

MEDICAL COUNCIL OF ZAMBIA

Accreditation of Sites for Provision of Antiretroviral Therapy

**Guidelines,
Inspection Tools,
and Implementation Plan**

**Lusaka
December 2006**



The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

Foreword

The Medical Council of Zambia is a Statutory Body established under an Act of Parliament – CAP. 297 of the Laws of Zambia. It is a regulatory body with statutory obligations to regulate the registration of health care facilities and health practitioners, as well as to maintain optimal standards of competence, care and professional conduct. Its mission is to set, promote and regulate ethical and professional standards of practice amongst health care professionals so as to ensure the provision of quality health care for the public.

In line with this statutory mandate, the Council has taken on the responsibilities to start an accreditation programme for all health care facilities whether public or private, which have or may wish to provide ART Services. The ART accreditation will be additional to the Council's overall responsibilities and functions related to inspections and registration of health care facilities. ART Services are an important intervention in the basic health care package for mitigation against HIV and AIDS. It is with this thought, that it was decided to invest time and resource to develop an accreditation program for ART sites, which should improve the health care delivery of ART medication to the general public. The accreditation of ART sites should, in the ultimate, help health facilities and practitioners to understand and implement the basic principles, which will benefit the patients.

The accreditation guidelines and assessment tools that have been developed for ART sites are designed to facilitate the process of assessing the extent to which a health facility or site, meets the prescribed and published standards. The guidelines will also be an essential handbook for all health facilities that may wish to provide ART services. The Parameters set in these guidelines for each service area or Domain of service should essentially be the ultimate aspiration for every health provider, health facility or indeed health practitioner.

It is the Council's hope that health facilities and indeed health practitioners will find these guidelines and assessment tools useful in enhancing quality in the provision of ART and health care in general.

Dr. M. Mukunyandela
Chairman

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W.W. Banda
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Table of Contents

Foreword.....	i
Acknowledgements	ii
Table of Contents	iii
List of Acronyms	v
Executive Summary	vi
1.0 Background	1
2.0 The Accreditation Procedure.....	2
3.0 Service Domains Evaluated to Assess Site Readiness.....	3
3.1 Definitions of Terms used in the Assessment of Service Domains	3
3.2 Minimum Acceptable Standards for Accreditation of Sites	4
3.2.1 HIV Care and ART Team Leadership	4
3.2.2 National Guidelines and Standard Operating Procedures and Quality Assurance Systems.....	5
3.2.3 Level of Health Care and Clinical Services.....	7
3.2.4 Laboratory Capacity	9
3.2.5 Health Management Information System (HMIS) and Monitoring and Evaluation	11
3.2.6 Human Resource Capacity and Experience.....	12
3.2.7 Pharmaceutical and Logistics Management System.....	13
4.0 Determination of Stages for Site Readiness.....	15
4.1 Mobilization (Stage 1)	16
4.2 Service Delivery Planning (Stage 2).....	17
4.3 Preparation (Stage 3)	18
4.4 Activation/Continuation (Stage 4).....	19
4.5 Centre of Good Standing (Stage 5).....	20

Annex i: MCZ Inspection Tools.....	21
Section 1: Inspection Tools for Health Facilities	21
Section 2: Inspection Tools for Accreditation for ART Sites.....	33
Annex ii: Implementation Plan.....	40
Guiding Principles	40
Aim and Objectives for Accreditation of ART Sites	41
Aim	41
General Objective	41
Strategic Objectives	41
Activity Description by Strategic Objective	41
To ensure high standards of practice in ART services	41
To ensure adherence to policies and procedures for accreditation.	42
To develop the accreditation database	42
To provide capacity building of surveyors/inspectors on accreditation	42
To roll out of the accreditation program.	42
To strengthen the awareness on accreditation among stakeholders.	43
Institutional Arrangements.....	44
Programme Financing	44
Monitoring and Evaluation Framework.....	45

List of Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Aminotransferase
ART	Antiretroviral Therapy
ARVs	Antiretroviral drugs
CIDRZ	Centre for Infectious Disease Research in Zambia
CO	Clinical Officer
CPD	Continuous Professional Development
CRS	Catholic Relief Services
CT	Counseling and Testing
DHMT	District Health Management Team
FBC	Full Blood Count
GNC	General Nursing Council
GRZ	Government of the Republic of Zambia
Hb	Hemoglobin
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HSSP	Health Services and Systems Program
ITG	Integrated Technical Guidelines
LFT	Liver Function Tests
LMIS	Logistics Management Information System
LMS	Logistics Management System
MCZ	Medical Council of Zambia
ML	Medical Licentiate
MO	Medical Officer
MoH	Ministry of Health
NAC	National Aids Council
NGOs	Non-Governmental Organizations
OI	Opportunistic Infections
PHO	Provincial Health Office
PLWHA	People Living With HIV/AIDS
PMTCT	Prevention of Mother To Child Transmission of HIV
QA	Quality Assurance
STI	Sexually Transmitted Infections
SOP	Standard Operating Procedures
TB	Tuberculosis
THPAZ	Traditional Health Practitioners Association of Zambia
UNAIDS	Joint United Nations Programme on AIDS
USAID	United States Agency for International Development
WBC	White Blood Cells
WHO	World Health Organisation
ZMA	Zambia Medical Association
ZPCT	Zambia HIV/AIDS Prevention, Care and Treatment (ZPCT) Partnership

Executive Summary

These accreditation guidelines and assessment tools have been developed for the assessment of both public and private health facilities that are or may be involved in the administration of ART. The guidelines are designed to address quality aspects in all the domains or service areas as required for accreditation purposes. They are absolute minimum below which accreditation cannot be considered or granted.

A team of trained Surveyors or Inspectors under the authority of the Medical Council of Zambia will assess the ART Site. Dependent on the outcome of the assessment report, the site will be graded in one of the following five categories:

Stage 1	Mobilisation Stage
Stage 2	Service Delivery Planning Stage
Stage 3	Preparation Stage
Stage 4	Activation/Continuation Stage
Stage 5	Centre of Good Standing

Only those sites graded in Stage 4 or 5 will be issued with an accreditation certificate. An accredited site or health facility shall be re-evaluated or re-assessed every two (2) years in order to continue to retain the status of being an accredited site for ART. Those sites that fall below Stage 4 at the time of re-assessment would lose their accreditation status until when they improve to stage 4 or 5.

The service areas or Domain of Service delivery listed below, shall be assessed or evaluated during a site assessment or inspection:

- HIV/AIDS Care and ART Team Leadership.
- National Guidelines, Protocols, Standard Operating Procedures and Quality Assurance of ART.
- Level of Health Care and Clinical Services.
- Laboratory Capacity (Diagnostic Capacity).
- HMIS, Monitoring and Evaluation Capacity.
- Human Resource and Continuous Professional Development (CPD).
- Pharmaceutical and Logistics Management Systems Capacity.

Minimum standards and requirements against each one of the above domains or service areas have been elaborated in these guidelines. A checklist or assessment tool has also been developed upon which the Assessors or Inspectors will base their scoring and eventual grading for the site.

All sites providing ART Services must attain a stage 4 or Stage 5 grading in order to be approved for administration of ART Services.

1.0 Background

In the early 1990s, the Government of Zambia (GRZ) embarked on health reforms with the vision “to provide equity of access to cost-effective, quality health care as close to the family as possible”. To archive this vision, Zambia needed a health system that was robust enough to embrace all the key elements of health care delivery, such as a strong health system structure and the availability of necessary inputs to ensure effective delivery of services.

One of the reform focus was on improving of care. Consequently, an accreditation programme was identified as a viable approach for improving quality in the health sector, particularly at hospital level. This programme was started in 1997 but discontinued in 2000 due to lack of funding and an independent legal framework.

With the emerging challenges of HIV/AIDS and the introduction of Antiretroviral Therapy (ART), the Government through Ministry of Health (MoH) is committed to improving the quality of health care in both the private and public health facilities. There is therefore need to develop systems for monitoring and evaluating standards of services in health facilities.

In line with this Policy direction, the Medical Council of Zambia (MCZ) provides services and an institutional framework that directs its efforts towards the provision of quality health care through an effective monitoring of the medical practice and improvement of health facilities in both the public and private sector. As a consequence of this, and mindful of the need to scale up HIV/AIDS interventions in the country, the MCZ in collaboration and consultation with all the relevant stake-holders, has come up with an accreditation system as part of its inspectorate services.

The provision of antiretroviral therapy is an essential step in the continuum of care and support for persons living with HIV and AIDS. As it is important to bring this service as close to all Persons Living with HIV/AIDS (PLWHA) as possible, it is even more important to ensure that the best quality of care is provided according to national guidelines and standards. This assures uniformity of standardised care, generally improves quality of care, and facilitates the identification and tracking of drug interactions and the emergence of drug resistance. It minimises as much as possible provider induced resistance to antiretroviral Pharmaceutical/agents. In order to ensure the attainment of the above, all sites/facilities and or individuals who provide or wish to provide antiretroviral therapy shall be subject to an accreditation and certification process.

2.0 The Accreditation Procedure

All facilities providing or intending to provide ART services must make a formal request for accreditation. The accreditation procedure shall be as follows:

- a) A formal request from the site for accreditation is submitted to the MCZ by the site or from the MoH through the Provincial Health Office (PHO).
- b) Preliminary assessment:
 - Verification of registration of site by MCZ to provide health care in Zambia.
 - Verification of certification of health care providers by MCZ or General Nursing Council of Zambia (GNC).
- c) The ART Accreditation Team (appointed by the MCZ) is informed of the request.
- d) Site visit:
 - The site is informed of the impending assessment for accreditation including the date of the exercise as decided by the MCZ.
 - A multidisciplinary ART Accreditation Team visits the site and uses the site assessment tool for evaluation.
 - The ART Accreditation Team provides a feedback to the management before leaving the site.
 - A comprehensive site assessment report is submitted to the MCZ by the team within 10 working days.
- e) The site assessment report is presented to the ART Accreditation Expert Panel at MCZ for recommendations.
- f) A formal report on the outcome of the assessment with recommendations is sent to the site and copied to the MoH by MCZ within 8 weeks after the assessment is reported to the ART Accreditation Expert Panel at MCZ.
- g) Follow up for corrective actions for accreditation will depend on the decision by the ART Accreditation Expert Panel at MCZ.
- h) Corrective follow up action (within the time specified by the MCZ) shall be the responsibility of the site.
- i) Sites that do not appropriately address the corrective recommendations will not be accredited until the corrective measures are taken.
- j) Sites that attain recognition of “Good Standing” will be given a certificate.
- k) All accredited ART sites need to be re-accredited every 2 years (no less than 3 months before expiry of previous accreditation) or if necessary on a needs basis.
- l) All accredited institutions will be published in the Government Gazette annually.
- m) The government may facilitate access, by the accredited private sector to preferentially priced ARV drugs, where this is feasible.

3.0 Service Domains Evaluated to Assess Site Readiness

The following seven ART program areas or domains of services delivery shall be evaluated during a site assessment to assess site readiness:

- Domain 1: HIV Care and ART Team Leadership
- Domain 2: National Guidelines, Standard Operating Procedures and Quality Assurance for ART;
- Domain 3: Level of Health Care and Clinical Care Services;
- Domain 4: Laboratory Capacity
- Domain 5: Health Management Information System (HMIS), Monitoring and Evaluation;
- Domain 6: Human Resource and Continuous Professional Development;
- Domain 7: Pharmaceutical and Logistics Management Systems

3.1 Definitions of Terms used in the Assessment of Service Domains

Below are the definitions of some of the important terms used in domain 1:

- A site or health facility is defined as a health institution that provides basic health services including but not limited to out patient department, Medical, Surgical, Paediatric, Obstetric and Gynaecological services and basic laboratory services, and an adequate level of health staff clinically supervised by a medical practitioner.
- Level of supervision: All sites should be supervised by a Medical practitioner in accordance with the Medical and Allied Professions Act. MCZ regulations further stipulate that the MP must be on-site for at least one clinic day per week.
- Availability of medical practitioner: the Medical and Allied Professions Act stipulates that a health facility All sites should be supervised by a Medical practitioner
- On-site: this is when a medical practitioner is based at a site full time.
- Resource person: any personnel in clinical team that is able to provide special services outside the usual job description such as providing various forms of training (including on the job training), outreach, technical support, and other pertinent national duties.
- Focal Point Person duties: able to provide support supervision and coordination of various activities in HIV care and ART services especially in areas such as Clinical care, pharmacy and logistics, laboratory, Information systems, Quality Assurance, Adherence counselling and fostering community and coordinated linkages

Below are the definitions of some of the important terms used in domain 3:

- Formal referral system: this is a referral system with documented procedures for referrals, referral directory, appropriate referral forms and with or with out a referral coordinator.
- Coordinated linkages: this is were there is written or documented evidence that the site and the referral site have agree to support each other

Below are the definitions of some of the important terms used in domain 6:

- **Clinical team:** this is a team comprising all the necessary cadres certified and trained in HIV care and ART services. The following are examples of acceptable clinical teams for various levels of health care.

i) District Hospital Team

- Medical practitioner
- Medical Licentiate /Clinical Officer
- Nurse (General Nursing and counselling)
- Laboratory personnel, Pharmacy personnel
- Data management officer/record clerks

ii) Health Centre Team

- Rotating or part time medical officer
 - Medical Licentiate /Clinical Officer
 - Nurse (general nursing, counselling and dispensing)
 - Laboratory personnel
- **Trained provider:** A licensed health personnel with recognized professional certificates (certificate, diploma or degree) from an appropriate regulatory body, trained in an approved course for HIV Care and ART services provision.
 - **Certified HIV care and ART service provider:** A trained provider who has successfully completed MoH approved ART/Opportunistic infections (OI) in-service training programmes (short courses, on-the-job training, and updates), which is recognized by an appropriate regulatory body (MCZ or GNC). Medical Practitioners with evidence of pre-service training in HIV Care and ART services provision will be certified. Only certified practitioners will be allowed to prescribe ARVs.

3.2 Minimum Acceptable Standards for Accreditation of Sites

Comprehensive HIV care and antiretroviral therapy consists of the following:

3.2.1 HIV Care and ART Team Leadership

The proposed site must have:

- A medical practitioner to supervise (stationed at the site or accessible for consultation according to MCZ guidelines) the clinical team.
- A medical practitioner, medical licentiate, clinical officer or nurse as a focal person trained in ART.
- The focal person must have had an advanced or basic training in ART and management of opportunistic infections according to MOH guidelines recognised by MCZ and GNC.

The following areas are evaluated to determine capacity:

Domain 1.HIV Care and ART Team Leadership		
Domain Area	Capacity	Score
Supervision	Has no medical practitioner at site.	1
	Has medical practitioner available but not for ART services.	2
	Has health care services, but needs assistance with setting up HIV care/ART and training.	3
	Has an ART trained medical practitioner stationed at the site or accessible for consultation.	4
	Has medical practitioner who is spearheading ART services on site, and is a resource person	5
Focal Point Person	Has no focal point person at site	1
	Focal point person identified	2
	Focal point person orientated in ART service provision	3
	A medical practitioner, medical licentiate, clinical officer or nurse as a focal person trained in ART.	4
	Focal point person trained and is a resource person	5
Total Leadership Score		
Leadership Domain Score (Total Leadership Score/2)		

3.2.2 National Guidelines and Standard Operating Procedures and Quality Assurance Systems

The proposed site must use MoH national guidelines, protocols and standard operating procedures (See table below for recommended documents):

- For the provision of HIV counselling & testing
- For the management of OIs and other related conditions.
- For the provision of antiretroviral therapy
- For Quality Assurance (QA) systems covering clinical, laboratory, pharmacy services; and waste disposal and infection prevention

Components of a QA System

- QA committee and focal point person
- QA meetings' minutes
- QA tools (guidelines, wall charts, clinical checklists and procedure manuals)
- QA support supervisors
- QA supervision/evaluation reports

Recommended Documents

Category A documents (Mandatory)	Type
National HIV/AIDS TB and STI Policy	Policy
National Guidelines on Management and Care of Adult HIV/AIDS	Guidelines
National Guidelines on Management and Care of Paediatric HIV/AIDS	Guidelines
National Guidelines for HIV Counselling and testing	Guidelines
MCZ Guidelines on ethical problems surrounding HIV and AIDS	Guidelines
MCZ Accreditation Guidelines	Guidelines
Nutrition guidelines for management of HIV/AIDS	Guidelines
Category B documents (Desirable)	
PMTCT Guidelines	Guidelines
Integrated Technical Guidelines (ITG)	Guidelines
Infection prevention Guidelines	Guidelines
HMIS/LMIS procedures manual	Guidelines
Pharmacy	Standard Operating Procedures
Laboratory	Standard Operating Procedures
Reference Manuals (ART, OIs, PMTCT, CT, HMIS)	Manuals

The following areas are evaluated to determine capacity:

Domain 2. National Guidelines and Standard Operating Procedures and QA systems		
Domain Area	Capacity	Score
National Guidelines and SOPs	Has no documents in any of the categories	1
	Has only documents in category (B)	2
	Incomplete documents in category (A)	3
	Have all the category (A) documents	4
	Have all documents in both category (A) and (B)	5
Quality Assurance Systems	Has no QA system	1
	Has committee for QA	2
	Has committee for QA an some tools	3
	Has committee and supervisors for QA	4
	Has all components of a QA systems	5
Total National Guidelines/SOP/QA Score		
National Guidelines/SOP/QA Domain Score (Total National Guidelines/SOP/QA Score/2)		

3.2.3 Level of Health Care and Clinical Services

The above services must be provided on-site in adequate clinic space or be available by coordinated linkages through formal referral systems. Some services are desirable and not mandatory. The proposed site must have the capacity for:

On-site Services

The following services must be available on site:

- Clinical monitoring by trained health care workers.
- Basic laboratory services (advanced laboratory monitoring e.g. CD4 count must be accessible but may not be available on site)
- Basic counselling (pre-ART, adherence and follow up) and patient education

Coordinated linkages

Where the service is not available on-site the proposed site must have evidence of coordinated external linkages (through formal referral system) to:

- Counseling and Testing (CT).
- Prevention of Mother to Child Transmission of HIV (PMTCT).
- Prophylaxis and management of OIs.
- Management of Tuberculosis (TB).
- Management of Sexually Transmitted Infections (STIs).
- Nutritional counseling, Pharmacy outlets (where applicable).
- Access to assistance with concrete family planning, and risk reduction.
- Access to assistance with nutritional support and shelter, where possible.
- Networking of the site/facility with the community (support groups, home-based care and psychosocial support) through a formal referral system.
- Other clinical (higher) services.

Comprehensive Services

The proposed site must have comprehensive services. Some services (Category A) are mandatory for any facility; others are desirable (Category B) services. See table below:

Category A Services (Mandatory)
Basic Laboratory Services
Counselling and Testing
Management of Sexually Transmitted Infections (STI)
Management of Tuberculosis (TB)
Pharmacy
Prevention of Mother To Child Transmission of HIV (PMTCT)
Prophylaxis and management of Opportunistic infections (OI)
Psychosocial support
Nutritional counselling
Risk reduction
Category B Services (Desirable)
Family planning
Home based care
Nutritional support
Shelter

Allocation of adequate space for ART

The proposed site must allocate adequate clinic space to ensure privacy for the clients as well as care to limit cross infections.

The following areas are evaluated to determine capacity:

Domain 3. Level of Health Care and Clinical Services		
Domain Area	Capacity	Score
Comprehensive services	Has no services in any of the categories	1
	Has only services in category B	2
	Incomplete category A services	3
	Have all the category A services	4
	Have all category A and more than 3 in category B	5
Physical space	Has no space for ART and no plan for location or designation of space	1
	Extremely limited space overall but limited plan for expansion	2
	Has no designated space yet for ART but has a plan.	3
	Has some space for ART and confidential space but over all space is limited	4
	Has defined and adequate space for ART including access to confidential space.	5
Total Level of Health Care and Clinical Services Score		
Level of Health Care and Clinical Services Domain Score (Total Level of Health Care and Clinical Services Score /2)		

3.2.4 Laboratory Capacity

The proposed site must have:

- Capacity to do the basic recommended tests (HIV test, Hb, WBC count and differential, serum glucose and pregnancy tests)

Basic Recommended Test	Category
HIV test, Hb, serum glucose and pregnancy tests	A
WBC count and differential	B

- Capacity to offer or have referral access to a high level facility offering desirable tests including CD4, LFT (ALT), Creatinine, FBC; as required by MoH/NAC protocols.
- Quality control measures in place for laboratory tests and equipment.

The following areas are evaluated to determine capacity:

Domain 4. Laboratory Capacity		
Domain Area	Capacity	Score
Staffing levels	Has no laboratory staff	1
	Has laboratory staff not qualified to do basic recommended tests	2
	Has minimum of one ART trained laboratory technician staff	3
	Has minimum of one laboratory technician not trained in ART	4
	Laboratory Technologist or Biomedical scientific officer to offer desirable and optional tests	5
Capacity to do investigations	Has no access to required labs as defined in national protocols.	1
	Has limited access to required labs as defined in national protocols.	2
	Has access to required category A basic recommended tests	3
	Has access to required category A and B basic recommended laboratory tests	4
	Has full spectrum of tests as required by site ART protocol including access to CD4 count and imaging capacity	5
Quality control	Has no laboratory access	1
	Has laboratory access but no quality control	2
	Laboratory able to provide evidence of internal Quality Control (report or records) for HIV and Hb	3
	Laboratory able to provide evidence of internal Quality Control (report or records) for all the basic recommended tests	4
	Laboratory able to provide evidence of internal and external quality control	5
Total Laboratory Capacity Score		
Laboratory Capacity Domain Score (Total Laboratory Capacity Score /3)		

3.2.5 Health Management Information System (HMIS) and Monitoring & Evaluation

The proposed site must have:

- A reliable data collection system for maintaining patient’s medical records (including Patient tracking system and programme monitoring & evaluation systems).
- Networking of the site/facility with other facilities through regular meetings and bulletins.

The following areas are evaluated to determine capacity:

Domain 5: Health Management Information System and Monitoring & Evaluation		
Domain Area	Capacity	Score
HMIS Staffing	Has no data staff/records clerk	1
	Has data management staff/records clerk but not computer literate	2
	Has minimum of one data management personnel/records clerk who is computer literate but not trained in ART HMIS	3
	Has minimum of one data management personnel/records clerk who is computer literate and trained in ART HMIS	4
	Has ART HMIS trained data management personnel who are resource persons	5
ART Monitoring and Evaluation	Has no components of the ART HMIS system	1
	Has some components of the ART HMIS System	2
	Has all components of ART HMIS system (Procedures manuals, data collection tools and/or computers) and but no ART HMIS trained data management staff	3
	Has ART HMIS trained data management staff and all ART HMIS system components for patient monitoring.	4
	Has facility level M&E processes which involves patient monitoring and routine use of this information for decision making in quality improvement	5
Total HMIS and M&E Score:		
HMIS and M&E Domain Score (Total HMIS and M&E Score /2):		

3.2.6 Human Resource Capacity and Experience

The proposed site must have:

- Adequate trained staff with experience in;
 - Clinical care
 - Pre-ART and follow up Adherence counselling and/or Psychosocial counselling
- Service providers who have undergone training according to MoH National training guidelines to provide antiretroviral therapy.
- Clearly defined job responsibilities and a plan for on-going training Continued Professional Development (CPD) in HIV care and ART for staff.

The following areas are evaluated to determine capacity:

Domain 6: Human Resource and Continuous Professional Development		
Domain Area	Capacity	Score
Staffing Levels	No ART clinical team	1
	Has an incomplete ART clinical team	2
	Has at least a rotating or part time Medical Officer(MO), Medical Licentiate (ML)/Clinical Officer (CO), Nurse (general nursing and counselling) as members of the clinical team but not trained	3
	Has at least a rotating or part time MO, ML/CO, Nurse (general nursing and counselling) as ART trained members of the clinical team	4
	Complete, on-site, ART trained clinical team with resource persons on the team	5
Certified Staff	No clinical team members are certified (by an appropriate regulatory body) to provide ART services	1
	Has only one cadre certified in the ART clinical team	2
	Has one cadre not certified in the ART clinical team	3
	Has at least one rotating or part time MO, one ML/CO, one Nurse, one Pharmacy and one Laboratory personnel certified (by an appropriate regulatory body) to provide HIV care and ART services	4
	All Clinical team members are certified to provide HIV care and ART services and are resource persons	5
Continued	Has no CPD plans of any kind	1

Professional Development	Has CPD plan development in progress	2
	Has CPD plan but does not address HIV/AIDS and ART	3
	Has CPD plan which addresses HIV/AIDS and ART	4
	Has evidence of implementing CPD plan which addresses HIV/AIDS and ART	5
Total Human Resource and CPD Score		
Human Resource and CPD Domain Score (Total Human Resource and CPD Score/3):		

3.2.7 Pharmaceutical and Logistics Management System

The proposed site must have:

- Secure and appropriate storage space for commodities (Pharmaceutical, reagents, medical supplies and non-health products-stationary, food supplements etc).
- The standard national logistic management information system (LMIS) for HIV/AIDS commodities including antiretroviral drugs.
- The standard national procedures for forecasting/calculating re-supply orders, routine stock status reporting, dispensing and ordering including emergency supplies.
- Personnel trained in the management of HIV/AIDS commodities (laboratory and pharmacy) including ARVs.

The following areas are evaluated to determine capacity:

Domain 7: Pharmaceutical and Logistics Management Systems (LMS)		
Domain Area	Capacity	Score
Staffing Levels	Has no pharmacy personnel (Pharmacists or Pharmacy Technologist)	1
	Has minimum of one pharmacy personnel not trained in LMS, LMIS, ART and Pharmaceutical management system.	2
	Has minimum of one pharmacy personnel trained in LMS and LMIS but not ART	3
	Has minimum of one pharmacy personnel trained in LMS, LMIS and ART	4
	Has computer literate pharmacy personnel trained in LMS, LMIS and ART and who are resource persons	5
Logistics Management Information System	Has no established procedure for inventory management of drugs.	1
	Has limited inventory management procedures for other essential drugs and no inventory management procedures for ARVs	2
	Has established inventory Management procedures for other essential drugs but lacks all the ART LMIS system components	3
	Has established inventory management procedures for other essential drugs and have all the LMIS system components	4
	Has all Drug inventory management systems and a minimum of one ART trained pharmacist who is a resource person	5
Total Pharmaceutical and Logistics Management Systems Score		
Pharmaceutical and Logistics Management Systems Domain Score (Total Pharmaceutical and Logistics Management Systems Score/2):		

4.0 Determination of Stages for Site Readiness

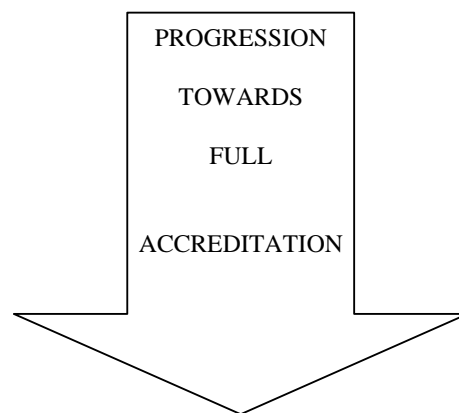
The qualitative tool presents a general assessment without emphasizing the importance of one domain over the other. The evaluation identifies steps needed to advance a potential antiretroviral therapy site. Each area should be rated based on a review of the site and interviews with key staff. It is required that a site attains at least a score of “4” in all areas in order to be accredited. The capacities available within the domains and the overall score determine which of the following five different stages the site falls into:

- Mobilization (Stage 1)
- Service delivery planning (Stage 2)
- Preparation (Stage 3)
- Site Activation/Continuation Stage (Stage 4)
- Centre of Good Standing (Stage 5)

An overall score that places a site at Stage Four or Five indicates the site has the capacity to provide ART, and a score that places a site at Stage One indicates that the site must seek technical assistance for progression. Below is the table for overall score and determination of staging:

Domain		Domain Score	Lowest Area Score in domain
1	HIV Care and ART Team Leadership		
2	National Guidelines, Standard Operating Procedures and Quality Assurance for ART		
3	Level of Health Care and Clinical Services		
4	Laboratory Capacity		
5	HMIS, Monitoring & Evaluation Capacity		
6	Human Resource and Continuous Professional Development		
7	Pharmaceutical and Logistics Management Systems		
	Overall Program Total		
	Stage		

Key to Scoring Range Stage	Stage	
7-13	1	Mobilization
14-20	2	Service delivery planning
21-27	3	Preparation
28-34	4	Activation/Continuation
35	5	Centre of Good Standing



Each stage is described below with specific activities and recommendations that will move an organization closer to Stage 5.

4.1 Mobilization (Stage 1)

Sites at this stage need to undertake the following actions:

4.1.1 HIV Care and ART Team Leadership

- Identify or recruit a Medical practitioner and implement training to develop a vision and will to embark on HIV care and ART service provision.
- Create links with other sites already providing ARV treatment, if possible, for local technical assistance and learning about successful models.
- Define possible models of care and identify space requirements.

4.1.2 National Guidelines and Standard Operating Procedures and QA Systems

- Begin to identify and adopt National Guidelines for basic HIV care and OI prophylaxis and treatment.
- Access assistance in developing indicators and appropriate system for M&E of HIV care, which can be expanded in the future for the ART services.
- Seek assistance in development or expansion of logistics QA

4.1.3 Level of Health Care and Clinical Services

- Identify critical areas that need immediate expansion to reach the next level (i.e. CT, OI treatment, etc.).
- Coordinate programs with referral system to ensure follow-up and continuum of care.

4.1.4 Laboratory Capacity

- Seek assistance in developing reliable access to lab services, whether on-site or referral, training, supplies, and expansion, as required by the national minimum standards.

4.1.5 HMIS, Monitoring & Evaluation Capacity

- Seek technical assistance improvement in HMIS system including, medical records, and charting.

4.1.6 Human Resource and Continuous Professional Development

- Identify mechanisms to recruit new staff or change models to reflect personnel types that are available.
- Expand and/or train staff resources in one or more areas to meet at least minimum essential staff for prescribing, follow-up, and adherence support.

4.1.7 Pharmaceutical and Logistics Management Systems

- Put in place procedures for supply chain management and address identified gaps or areas for improvement including training, systems, and pharmacy staff.
- Secure a regular supply of essential Pharmaceutical for HIV care including OI management and prevention.

4.2 Service Delivery Planning (Stage 2)

Sites at this stage need to undertake the following actions:

4.2.1 HIV Care and ART Team Leadership

- Seek assistance with design of an appropriate service delivery system, including defining vision and goals, management plans, identification of space, definition of model, staffing plan, and site spectrum of care.
- Develop linkages with other sites already providing ART, if possible.

4.2.2 National Guidelines and Standard Operating Procedures and QA Systems

- Adopt national guidelines for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, treatment interruption, and treatment failure.
- Seek assistance in development or expansion of QA for monitoring ART and other product availability.

4.2.3 Level of Health Care and Clinical Services

- Begin to identify and adopt standard operational procedures for HIV care and ARV use.

- Coordinate linkages with a formal referral system to ensure follow-up and continuum of care.
- Identify critical areas needing immediate expansion to reach the next level (i.e., CT, OIs treatment, etc.).

4.2.4 Laboratory Capacity

- Seek assistance in maintaining reliable access to lab services, whether on-site or referral, training, supplies, and expansion, as required by national protocols.

4.2.5 HMIS, Monitoring & Evaluation Capacity

- Seek assistance in developing indicators and appropriate system for M&E of HIV care and ART services that reflects the site's resources and capacity.

4.2.6 Human Resource and Continuous Professional Development.

- Expand and train staff resources in one or more areas to meet at least minimum essential staff for prescribing, follow-up, and adherence.

4.2.7 Pharmaceutical and Logistics Management Systems

- Obtain assistance with improving procedures for supply chain management and addressing identified gaps or areas for improvement, including training, systems, and pharmacy staff.
- Seek assistance in securing essential Pharmaceutical for HIV care including OIs management and prevention.

4.3 Preparation (Stage 3)

Sites at this stage need to undertake the following actions:

4.3.1 HIV Care and ART Team Leadership

- Better define goals and vision and more incorporated into day-to-day activities and future plans.
- Seek assistance with design, including definition of model, staffing plan, and site continuum of care (comprehensive services).

4.3.2 National Guidelines and Standard Operating Procedures and QA Systems

- Identify and adopt national guidelines for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, treatment interruption, and treatment failure.
- Seek assistance in developing program indicators and appropriate system for M&E of HIV care including ARV treatment that reflects the site's resources and capacity.

4.3.3 Level of Health Care and Clinical Services

- Seek assistance with identification of space.
- Expand scope of services to meet requirements as defined by chosen model of care, and linkages to other organizations to meet other needs.

4.3.4 Laboratory Capacity

- Seek assistance in maintaining reliable access to lab services, training and supplies, and expansion, as required by adopted national guidelines.

4.3.5 HMIS, Monitoring & Evaluation Capacity

- Seek technical assistance in development or improvement in HMIS system including medical records, and charting.

4.3.6 Human Resource and Continuous Professional Development

- Expand and/or train staff resources in one or more areas to meet at least minimum essential staff for prescribing, follow-up, and adherence.

4.3.7 Pharmaceutical and Logistics Management Systems

- Seek assistance with improving procedures for supply chain management and addressing identified gaps or areas for improvement.
- Seek assistance in ensuring access to other essential Pharmaceutical for HIV care.
- Seek assistance in development or expansion of QA for monitoring ART and other product availability.

4.4 Activation/Continuation (Stage 4)

Sites at this stage need to undertake the following actions

4.4.1 HIV Care and ART Team Leadership

- Better define goals and vision and be more incorporated into day-to-day activities and future plans.
- Seek assistance in estimating needs, problem solving, and planning.
- Seek assistance in long term planning.

4.4.2 National Guidelines and Standard Operating Procedures and QA Systems

- Seek assistance in development or formalization of written standard operating procedures for eligibility, regimens, initiation, clinical and lab monitoring and follow up, adherence, management of side effects, treatment interruption, and treatment failure.

- Seek assistance in establishing appropriate operational procedures that reflect site resources and capacity.

4.4.3 Level of Health Care and Clinical Services

- May need a formal plan for initiation or expansion of ARVs at the site.
- Seek assistance in identifying confidential space or other areas, as needed, to reflect increased services.
- Seek assistance in expanding scope or capacity of limited number of services through additional resources, hiring or cross training, or creation of linkages with other organizations to fill gaps.

4.4.4 Laboratory Capacity

- Seek assistance in maintaining reliable access to lab services, training, and supplies.
- Seek assistance in identifying additional monitoring as determined by protocol (especially CD4 cell counts).

4.4.5 HMIS, Monitoring & Evaluation Capacity

- Seek assistance in developing program indicators and appropriate system for M&E that reflect the site's resources and capacity.

4.4.6 Human Resource and Continuous Professional Development

- Further training for additional support staff, plans for additional hiring, or assistance with linkages to other organizations to supply other needed services that may be required.

4.4.7 Pharmaceutical and Logistics Management Systems

- Seek assistance in supply chain logistics to address identified gaps.
- Seek assistance in regular provision of ARVs and additional essential Pharmaceutical for HIV care including OI prevention and treatment.
- Seek assistance in development or expansion of QA for monitoring ARV and other product availability.

4.5 Centre of Good Standing (Stage 5)

These sites are already operational and working well. They may also serve as training sites for other organizations in other stages, may serve as models, or may provide technical assistance for replication at other sites locally or elsewhere (scale out). Sites at this stage will be maintaining or expanding capacity, on-going education (patients and providers), training of site and staff to serve as resources for other sites and disseminate lessons learned, and work to identify additional resources for expansion. Some ART sites will not achieve this stage, particularly in more remote areas. However, stage 5 sites too may require assistance in maintaining or expanding current efforts of scale-up, efforts to evaluate program and protocols through continuous quality improvement.

Annex i: MCZ Inspection Tools.

Section 1: Inspection Tools for Health Facilities

Particulars of the Health Institution

- 1. Name of facility.....
- 2. Type of facility.....
- 3. Owner of the facility.....
- 4. Physical address.....
- 5. (a) Telephone No.....
(b) Fax No.....
(c) Email.....

6. Are premises approved by Local/Provincial Planning Authority?

YES	NO

7. Is the location of the facility in relation to other business premises acceptable?

YES	NO

Outpatient/Casualty Department

Reception/Waiting Area

Are the following items available?	YES	NO
a) Sufficient sitting facilities?		
b) Good maintenance of the sitting facilities?		
c) Patient Register?		
d) Patient Cards?		
e) Filing Facility?		
f) Good record keeping?		
g) Adequate ventilation?		
h) Adequate lighting?		
i) A waste bin with tight fitting lid?		
j) Cleanliness in the room?		
k) Is structure in a good state of repair?		
Comments:		

Examination Room

Are the following items available?	YES	NO
a) A couch?		
b) Couch linen?		
c) A desk with adequate chairs?		
d) Adequate privacy?		
e) Adequate ventilation?		
f) Adequate lighting?		
g) A foot stool?		
h) A hand washing basin with adequate running water?		
i) Soap disinfectant?		

j) Disposable paper wipes or hot air driers?		
k) Waste bin with a tight fitting lid?		
l) Cleanliness in the room?		
m) A sink?		
n) Is structure in a good state of repair?		
Comments:		

Treatment Room

Emergency Tray

Are the following items available on the emergency tray?	YES	NO
a) Hydrocortisone?		
b) Adrenaline?		
c) Diazepam?		
d) Aminophyline?		
e) Phenobarbitone?		
f) Atropine?		
g) Potassium Chloride?		
h) Calcium gluconate?		
i) 50% Dextrose?		
j) I. V. Fluids?		
Comments:		

Emergency Equipment

Are the following items available?	YES	NO
a) A full oxygen cylinder with working gauge?		
b) Suction machine?		
c) Ambu bag?		
d) Cannulae?		
e) Giving sets?		
f) Endo Tracheal Tube?		
g) Laryngoscope?		
h) Airway?		
i) ECG?		
j) Syringes?		
k) Needles?		
l) Spatula?		
Comments:		

Out Patient/Casualty Equipment

Are the following items available and in good working condition?	YES	NO
a) Adult weighing scale?		
b) Infant weighing scale?		
c) Blood pressure machine?		
d) Stethoscope?		
e) Clinical thermometer?		
f) Auriscope?		
g) Ophthalmoscope?		
h) Laryngoscope?		
i) Foetal scope?		
j) Sterilizer?		
k) Refrigerator?		
l) Patella hammer?		
m) Wheel chair?		
n) Stretcher?		
o) Fire extinguisher?		

p) Couch?		
Comments:		
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Outpatient Dispensary

Are the following items available?	YES	NO
a) A Dispensing room?		
b) Is there a counselling room?		
c) Qualified staff dealing with dispensing?		
d) Adequate shelves for storing drugs?		
e) A lockable cupboard for storage of restricted drugs?		
f) A register for control of dangerous drugs?		
g) Adequate ventilation?		
h) Adequate lighting?		
i) Security?		
j) A dispensing impervious bench?		
k) Sink with access to both hot and cold water supply?		
l) A weighing scale?		
m) A refrigerator?		
n) Reference material		
o) Graduated glass measures		
p) Suitable range of labels for labeling reparked medicines?		
q) Suitable means of counting tablets?		
r) A container of distilled water for reconstitution?		
s) A good dispensing practice?		
t) A stock surveillance system?		
u) Procedure for the disposal of drugs?		
v) Fire extinguisher?		
w) Good repair of the structure?		

x) Expired drugs?		
Comments:		
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Toilets

Are the following items available?	YES	NO
a) Separate toilets for both sexes?		
b) Adequate female toilets?		
c) Adequate male toilet with a urinal?		
d) Toilets in good working condition?		
e) Toilets kept clean?		
f) Are the toilets: - i. Water borne type? ii. Dry closets type? (VIP) iii. Are they labelled?		
g) Is there a sluice room in the OPD/Casualty Department?		
h) Adequate lighting?		
i) Adequate ventilation?		
j) Good state of repair of the structure?		
k) Hand wash basins with adequate running water?		
Comments:		
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Provision of Disaster/Epidemic Care Services to the Patients

Are the following items available?	YES	NO
a) Does the hospital have a disaster/epidemic preparedness plan?		
b) Does the hospital have a disaster/epidemic preparedness committee?		
c) Do the staff receives appropriate education on their role and responsibility during an emergency e.g. bus accident or cholera?		
d) Are the initial assessment, medical history and physical examination completed in a timely manner to meet patient needs?		
e) Are the services available in a timely manner to meet patient needs?		
f) Are there ambulances?		
g) Is there intra-facility communication?		
Comments:		

Observation of Case Management of Patients in Out-Patient/Casualty Department

Are the following issues addressed during case management?	YES	NO
a) Is the taking of history and physical examination adequate and comprehensive?		
b) Is the admission assessment conducted by physician/clinical officer?		
c) Is admission assessment performed in a manner that respects privacy?		
d) Has a working diagnosis been made?		
e) Are relevant investigations ordered?		
f) Is patient assessment documented in the patient record?		
g) How long did the assessment of the patient take?		
Comments:		
.....		
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Observation of Nursing Procedures

Injection Procedures	YES	NO
a) Has the nurse explained the procedure to the patient?		
b) Has she made the patient comfortable?		
c) Is there adequate privacy?		
d) Is all the necessary equipment present?		
e) Is the prescription counter checked for correct drug?		
f) Is the correct amount of drug drawn?		
g) Is the correct injection site chosen?		
h) Is the injection site properly cleaned?		
i) Is the injection administered correctly?		
j) Are instruments kept sterile throughout the procedure?		
k) Is the nurses' attitude towards patient positive?		
l) Are the side effects of medicine explained?		
m) Has the nurse checked for expiry date of the drug?		
n) Has the nurse given Health Education to the patient?		
o) Is there disposal of sharps?		
<p>Comments:</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>		

Infection Control in Patient Care Areas (e.g. Wards, Laboratory, Radiology, Pharmacy and OPD)

Are the infection control procedures in place?	YES	NO
a) Is the place of operation kept clean?		
b) Is the procedure explained to the patient?		
c) Are fresh wounds protected from contamination?		
d) Are all necessary instruments present?		
e) Are instruments sterile?		
f) Is dressing and bandage correctly applied?		
g) Are instruments cleaned after use?		
h) Are dirty dressings properly disposed of?		
i) Is patient made comfortable?		
j) Is health education given to the patients?		
k) Is equipment that is reused appropriately cleaned, sterilized or disinfected between uses?		
l) Does staff monitor sterilizer equipment (e.g. steam under pressure) for time, temperature and pressure to achieve sterilization?		
m) Is the solution for disinfecting instruments in correct amount and concentration?		
n) Are the instruments sterilised for the proper duration?		
o) Is there availability and use of supplies such as gloves, soap, masks and disinfectant?		
p) Is laundry and linen management carried out properly?		
q) Is handling and disposal of “sharps” and needles done properly?		
r) Is the infection control process documented in written policies and procedures?		
s) Is there an Infection control Committee?		
t) Is there a system that ensures effective infection control?		
u) Is there proper disposal of blood wastes?		
Comments:		

State of the Building and General Observations in all Areas of the Hospital

Are the following in good condition (cleanliness and good state of repair)?	YES	NO
a) External walls?		
b) Internal walls?		
c) Floors?		
d) Ceiling?		
e) Roof?		
f) Doors?		
g) Windows?		
Are the following items available?		
h) Artificial lighting?		
i) Natural lighting?		
j) Artificial ventilation?		
k) Natural ventilation?		
l) A copy of relevant Fire Safety Laws and Regulation?		
m) Artificial lighting?		
n) Natural lighting?		
Comments:		
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Laboratory Services

Are the following items available?	YES	NO
a) Management of the laboratory services by a qualified and licensed individual?		
b) Critical and essential laboratory equipment?		
c) Essential laboratory reagents and supplies at all times?		
d) Use of standard operating procedures?		
e) Evidence of quality assurance and control procedures?		
f) Is equipment used in the laboratory appropriate for the level of laboratory and tests performed?		
g) Is infection control measures practised in the laboratory?		
h) Is protective clothing available to staff?		
i) Is there proper documentation and record keeping?		
j) Is there a system that ensures a timely release of laboratory results to appropriate clinical staff?		
k) Is there a Laboratory Safety Committee?		
l) Is there infection control and safe disposal of water?		
m) Is there a Laboratory Register?		
n) Is there good record keeping?		
o) Adequate ventilation?		
p) Adequate lighting?		
q) A waste bin with a tight fitting lid?		
r) Cleanliness of the room?		
s) Hand washing basin with adequate running water?		
t) Soap/disinfectant?		
u) Sharp boxes?		
v) Adequate hygienic hand drying facilities?		
w) Good repair of the structure?		

Patient Satisfaction

Are the following issues addressed?	YES	NO
a) Is there a written document that addresses patient rights that reflect National Policy?		
b) Are complaint handling and resolution addressed?		
c) Are confidentiality and privacy addressed?		
d) Is written information consent for surgical procedures obtained from a patient or a close relative?		
e) Does the hospital distribute patient rights documents to patients and staff?		
f) Are patients also informed verbally about their rights and responsibilities?		
g) Does hospital leadership evaluate patient satisfaction?		
<p>Comments:</p> <p>.....</p> <p>.....</p>		
<p><u>Fire Services</u></p>		
Are the following items available?	YES	NO
a) Clearly marked location of fire extinguishers in all patient areas?		
b) Sprinkler system?		
c) Safe storage and handling of potentially inflammable materials?		
d) Is the staff trained and knowledgeable in the event of a fire outbreak?		
e) Do the staff members participate in a fire drill at least twice a year?		
<p>Comments:</p> <p>.....</p> <p>.....</p>		

Section 2: Inspection Tools for Accreditation of ART Sites

Domain 1.HIV Care and ART Team Leadership		
Domain Area	Capacity	Score
Supervision	Has no medical practitioner at site.	1
	Has medical practitioner available but not for ART services.	2
	Has health care services, but needs assistance with setting up HIV care/ART and training.	3
	Has an ART trained medical practitioner stationed at the site or accessible for consultation.	4
	Has medical practitioner who is spearheading ART services on site, and is a resource person	5
Focal Point Person	Has no focal point person at site	1
	Focal point person identified	2
	Focal point person orientated in ART service provision	3
	A medical practitioner, medical licentiate, clinical officer or nurse as a focal person trained in ART.	4
	Focal point person trained and is a resource person	5
Total Leadership Score		
Leadership Domain Score (Total Leadership Score/2)		

Domain 2. National Guidelines and Standard Operating Procedures and QA systems		
Domain Area	Capacity	Score
National Guidelines and SOPs	Has no documents in any of the categories	1
	Has only documents in category (B)	2
	Incomplete documents in category (A)	3
	Have all the category (A) documents	4
	Have all documents in both category (A) and (B)	5
Quality Assurance	Has no QA system	1

Systems	Has committee for QA	2
	Has committee for QA an some tools	3
	Has committee and supervisors for QA	4
	Has all components of a QA systems	5
Total National Guidelines/SOP/QA Score		
National Guidelines/SOP/QA Domain Score (Total National Guidelines/SOP/QA Score/2)		

Domain 3. Level of Health Care and Clinical Services		
Domain Area	Capacity	Score
Comprehensive services	Has no services in any of the categories	1
	Has only services in category B	2
	Incomplete category A services	3
	Have all the category A services	4
	Have all category A and more than 3 in category B	5
Physical space	Has no space for ART and no plan for location or designation of space	1
	Extremely limited space overall but limited plan for expansion	2
	Has no designated space yet for ART but has a plan.	3
	Has some space for ART and confidential space but over all space is limited	4
	Has defined and adequate space for ART including access to confidential space.	5
Total Level of Health Care and Clinical Services Score		
Level of Health Care and Clinical Services Domain Score (Total Level of Health Care and Clinical Services Score /2)		

Domain 4. Laboratory Capacity		
Domain Area	Capacity	Score
Staffing levels	Has no laboratory staff	1
	Has laboratory staff not qualified to do basic recommended tests	2
	Has minimum of one ART trained laboratory technician staff	3
	Has minimum of one laboratory technician not trained in ART	4
	Laboratory Technologist or Biomedical scientific officer to offer desirable and optional tests	5
Capacity to do investigations	Has no access to required labs as defined in national protocols.	1
	Has limited access to required labs as defined in national protocols.	2
	Has access to required category A basic recommended tests	3
	Has access to required category A and B basic recommended laboratory tests	4
	Has full spectrum of tests as required by site ART protocol including access to CD4 count and imaging capacity	5
Quality control	Has no laboratory access	1
	Has laboratory access but no quality control	2
	Laboratory able to provide evidence of internal Quality Control (report or records) for HIV and Hb	3
	Laboratory able to provide evidence of internal Quality Control (report or records) for all the basic recommended tests	4
	Laboratory able to provide evidence of internal and external quality control	5
Total Laboratory Capacity Score		
Laboratory Capacity Domain Score (Total Laboratory Capacity Score /3)		

Domain 5: Health Management Information System and Monitoring & Evaluation		
Domain Area	Capacity	Score
HMIS Staffing	Has no data staff/records clerk	1
	Has data management staff/records clerk but not computer literate	2
	Has minimum of one data management personnel/records clerk who is computer literate but not trained in ART HMIS	3
	Has minimum of one data management personnel/records clerk who is computer literate and trained in ART HMIS	4
	Has ART HMIS trained data management personnel who are resource persons	5
ART Monitoring and Evaluation	Has no components of the ART HMIS system	1
	Has some components of the ART HMIS System	2
	Has all components of ART HMIS system (Procedures manuals, data collection tools and/or computers) and but no ART HMIS trained data management staff	3
	Has ART HMIS trained data management staff and all ART HMIS system components for patient monitoring.	4
	Has facility level M&E processes which involves patient monitoring and routine use of this information for decision making in quality improvement	5
Total HMIS and M&E Score:		
HMIS and M&E Domain Score (Total HMIS and M&E Score /2):		

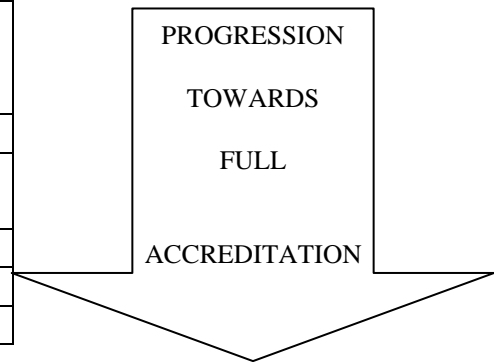
Domain 6: Human Resource and Continuous Professional Development		
Domain Area	Capacity	Score
Staffing Levels	No ART clinical team	1
	Has an incomplete ART clinical team	2
	Has at least a rotating or part time Medical Officer (MO), Medical Licentiate (ML)/Clinical Officer (CO), Nurse (general nursing and counselling) as members of the clinical team but not trained	3
	Has at least a rotating or part time MO, ML/CO, Nurse (general nursing and counselling) as ART trained members of the clinical team	4
	Complete, on-site, ART trained clinical team with resource persons on the team	5
Certified Staff	No clinical team members are certified (by an appropriate regulatory body) to provide ART services	1
	Has only one cadre certified in the ART clinical team	2
	Has one cadre not certified in the ART clinical team	3
	Has at least a rotating/part time MO, ML/CO, Nurse, Pharmacy and Laboratory personnel certified to provide HIV care and ART services	4
	All Clinical team members are certified to provide HIV care and ART services and are resource persons	5
Continued Professional Development	Has no CPD plans of any kind	1
	Has CPD plan development in progress	2
	Has CPD plan but does not address HIV/AIDS and ART	3
	Has CPD plan which addresses HIV/AIDS and ART	4
	Has evidence of implementing CPD plan which addresses HIV/AIDS and ART	5
Total Human Resource and CPD Score		
Human Resource and CPD Domain Score (Total Human Resource and CPD Score/3):		

Domain 7: Pharmaceutical and Logistics Management Systems (LMS)		
Domain Area	Capacity	Score
Staffing Levels	Has no pharmacy personnel (Pharmacists or Pharmacy Technologist)	1
	Has minimum of one pharmacy personnel not trained in LMS, LMIS, ART and Pharmaceutical management system.	2
	Has minimum of one pharmacy personnel trained in LMS and LMIS but not ART	3
	Has minimum of one pharmacy personnel trained in LMS, LMIS and ART	4
	Has computer literate pharmacy personnel trained in LMS, LMIS and ART and who are resource persons	5
Logistics Management Information System	Has no established procedure for inventory management of drugs.	1
	Has limited inventory management procedures for other essential drugs and no inventory management procedures for ARVs	2
	Has established inventory Management procedures for other essential drugs but lacks all the ART LMIS system components	3
	Has established inventory management procedures for other essential drugs and have all the LMIS system components	4
	Has all Drug inventory management systems and a minimum of one ART trained pharmacist who is a resource person	5
Total Pharmaceutical and Logistics Management Systems Score		
Pharmaceutical and Logistics Management Systems Domain Score (Total Pharmaceutical and Logistics Management Systems Score/2):		

Determining a Site's Program Readiness Stage

Domain		Domain Score	Lowest Area Score in domain
1	HIV Care and ART Team Leadership		
2	National Guidelines, Standard Operating Procedures and Quality Assurance for ART		
3	Level of Health Care and Clinical Services		
4	Laboratory Capacity		
5	HMIS, Monitoring & Evaluation Capacity		
6	Human Resource and Continuous Professional Development		
7	Drugs and Logistics Management Systems		
	Overall Program Total		
	Stage		

Key to Scoring Range Stage	Stage	
7-13	1	Mobilization
14-20	2	Service Delivery Planning
21-27	3	Preparation
28-34	4	Activation/Continuation
35	5	Centre of Good Standing



Annex ii: Implementation Plan

Guiding Principles

This plan will focus on the following interventions:

- Putting in place an efficient quality assurance system.
- Ensuring use of routine health information and patient-level data analyses.
- Accrediting public and private health care institutions
- Certifying health care providers providing ART.
- Ensuring availability and quality of Pharmaceutical, nutrition supplements, reagents and other medical supplies.
- Ensuring rational use of ART medicines and other medical supplies.
- Putting in place national ARV drug resistance surveillance and pharmacovigilance systems.
- The program will observe and promote equity in accessing of ART services. Every client will be offered a package of essential health services on the basis of nothing else, but need.
- The program will recognize the synergy inherent in a multi-disciplinary approach, and will therefore elaborate an overarching approach to include public-public and public-private partnerships.
- The program will encourage and support community participation.
- The program will be structured in such a way that it wins universal acceptability among users
- The program will borrow from the constitutional imperatives on the bill of rights that, every citizen has a right to good health and a legal duty of right of access to healthcare.
- To promote sustainability, the program will not constitute one off events, but will have continuous processes, a dedicated budget and adequately trained staff.

Aim and Objectives for Accreditation of ART Sites

Aim

To establish an accreditation system that will respond to the demands of providing ART and other health services.

General Objective

The main objective of the accreditation system is to assess a site's ability to provide antiretroviral therapy and other services.

Strategic Objectives

- To ensure high standards of practice in ART services.
- To ensure adherence to policies and procedures for accreditation.
- To develop the accreditation database.
- To provide capacity building to surveyors/inspectors on accreditation.
- To roll out of the accreditation programme.
- To strengthen the awareness on accreditation among stakeholders.

Activity Description by Strategic Objective

To ensure high standards of practice in ART services

This objective shall be achieved through the following activities:

1. Adoption of the approved guidelines on implementation of ART services.
2. Ensure dissemination of guidelines on implementation of ART services.
3. Establish a library at MCZ for guidelines/policy documents on implementation of ART services.
4. Collaborate with MoH in ensuring that all guidelines are available to all stakeholders providing ART services.
5. Monitor the compliance to the prescribed standards of practice in ART services.
6. Strengthen the CPD with the help of the Professional Associations.

To ensure adherence to policies and procedures for accreditation.

It shall be mandatory for all stakeholders to adhere to the policies and procedures for accreditation of facilities providing ART. MCZ will conduct the following activities:

1. Conduct periodic updates of the rules as need arises.
2. Facilitate alignment of accreditation to the Medical & Allied Professions Act.
3. Collaborate with professional associations in dissemination of information on the Act
4. Assess all practitioners/facilities on the knowledge of the Act prior to registration.

To develop the accreditation database

The process of accreditation is data-driven and uses multiple data sources. It involves data collection, data review and analysis. Therefore, it will be required that the MCZ refurbishes its office with new equipment for use in support of the accreditation program.

1. Hire a consultant to develop a database and train staff in IT, HMIS and LMIS.
2. Purchase office equipment.
3. Acquire new office premises (with the help of MoH).
4. Create a website.
5. Recruit additional staff for Monitoring and Evaluation.

To provide capacity building of surveyors/inspectors on accreditation

To achieve this objective the following activities shall be taken:

1. Develop training manuals for Inspectors/Surveyors.
2. Recruit field Inspectors/ Surveyors.
3. Conduct training of Inspectors/Surveyors and familiarise them with the harmonised inspection guidelines.
4. Conduct an international study tour focused on the aspects of accreditation program such as field education, scheduling, certification and legal activities.


To roll out of the accreditation program.

The roll out of accreditation process will start in March 2007 with facilities in Lusaka and the Copperbelt provinces and eventually scale up to the other areas. The accreditation exercise for the existing facilities is expected to be completed by the end of December 2007. Accreditation will eventually be a prerequisite for registration of a facility five years after the launch of this programme. The following are some of the activities to be conducted:

1. Launch the Accreditation programme in December 2006.

2. Conduct inspection field visits.
3. Conduct a survey on knowledge and practices about the quality of ART services.
4. Conduct an annual evaluation of the accreditation system.

To strengthen the awareness on accreditation among stakeholders.

1. Conduct dissemination seminars to the entire professional associations, the media, and health care institutions on accreditation of ART sites.
 2. Publish a periodic newsletter on the implementation of accreditation.
 3. Conduct advocacy to all professional bodies on sensitization of accreditation
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Institutional Arrangements

The MCZ is responsible for setting, promoting and regulating ethical and professional standard of practice of health care professional so as to ensure the provision of quality health services to the public within the framework of the Medical and Allied Professions Act, Cap. 297 of the Laws of Zambia. This statutory mandate includes the registration and certification of practitioners and health facilities so that standards are maintained. .

The existing internal structural arrangements within the Council will be the same with an expansion of the Inspectorate Unit to cover for the expanded responsibilities. Additional staff within the Inspectorate Unit will be needed in line with the approved establishment.

Programme Financing

All activities will fall within the existing Council financing mechanisms as elaborated under Section 14 and 15 of the Act. The implementation of this programme will cost approximately **ZMK 1,256,027,500.00**.

Monitoring and Evaluation Framework

The accreditation system shall fall within the MCZ consulting room inspection and monitoring programme. However, for the first two years of the accreditation of ART sites, evaluation of the accreditation system shall be done bi-annually until such a time that the system takes root.

Objectives/Main Activities	Time frame									Responsible Authority	Indicator	Target			Budget (ZMK)	
	Year 1 (2007)				Year 2 (2008)				Year 3-5			Year 1	Year 2	Year 3-5		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4								
To ensure high standards of practice in ART services																
1. Adopt approved guidelines/protocols on implementation of ART services.		X	X	X	X	X	X	X	X	X	MCZ	Number of accredited ART sites compliant to standard of practice	80%	80%	80%	336,543,500
2. Dissemination of guidelines on implementation of ART services.		X	X	X	X	X	X	X	X	MCZ						
3. Establish a documentation centre/library at MCZ for ART reference materials.		X	X	X	X	X	X	X	X	MCZ						
4. Collaboration with MOH for submission of guidelines to MCZ.		X	X	X	X	X	X	X	X	MCZ						
5. Strengthen CPD	X	X	X	X	X	X	X	X	X							

Objectives/Main Activities	Time frame									Responsible Authority	Indicator	Target			Budget (ZMK)
	Year 1 (2007)				Year 2 (2008)				Year 3-5			Year 1	Year 2	Year 3-5	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4							
system through profession associations															
6. Monitor compliancy to standards of practice in ART sites.		X	X	X	X	X	X	X	X						
To ensure adherence to policies and procedures for accreditation															
1. Conduct periodic updates of guidelines/protocols			X	X			X	X	X	MCZ	Number of accredited facilities compliant to accreditation policies and procedures				209,487,000
2. Align accreditation to the Medical and Allied Professions Act (Cap 297)		X	X							MCZ		80%	80%	80%	
3. Collaborate with professional associations for the dissemination of information on the Act				X	X	X	X	X	X	MCZ		90%	90%	90%	
4. Assess practitioners and sites (ART) on knowledge of the law				X	X	X	X	X	X	MCZ					

Objectives/Main Activities	Time frame									Responsible Authority	Indicator	Target			Budget (ZMK)
	Year 1 (2007)				Year 2 (2008)				Year 3-5			Year 1	Year 2	Year 3-5	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4							
To develop accreditation database.															
1. Hire a consultant to develop a database and train staff in IT, HMIS and LMIS		X								MCZ	Database created and in use	Database development for accreditation completed by end of 2007		276,950,000	
2. Purchase office equipment for ART accreditation administration		X	X							MCZ					
3. Create a website for MCZ					X	X	X	X	X	MCZ					
4. Recruit additional staff		X	X												
To provide capacity building of surveyors/Inspectors on accreditation															
1. Develop a training manual for inspectors/surveyors.	X									MCZ	Number of inspector/surveyors trained in accreditation	50	50		196,073,500
2. Recruit field surveyors	X	X	X	X	X	X	X	X	X	MCZ					

Objectives/Main Activities	Time frame										Responsible Authority	Indicator	Target			Budget (ZMK)
	Year 1 (2007)				Year 2 (2008)				Year 3-5	Year 1			Year 2	Year 3-5		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4								
3. Conduct training /orientation workshop for inspectors and surveyors	X	X	X	X	X	X	X	X	X		MCZ					
4. Undertake an international study tour on accreditation	X	X									MCZ					
To roll out the accreditation programme.																
1. Launch the accreditation programme	X										MCZ	Number of facilities accredited in provision of ART	50	150	300	114,650,000
1. Conduct field inspection	X	X	X	X	X	X	X	X	X		MCZ					
3. Conduct a KAP survey of ART services							X	X	X		MCZ					

Objectives/Main Activities	Time frame									Responsible Authority	Indicator	Target			Budget (ZMK)
	Year 1 (2007)				Year 2 (2008)				Year 3-5			Year 1	Year 2	Year 3-5	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4							
4. Conduct an annual evaluation of the accreditation system				X				X	X	MCZ					
To strengthen the awareness on accreditation among stakeholders															
1. Conduct dissemination seminars on accreditation to stakeholders	X	X								MCZ	Number of practitioners aware of accreditation	90%	90%	90%	122,323,500
2. Publish a periodic newsletter and leaflets on accreditation		X		X		X		X	X	MCZ					
3. Conduct advocacy on accreditation of ART sites to professional associations	X	X	X	X	X	X	X	X	X	MCZ					

