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Zimbabwe

Health Laboratory Policy



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Foreword

The value of laboratory services is often overlooked despite its vital contribution to the provision of cost effective quality health care. Laboratory results provide the only scientific approach to patient management allowing the clinician to make accurate diagnosis and rationalize drug use. It is estimated that 70% of all diagnosis depend on the laboratory.

A lack of diagnostic facilities contributes to the high incidence of non-specific as well as false diagnoses. This in turn impacts on treatment strategies and lengths of hospital stay, ultimately increasing the cost of health care delivery, and stretching already scarce resources. On this premise an improvement in laboratory service will ultimately lead to a reduction in the national health expenditure, while improving the quality of patient care and health status of the nation.

Laboratories play a vital role in epidemiological surveillance, control of infectious diseases such as cholera, TB, diarrheal diseases and other communicable diseases. With the advent of the ART the role of the laboratory is even more critical for initiating treatment and monitoring ART including the emergence of resistance to anti-retrovirals, SARS, Avian Influenza, Influenza A H1N1 (Swine flu), MDR and XDR TB.

The Ministry of Health and Child Welfare recognizes the importance of the laboratory services and that it is an integral part of the health delivery system. The overall objective of the policy is to provide a road map to strengthen laboratory service delivery and give basis to the development of a national strategic plan.

I wish to thank all who contributed to the development of this national laboratory policy and call upon all the concerned stakeholders to implement it. The successful implementation of the policy will contribute significantly to improved health service delivery in general.

Brigadier General Dr G. Gwinji

Permanent Secretary

Ministry of Health and Child Welfare





Acknowledgements

The development of the Zimbabwe Health Laboratory Policy involved the participation of stakeholders at different stages of the consultative process. In particular the consultative process included planning meetings and review of key documents.

I would like to acknowledge the consultants and all participants from the National Reference laboratories, Central and District hospital laboratories, other organizations and individuals for their significant contributions in revising the Zimbabwe Health Laboratory Policy.

On behalf of the MOHCC, I would like to thank UNICEF, which provided both financial and technical support in the revision of the policy.

Mr D. Mangwanya

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Abbreviations and Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral therapy
ARV	Antiretroviral drugs
BRTI	Biomedical Research and Training Institute
CDC	Centers for Disease Control and Prevention
DLS	Department of Laboratory Services
GOZ	Government of Zimbabwe
HIV	Human Immunodeficiency virus
M&E	Monitoring and Evaluation
MLCSCZ	Medical Laboratory and Clinical Scientists Council of Zimbabwe
MOHCC	Ministry of Health and Child Care
NBSZ	National Blood Services Zimbabwe
NMRL	National Microbiology Reference Laboratory
NTRL	National TB Reference Laboratory
PT	Proficiency Testing
EQA	External Quality Assessment
QC/IQC	Quality Control/ Internal Quality Control
UZ	University of Zimbabwe
WHO	World Health Organisation
ZINQAP	Zimbabwe National Quality Assurance Program

1. Introduction

The Government of Zimbabwe (GOZ) recognizes the health laboratory services as an essential component of health care services and is committed to facilitating the provision of quality laboratory support. Poor health laboratory services subject patients to inappropriate treatments, chronic ill-health, and high costs on health care, loss of incomes and ultimately loss of confidence in health services.

The laboratory services in Zimbabwe has the responsibility to fulfil the needs of all patients and clients, and promote the health and well-being of the public in the following service areas; public health and epidemiological needs, clinical health and the provision of safe blood and blood products, national reference laboratory function, quality assurance, teaching and research. These laboratories operate with minimum standard requirements for equipment, reagents and supplies, staffing levels and qualifications, repertoire of available tests at each level of the tiered system from Rural Health Centre right up to the National Reference Laboratories.

The legal and procedural framework for collaboration between MOHCC and all stakeholders (such as Mission Hospitals, Mine Hospitals, Private Hospitals, and Agricultural Estates) is premised on a supervisory role for the MOHCC through the Director Laboratory Services. This collaboration is important for maintenance of adequate standards both in terms of staffing and quality of services as well as training and development. The MOHCC also provides support to research institutions and training institutions in terms of public- private, private- private, private- public partnerships (PPP) and collaboration and vice-versa.

The Medical Laboratory and Clinical Scientists Council of Zimbabwe is a statutory regulatory body enacted by an Act of Parliament of the Republic of Zimbabwe under the Health Professions Act Chapter 27:19 of 2001, which is responsible for the licensing of medical laboratory personnel, medical laboratories/test sites and setting of standards of training for medical laboratory personnel

The ministry recognizes the importance of quality hence a department of quality assurance and performance monitoring has been established. There is no Accreditation body currently in Zimbabwe. The Ministry intend to establish of an Accreditation Board which will see to the creation of an Accreditation Body.

Existing Laboratory Services

Health laboratories refer to government institutions, private institutions, research and

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teaching institutions. The MOHCC laboratories are organized under the Laboratory Services Directorate covering the disciplines of Medical Microbiology, Chemical Pathology, Haematology, Histopathology and Blood Bank/ Blood Transfusion.

The Health Laboratory System has two major arms; first the public health laboratories that serve the department of epidemiology and disease control in the Ministry of Health and Child Care (MOHCC). These include institutions such as the Government Analyst and the (National Institute of Health Research) NIHR. These laboratories are community focused as opposed to clinical care of individual patients.

The second arm of the laboratory system is the diagnostic laboratory service based in hospital institutions, independent private laboratory facilities and the National Blood Service of Zimbabwe (NBSZ), which is an independent body. The diagnostic laboratory services focus on patient clinical quality care. These laboratories include public health laboratories, mission laboratories, uniformed forces laboratories, local authorities, city council laboratories, national reference laboratories [National Microbiology Reference Laboratory (NMRL), National Tuberculosis Reference Laboratory (NTBRL) & National Virology Reference Laboratory, (NVRL)], private clinical laboratories, veterinary laboratories, research laboratories, training institutions laboratories and Zimbabwe National Quality Assurance Programme, (ZINQAP).

Public facilities

National Reference laboratories/Central/Province/District/Rural health centers

A menu of tests for each level of services has been defined with reference laboratories offering reference services. Central hospital laboratories offer a greater range of more complex tests than provincial and district laboratories. At the lowest level the health centers offer low complexity testing (e.g rapid HIV tests, malaria, malaria and TB smear microscopy and other point of care tests). Stand-alone VCT for HIV are also offered by NGO's. Services are offered nationwide with an equitable distribution of health facilities.

The National Blood Services Zimbabwe (NBSZ)

The NBSZ is registered as a non-profit making company under section 26 of the Companies Act, Chapter 24:03 and is also registered as a private voluntary organization (WO/54/68) as required by the Private Voluntary Organizations Act, Chapter 17:05. The Service has managed to provide a nationally and internationally recognised and renowned blood service. The Service attained the WHO Collaborating Status and it was requested by WHO to be a Regional Quality Training centre. A Quality Management System based on ISO9001:2000 was introduced in 2004. The transfusion of blood and

blood products is recognized as one of the essential therapeutic interventions in modern health care, hence, the service is commitment to provision of effective blood service. The donation of blood is governed by the Anatomical Donations and Post-Mortem Examinations Act, Chapter 15:01. The administration of the Act falls under the Ministry of Health and Child Care (MOHCC).

Consequently, those operations of the NBSZ relating to the collection and use of donated blood are regulated by the Act. However, this does not make all the operations of the NBSZ accountable to the MOHCC. The National Committee is the highest decision making body of NBSZ with responsibility to provide an enabling environment for management to implement agreed policies. The National Committee is made up of elected blood donors and co-opted members representing the MOHCC, the Secretary General of Zimbabwe Red Cross Society (ZRCS), National AIDS Council (NAC) and the Executive Secretary of National Association of Medical Aid Societies (NAMAS) and the Pledge 25Club Chairperson. From NBSZ, the Chief Executive Officer, Medical Director, Bulawayo Branch Manager are ex-officio members of the National Committee.

The NBSZ provides safe blood and blood products to all hospitals in Zimbabwe and is the sole provider of this service. Its main customers are MOHCC, mission and private hospitals. MOHCC by virtue of it being the largest provider of healthcare in Zimbabwe is also its largest customer. It is internationally accredited and recognized as a center of excellence.

Government Analyst's Laboratory

The Government Analyst's Laboratory is funded directly by MOHCC and is situated in Harare. It is the reference laboratory for all chemical analysis in public health and organizationally it is divided into units namely: Customs and Industrial, Clinical and Toxicology; Food Unit, Waters Division, Urine and Iodine Laboratory.

National Institute of Health Research

The National Institute of Research formerly Blair Research Institute of the Ministry of Health & Child Care is situated in Harare and its core business is research in biomedical sciences, communicable and vectors borne diseases, health systems policies and technologies. It has well qualified staff and has an active research program that provides useful information to support government health policies and information to program managers to combat the most prevalent diseases. It is organized into 3 sectional departments namely Vector Borne Diseases, Communicable & Infectious Diseases, Health Systems & Technologies and two support units. The Support units are divided into administration and technical support services; the laboratory is one of these support





units that provide services to the research activities. The laboratories are in microbiology, immunology, molecular biology, schistosomiasis, serology and malaria and mainly support research activities.

Central Veterinary Laboratory

It belongs to the Department of Veterinary Services, Ministry of Lands and Agriculture. It is the referral laboratory and part of a network of veterinary laboratories with services decentralized to the provincial laboratories. It plays a key role in zoonosis control. Its main services are disease diagnosis, outbreak investigations and disease preparedness, specialist referral and advisory service, and research. It collaborates with a number of overseas research institutes in research projects and with the University of Zimbabwe (UZ) and National Institute of Health Research. It receives specimens from National Public Health Laboratories for specialist tests, Environmental Health Department and private veterinarians. It participates in reporting notifiable diseases to the Health Information System, Department of Epidemiology & Disease Control. It provides also attachment training for students from the UZ.

Zimbabwe National Quality Assurance Programme (ZINQAP)

The Zimbabwe National Quality Assurance Program (ZINQAP) was established in 1995 with a mandate to assist all laboratories in Zimbabwe attain and maintain a high standard of performance and to improve the quality of testing services. It is the only laboratory quality assurance body in Zimbabwe conducting a proficiency-testing program. It attained international accreditation to SANAS ISO Guide 43 in February 2005 making it the first internationally recognized PT body in Zimbabwe and the second in Africa to attain this standard. It provides a comprehensive PT service to 130 medical laboratories both public and private and testing sites in Zimbabwe. These laboratories perform at different levels of participation and complexity in the major laboratory disciplines which include Immunology, Microbiology, Hematology/Blood Transfusion Medicine and Clinical Chemistry. ZINQAP'S organizational structure is made up of a Board of Trustees who oversees the work of the organization.

Private sector and other research institutions

In Zimbabwe, the capacity of the public sector to provide quality and accessible health care services to the citizens is complimented by private providers. The largest of these are CIMAS Laboratories, Premier Laboratories and Clinical Laboratories. Public-private partnerships have existed at various levels for many years with cross referral of specimens and joint training and technical committees.

Other non-governmental research institution exists and includes Biomedical Research and Training Institute (BRTI) and the African Institute of Biomedical Science & Technology (AiBST).

2. The Rationale for a health laboratory policy

The policy aims to provide a framework for ensuring that the health laboratory services in Zimbabwe are adequately strengthened so that they are efficient and effective. It defines the laboratory governance, coordination and administrative structures and providers at each tier. It is anticipated that the policy will provide a structured development and professional growth of the laboratory system in Zimbabwe.

Situation Analysis

The HIV pandemic has resulted in a huge increase in demand for laboratory services to support the national HIV and AIDS prevention, treatment and care programme in Zimbabwe in both the public and private sector. The laboratory is also required to provide timely confirmation of outbreaks, if appropriate control measures are to be instituted early at lower levels of health care service provision. Laboratory services are an integral part of the health delivery system and laboratory tests are essential in disease diagnosis, treatment, monitoring and control. However, this component of the health system has been neglected and lost out in competing for scarce resources with priority given to the procurement of medicines. Assessments reveal that the laboratory services have inadequate resources to provide a good service.

As a result, laboratory services have experienced challenges in many areas including equipment and equipment spares/accessories. This has seen a general deterioration of laboratory services where the tiered system has failed to provide the standard package of laboratory tests in support of the health delivery system at each level of healthcare. This has resulted in patients seeking services from the private sector where the costs are unaffordable and continue to increase beyond the reach the average Zimbabwean.

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Tests such as CD4, liver function and some related tests for screening patients before enrolment into the national ART programme continue to have logistical challenges in that the reagents required to perform the tests are not always available.

Human resources remain a major challenge as experienced Medical Laboratory Scientists and those graduating from the Department of Medical Laboratory Sciences at the University Of Zimbabwe College Of Health Sciences continue to leave the country into the region and overseas. Strategies to motivate and retain staff should be put in place as part of the Human Resources for Health Policy and Strategy to ensure that the health delivery system continues to get high quality laboratory support for both curative and preventive services in the MOHCC.

The procurement supply chain management of laboratory logistics including equipment needs strengthening. This is a critical component of laboratory service provision which when properly managed can result in an improvement of health services in the public sector. There is also a need to mobilize resources for laboratory services through a costed strategic plan and annual plans which can be shared with partners for funding the gaps identified. There is need to strengthen coordination of laboratory support from partners as they have tended to support specific districts directly instead of coming through one focal point. An ideal situation would be one where the partners buy-into a national laboratory strategic plan that identifies national priorities for laboratory services by geographical area and level of service provision.

The establishment of a laboratory Logistician working with the logistics sub unit (LSU), has substantially improved coordination, procurement and supply management of laboratory commodities. It is responsible for forecasting, quantification, procurement and distribution of all commodities (Laboratory Equipment and Reagents/ Consumables).

National reference laboratories namely, the National Microbiology Reference Laboratory, the National TB Reference Laboratory and the National Virology Laboratory need to have their activities harmonized so that they are responsive to the needs of the MOHCC. Currently each is operating in isolation and incorporation of the heads of the last two into the National Technical Advisory Committee that meets with the Director Laboratory Services will go a long way in ensuring that these institutions are guided by the national laboratory agenda. Public health challenges such as MDR and XDR TB, monitoring of HIV drug resistance, Avian influenza, SARS, Swine Flu to name a few need strong national reference laboratory support to ensure that disease prevention and control is adequately supported in times of need. Efforts should therefore be made to have national reference laboratories have a close working relationship with the laboratory services directorate in the Ministry of Health and Child Care.

3. Process of Policy Review

This policy has been revised under the stewardship of the MOHCC through a participatory and consultative process. Several meetings and consultations involving the wider stakeholders were held to finalize the revision of the policy. Experts were drawn from the laboratory, academic sectors, program managers, implementing partners and MOHCC for a review workshop .The policy will be validated and approved by the MOHCC.

4. Scope

This policy covers Government of Zimbabwe funded Health Laboratory Services; Range of laboratories includes Public Health, Clinical, Health Research, and Training and Veterinary laboratories. The purpose of this policy is to articulate the shared vision, mission and goals for the laboratory services in order to successfully support the National Health delivery system. This will set the basis for advocacy, resource mobilization and programme definition for the laboratory operational plans. The laboratories will operate under direct regulation from the state. The role of the health laboratories include public health diagnostic services, clinical health diagnostic services , quality control and quality assurance, health research and teaching.

5. Organisation of the Policy

The general principles and policy statements are grouped into the following thematic areas;

1. Laboratory organization and structure
2. Laboratory tiered network and referral
3. Legal and Regulatory Frameworks
4. Human Resources
5. Laboratory Equipment and Commodities
6. Infrastructure
7. Quality Management System (including Biosafety)
8. Laboratory Information System
9. Research, development and Collaboration
10. Monitoring and Evaluation
11. Financing Laboratory Services

The general principles provide guidance on laboratory management, administration and service delivery.





6. Vision

To provide the best, high quality evidence based laboratory services, which are accessible and affordable to the population of Zimbabwe.

7. Mission Statement

To timeously provide the best quality laboratory services and results to clients, in order to fulfill the laboratory services role in the health delivery system.

8. Good governance

The following principles will guide the implementation of this policy:

- a) Efficient and effective utilisation of resources
- b) Integrity and honesty
- c) A transparent system shall be in place to ensure programmatic and financial accountability of the laboratory services
- d) Ethics

9. Policy Statements

9.1 Laboratory organization and structure

Policy Objective

To have a clear organizational structure with appropriate authority to coordinate and manage the provision of comprehensive health laboratory services at all levels in the country.

Policy statements

1. The Laboratory Directorate shall provide administrative and technical oversight over laboratory services across all agencies and the private sector.
2. The Laboratory Directorate shall facilitate and enhance service provision across all tiers of the laboratory systems.

3. The National Reference Laboratories (eg NMRL, NBSZ, etc) shall provide technical support and guidance to the Laboratory Directorate.
4. The Laboratory Directorate shall facilitate resource mobilization for expansion of laboratory services.
5. To enhance laboratory Management & operations of the Laboratory Services, the Laboratory Directorate shall have heads/ representation at all levels of the tiered system as below. The heads shall be involved in planning, management and coordination for activities at each level:
 - a) District Laboratory Scientist (DLS)
 - b) Provincial Laboratory Scientist (PLS)
 - c) Central Hospital Laboratory Head
 - d) Reference Laboratory Head

9.2 Laboratory tiered network and referral

Principle

The Laboratory Services Directorate operate an integrated tiered network consisting of over 170 Registered diagnostic centers/ Laboratories operating at five main levels organized along the referral chain of health service delivery as indicated below:

The National Reference Laboratories (Specialized Referral Centers and Services) include the National Microbiology Reference Laboratory (NMRL), The National TB Reference Laboratory (NTBRL), National Virology Laboratory (WHO-Polio and Measles Laboratories at the College of Health Sciences- Department of Medical Microbiology) and the Zimbabwe Quality Assurance Programme (ZINQAP) Laboratories which provides quality control and quality assurance to all the registered laboratories focused on patient clinical and quality care.

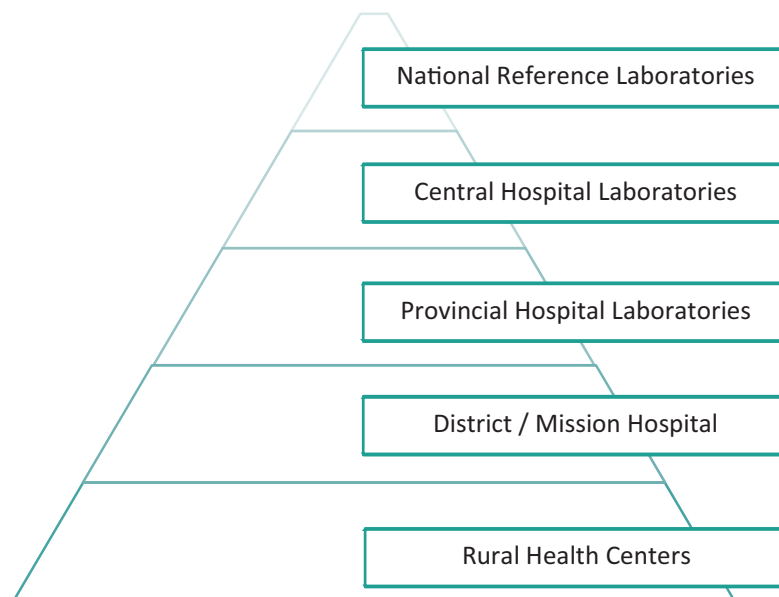
Policy Objective

To provide laboratory services appropriate to each level and that meets the needs for the delivery of health services at that level.

Policy statements

1. The scope of testing of each lab within the tier system would be as defined in the MOHCC Laboratory strategic plan which will be reviewed regularly. It will be the responsibility of MOHCC to ensure equitable coverage and access to laboratory services by the entire population.
2. Laboratory specimen referral shall be cost effective and follow the tier system that will allow for services at all levels





9.3 Legal and Regulatory Frameworks

General Principles:

Medical Laboratory and Clinical Scientists Council of Zimbabwe (MLCZCZ) shall regulate the training, practice, licensing of personnel and laboratory facilities as per Health Professions Act [Section 30 of the Health Professions Act (Chapter 27:19)].

Policy Objective

To ensure registration, licensing, education and discipline in the medical laboratory professions and maintenance of quality standards for laboratories

Policy Statements

1. Personnel performing laboratory tests shall be licensed by MLCSCZ
2. All laboratories shall be registered and monitored by the MLCSCZ in line with National Standards for Medical Laboratories for Zimbabwe
3. The DLS, together with the MLCSCZ, shall periodically review the Zimbabwe Medical Laboratory Training Standards and ensure all training institutions curricula meet the minimum standards and the evolving laboratory testing requirements
4. The DLS, in collaboration with the MLCSCZ, shall establish minimum guidelines for classification and licensing of tests (including Point of Care) and personnel at different levels of operation to ensure optimal quality management

5. The DLS, together with the MLCSCZ, shall periodically update the National Standards for Medical Laboratories for Zimbabwe to meet evolving laboratory testing requirements

9.4 Human Resources

General Principles

Laboratories shall have adequate and appropriately qualified staff to meet the needs of the laboratory, cover the entire scope of services provided and the workload. Laboratories will be staffed in line with National Standards for Medical Laboratories for Zimbabwe to ensure equitable access to laboratory services.

Policy Objectives

To ensure adequate availability of laboratory personnel with the appropriate skills and competencies to support the delivery of a comprehensive laboratory services at each level of health care

Policy Statements

1. The DLS shall ensure that all laboratory personnel have the required skills and competencies for their assigned duties.
2. MOHCC DLS will periodically review its staffing and skills requirements to adequately support the management of lab services and implementation of this policy
3. All laboratories shall conduct human resources audits periodically to determine and fill staffing gaps within laboratories
4. MOHCC shall deploy laboratory staff based on evidence and need to ensure equity of access to laboratory services
5. MOHCC in conjunction with the Health Services Board, MLCSCZ and Ministry of Higher Education shall develop and implement innovative strategies to train and retain laboratory professionals
6. All laboratories shall facilitate access for staff to Continuous Professional Development (CPDs)
7. Laboratory professionals shall abide by the Code of Ethics and Code of Conduct

9.5 Laboratory Equipment and Commodities

Equipment





General principles

The equipment used in the laboratory to generate laboratory test results play a significant role in ensuring the quality of services.

Policy objective

To ensure that laboratories are adequately and appropriately equipped in order to meet requirements of the service delivery system

Policy statements

1. The DLS shall be responsible for the harmonization and standardization of equipment
2. The DLS shall, in liaison with the Equipment & Infrastructure department, be responsible for providing guidance on specifications for procurement (including Point of Care) by GOZ and partners for deployment to laboratories and health facilities.
3. All equipments shall be evaluated for suitability of use including Point of Care
4. The DLS shall make available guidelines for a minimum package for equipment procurement including reagents, service and maintenance, deployment plans and necessary training.
5. Laboratories shall ensure that equipment in use is serviced and maintained by appropriate service providers
6. All obsolete equipment shall be removed from laboratories and disposed of according to the National guidelines

Commodities

General principles

Timely and uninterrupted supply of commodities is critical in ensuring continued provision of laboratory services. An effective supply chain management system (SCMS) of laboratory reagents and consumables will need to be maintained at all levels.

Policy objective

To ensure uninterrupted supply of laboratory reagents and consumables at all levels of health care

Policy statements

1. The MOHCC/DLS shall ensure availability of laboratory reagents and consumables by optimizing the selection, procurement, quality assurance, storage and distribution.
2. The DLS shall be consulted and participate in the procurement process of laboratory commodities.
3. The DLS shall provide guidance on the appropriate storage of lab reagents at all levels of healthcare
4. The DLS shall coordinate regular maintenance of logistic management information systems
5. The DLS shall monitor the performance of suppliers.
7. All expired reagents and consumables shall be removed from laboratories and disposed of according to the National guidelines

9.6 Infrastructure

General principles

Each level of laboratory service will be provided with adequate and appropriate infrastructure to ensure effective and efficient service. Laboratories shall be designed in such a way as to provide enough space for placement of equipment and free movement and safety of personnel and clients/patients.

Policy objective

To ensure all laboratories meet minimum infrastructural requirements as defined by National Guidelines for Medical Laboratories

Policy statements

1. The MOHCC shall ensure infrastructure is available to match scope of testing at every health institution
2. The MOHCC shall, in liaison with the MoPWD department, be responsible for providing guidance on specifications for construction by GOZ and partners for deployment to public health laboratories.
3. HPA shall ensure that all laboratory infrastructures are routinely inspected for compliance to National Guidelines for Medical Laboratories.





9.7 Quality Management System (including Biosafety)

General Principle

Implementation of quality management systems (QMS) ensures quality laboratory testing and improved patient care. The cost of poor quality is higher than the investments of establishing a quality management system in the laboratory. Hence it is vital that quality management systems are available and implemented in all laboratories.

Policy objective

To provide quality laboratory services that meet international standards of practice.

Policy Statements:

1. MOHCC shall establish a national laboratory certification authority to support certification and accreditation of laboratories that perform diagnostic testing of human specimens.
2. All laboratories shall meet the minimum QMS requirements as defined by the Zimbabwe Medical Laboratory Guidelines.
3. All laboratories shall work to be compliant with the requirements of the local laboratory certification authority.
4. All laboratories shall participate in PT schemes and/ or interlaboratory comparison recognized by the MLCSCZ.
5. MOHCC, DLS and Directors of Laboratories shall ensure that all laboratories are adequately funded for IQC and participation in PT schemes and/ or interlaboratory comparison for all testing done including Point of Care.
6. There shall be a Quality Assurance Unit for the Laboratory Directorate to oversee quality management.
7. Standard Operating Procedures (SOPs) addressing the entire analytical cycle shall be developed and implemented by each laboratory
8. Each laboratory shall ensure that there is designated staff responsible for implementation of quality management

9.8 Biosafety

General Principle

The risk of laboratory acquired infections is high among laboratory personnel handling infectious materials. The risk increases where there is low awareness, lack of training and inability to adhere to recognized preventive and precautionary measures. Hence it

is necessary that all laboratories take precautions to protect staff, patient, the environment and control access to the laboratory.

Policy objective

To promote safe and secure laboratory practices at all levels.

Policy statements

1. All laboratory facilities shall have appropriate space and safe environment for health personnel, clients, the general public and environment.
2. All laboratory workers shall be trained in Biosafety.
3. All laboratories shall have a designated person responsible for laboratory safety.
4. Institutions and individuals involved in the shipment/transportation of specimens shall be required to comply with national and International Health Regulations
5. Laboratories handling highly infectious pathogens and organisms shall have systems of access control and containment that meet nationally acceptable standards.
6. MLCSCZ / DLS shall ensure that laboratories abide by framework for disposal of biological and bio-hazard material

9.9 Laboratory Information System

Principle

The laboratory is a source of data for patient management and public health interventions. Data must be accurate, complete and timely for public health interventions including planning and outbreak response. As a result, the LIS needs to be strengthened nationally to ensure support to clinical and public health programs. It is vital that systems are put in place to strengthen data collection, use, and management at all levels.

Policy objective

To ensure that all levels of laboratory services have a functional and comprehensive laboratory information system that manages and disseminates data for use by all relevant stakeholders





Policy Statements

1. Laboratory information systems shall be strengthened to promote laboratory performance, quality patient care, surveillance, evidence-based medicine and planning, policy formulation and research.
2. Laboratory staff shall be trained to accurately record, collate, analyze, interpret and communicate laboratory data in a timely manner.
3. MOHCC shall establish standards for record management which shall be followed by all laboratories.
4. Use and dissemination of laboratory information shall be in accordance with national guidelines to ensure confidentiality.

9.10 Research, development and Collaboration

General principles

The health laboratory generates a lot of data that could, if properly analysed and packaged, produce immensely useful research information. However, there is inadequate capacity among the majority of laboratory professionals to exploit these data, develop proposals and conduct research. There is weak collaboration between the existing research institutions and the general health laboratories.

Policy objective

To promote the development of research that is relevant to the health priorities of the country

Policy statements

1. DLS shall promote research all levels of the tier system that are in line with the priorities of the MOHCC
2. Data utilisation at facility level to inform operations and improvement
3. All laboratory-related research shall be approved by relevant ethical institutional and / or national review boards
4. DLS shall encourage collaborative research nationally, regionally and internationally

9.11 Monitoring and Evaluation

General principles

A comprehensive monitoring and evaluation system is needed to measure the delivery of quality laboratory services and provide the means for continual quality improvement.

General objective

To monitor and evaluate the quality of the laboratory services using clearly defined laboratory indicators

Policy statements

1. Laboratory service shall monitor and regularly review the implementation of each component of this policy
2. Laboratory services shall establish clearly defined laboratory indicators and M & E tools
3. Laboratory services shall have an integrated M and E system that builds onto an existing information system
4. There shall be a feedback mechanism at all levels

9.12 Financing Laboratory Services

General principles

Availability of adequate funding ensures continued provision of laboratory services. As the custodian of the laboratory services, MOHCC needs to take the leading role in resource mobilization internally and externally.

General objective

To ensure provision of sufficient funding for the implementation of the laboratory services

Policy statements

1. MOHCC shall plan, budget and ensure provision of sufficient funding for the implementation of the various components of the policy





2. The DLS shall expend any funds according to an approved budget and following government guidelines on the use and accounting of public funds
3. MOHCC shall recover costs to ensure sustainability of laboratory service
4. In the event of an emergency, the MOHCC shall make special budgetary provisions to provide the required laboratory service

10. Risk assessment

There are no risks or conflicts that are immediately discernible resulting from the approval of this policy. In particular:

- a) The policy provides general overarching statements that are adaptable to changing political, economic and technological circumstances. The policy directs the establishment of standards and norms to be implemented. It is envisaged that the development of these standards will take cognizance of the economic and technological situation in the country.
- b) The policy has been made broad enough to include all stakeholders involved in laboratory service delivery while ensuring that laboratory practice meets the minimum standards for quality and safety and is accessible to all.
- c) The policy has been aligned to the National Health Policy to ensure that it contributes to the national health agenda and supports the programmes of the MOHCC.

