must maintain adequate records of their work with clients or patients and take all reasonable steps to preserve the confidentiality of information obtained through client contact.

They should take steps to protect the identity of individuals, groups and others revealed through counselling.

- Confidentiality should be upheld and no information concerning the client or patient given away without the permission of the client. The results of HIV tests must be kept absolutely confidential. However, shared confidentiality is encouraged. Shared confidentiality refers to confidentiality that is shared with family members, loved ones, care givers, and trusted friends. Shared confidentiality is provided only upon request of the person undergoing testing. Although results of HIV tests should be kept confidential, other professionals such as health workers might also need to be aware of a person's HIV status in order to provide appropriate care.
- HTS providers must take all reasonable steps to communicate clearly the extent of confidentiality they are offering to clients. Normally this should be made clear in the pre-counselling information or initial contracting.
- HTS providers must not disclose any information about a client or patient to colleagues not directly involved in their care or their patients without first seeking consent of the client.
- HTS providers must make provisions for maintaining confidentiality in the storage and disposal of client or patient records.
- HTS providers may break the confidentiality agreement only if there are sound reasons for doing so, such as:
 - Believing that a client will cause serious physical harm to himself or herself, or to other persons,; or that the client will be harmed by someone else;
 - Believing that a client is no longer able to take responsibility for his or her decisions and actions.
- The decisions to break confidentiality agreed upon between an HTS provider and client should be made only after consultation with an HTS supervisor or an experienced HTS provider.

Culture, Religion, Gender and Racial differences

HTS providers must recognise the fundamental human rights, dignity and worth of all people.

Like any other health professionals, HTS providers are expected to provide services to people irrespective of their race, culture, religion, values, or belief systems.

HTS providers must:

- Be aware of the clients cultural and role differences of gender, race, ethnicity, religion, sexual orientation, disability and socio-economic status.
- Be aware of personal prejudices and biases based on the above-mentioned human differences, and not to allow these to interfere with the counselling process.
- Refer clients to another HTS provider if cultural and role differences of gender, race, ethnicity, religion, sexual orientation, disability and socio-economic status interfere with the service provision in any way.
- Refrain from participating in, or condoning any discriminatory practices based on the above-mentioned human differences.

Personal Conduct

- HTS providers must provide services in a way that does not damage the interests of their clients or undermine public confidence in their service or their colleagues.

- HTS providers must maintain respect for clients in the counselling relationship by not engaging in activities that seek to meet the provider's personal needs at the expense of clients, and not attempt to secure financial or other benefits other than those contractually provided for or awarded by salary.
- HTS providers should not exploit any counselling relationship for the gratification of personal desires. Sexual harassment, unfairness, discrimination, stigmatisation, and derogatory remarks must be avoided.
- HTS providers should refrain from counselling when their physical or psychological condition is impaired through the use of alcohol or drugs, or when their professional judgment and abilities are impaired for any other reason.
- HTS providers should appear professional and presentable in dress and manner.

Integrity

- HTS providers must seek to promote integrity through honesty, fairness and respect for others, and avoid improper and potentially harmful dual relationships with clients.
- They should not engage in a personal or sexual relationship with current clients.
- They should not accept to counsel clients with whom they have engaged in former sexual relationship or with whom they have a current personal relationship.