



Republic of Rwanda
Ministry of Health

Rwanda National Medical Laboratory Policy

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FOREWORD

The Ministry of Health has begun the process of decentralization and planning based on the Vision 2020, which aims at combating the spread of high-burden and emerging diseases in the country. It is important to improve the quality of laboratory services in support of quality health care delivery at all levels. It is also well recognized that laboratories support diagnosis, rational use of drugs, monitoring of response to treatment, epidemiological surveillance, and research activities.

The absence of a National Medical Laboratory Policy for Rwanda has contributed to the deterioration of the services over the years. As a result, the Ministry of Health is committed to the improvement of laboratory services through its support for the development and implementation of the National Laboratory Policy. This document will provide the guidance and direction necessary to all stakeholders involved in the implementation plan for improving the quality of laboratory services in the country.

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ACRONYMS AND ABBREVIATIONS

| | |
|-----------|---|
| ACM | Atelier Central de Maintenance |
| CAMERWA | Central Drug Purchasing Agency for Rwanda |
| HIV | human immunodeficiency virus |
| KHI | Kigali Health Institute |
| LMIS | Laboratory Management Information Systems |
| MINECOFIN | Ministry of Finance and Economic Planning |
| MINEDUC | Ministry of Education, Science, Technology and Research |
| MININFRA | Ministry of Infrastructure |
| MOH | Ministry of Health |
| MSH | Management Sciences for Health |
| NEQAP | National External Quality Assessment Program |
| NHMIS | National Health Management Information Systems |
| NRL | National Reference Laboratory |
| QAP | Quality Assessment Program |
| RPM Plus | Rational Pharmaceutical Management Plus Program [MSH] |
| SOPs | standard operating procedures |
| TB | tuberculosis |

1. INTRODUCTION

- 1.1 Since the 1980's, Rwanda has adhered to the Alma Ata declaration, which adopted a strategy of primary health care to promote public health. Following the Lusaka conference in 1985, Rwanda decided to decentralize its health care system, including laboratory services, and base it on health districts. However, the success of this policy was limited because the administration of health services remained centralized.
- 1.2 Shortly after the genocide of 1994¹, the Ministry of Health (MOH) started introducing reforms in the health sector in keeping with the Lusaka declaration. In 1996, the National Unity Government adopted these reforms, whose purpose was to contribute to the improvement of public welfare by providing accessible and acceptable quality health care to the majority of the population with full participation of the community. To achieve these goals, the reform policy was based on three main strategies: namely, the effective decentralization of health services, the development of a primary health care system through eight components, and the strengthening of community participation in managing and financing health services. The organisation of the health system in Rwanda is based on a pyramidal structure: At the base of the pyramid is the health centre; the intermediate level comprises district hospitals; and the top of the pyramid consists of the referral hospitals. Each level of the health system is expected to provide a minimum package of laboratory services.
- 1.3 Laboratories are known to play an important role in the prevention, diagnosis, treatment, and monitoring of diseases, as well as in biomedical training and research.
- 1.4 The National Medical Laboratory Policy covers the infrastructure and design of medical laboratories; development of human resources; establishment of a quality assurance system; biosafety; establishment of a professional code of ethics; standard laboratory equipment, reagents, and supplies; laboratory packages, research and development for laboratories; and partnership and collaboration with other laboratories.

¹ Health Sector Policy, Government of Rwanda, September 2004

2. SITUATIONAL ANALYSIS OF MEDICAL LABORATORY SERVICES²

- 2.1 A situational analysis was carried out by the National Reference Laboratory (NRL) in November and December 2004 to assess the status of medical laboratory services in the country. The major findings were that the majority of the health centre and hospital laboratories failed to meet the basic requirements (human resources, infrastructure, equipment, and supplies) for the laboratory to function: 50% lacked qualified laboratory personnel; 78% lacked laboratory supplies and reagents; 76% lacked equipment; and 71% had poor laboratory infrastructure. The quality assurance system was not well established, and only 50% of the laboratories participated in External Quality Assessment for tuberculosis (TB) and HIV diagnosis. The management of laboratory services was poor, with a score of 12%; laboratory personnel did not participate in management, planning, and budgeting meetings. In addition, the procurement system was found to be inefficient.
- 2.2 The development of a national laboratory policy arose from the findings of the situational analysis. The objective of the laboratory policy is to provide a legal framework and guiding principles to improve laboratory services in the country.

² Rwanda Ministry of Health (MOH). 2005. *Rwanda Medical Laboratory Situational Analysis*. MOH: Kigali.

3. POLICY CONTEXT

- 3.1 ***Vision.*** A health system with comprehensive laboratory services, which are accessible and affordable, to promote the well-being of the population.
- 3.2 ***Mission statement.*** To support the delivery of health services to prevent, diagnose, and manage Rwanda's burden of diseases by providing quality-assured laboratory services at all levels of care.
- 3.3 ***Policy objectives.*** In order to carry out its mission, the laboratory services sector has defined the following major policy objectives: (i) to provide standard packages of laboratory tests at each level of care of Rwanda's health system and to promote their rational use in order to ensure prevention, diagnosis, and treatment; (ii) to provide the necessary knowledge, competencies, and skills to support the packages of care and maintain professionalism among laboratory personnel; (iii) to provide appropriate standardised equipment and supplies at each level of care; (iv) to establish and maintain a quality assurance system in order to ensure quality laboratory services; (v) to promote and strengthen research and development; (vi) to establish appropriate standardised laboratory designs for each level of care; and (vii) to promote partnership and collaboration at local, regional, and international levels.
- 3.4 ***Values and guiding principles.*** The laboratories shall adhere to a number of values in their effort to fulfill their mission: solidarity, patriotism, equity, ethics, cultural identity, and gender-specific respect. The laboratories are also guided by a number of principles: acceptability and quality of laboratory services, effectiveness and efficiency, intersectoral coordination, community participation, decentralization, and integration.

4. POLICY STATEMENTS

- 4.1 Seven policy objectives, identified and elaborated into policy statements based on the values, guiding principles, and the desired characteristics of the laboratory services sector, were drafted to enable the laboratory sector to fulfill its vision and mission.

Equipment and Supplies

- 4.2 The MOH shall provide a standard list and specifications for laboratory equipment to be used at all levels of the health system.
- 4.3 The MOH shall ensure that public laboratory facilities are equipped according to established standards.
- 4.4 There shall be adequate representation of laboratory personnel on all local and national tender committees and advisory bodies involved in procuring laboratory equipment, supplies, and reagents.
- 4.5 Procurement and donation of laboratory equipment, supplies, and reagents shall conform to nationally established standards.
- 4.6 A separate budget shall be established for the procurement of laboratory equipment, supplies, and reagents.
- 4.7 A central workshop on maintaining laboratory equipment shall be established to operate in accordance with national guidelines and standards.
- 4.8 The MOH shall establish guidelines on procurement procedures for laboratory equipment, reagents, and supplies.

Human Resources Development

- 4.9 The Government shall upgrade and strengthen medical laboratory training institutions by providing resources (qualified teachers, equipment, and supplies) to meet the minimum standards.
- 4.10 The MOH shall ensure the certification of laboratory personnel and encourage the establishment of professional laboratory associations.
- 4.11 Medical laboratory training institutions shall be improved and upgraded to meet the minimum recommended standards of A1 qualifications.
- 4.12 Training curricula shall be reviewed and updated to include emerging diseases and advances in biomedical sciences and shall be conducted by approved institutions.
- 4.13 The Government shall encourage and support the establishment of BSc, MSc and PhD programs in biomedical sciences.

- 4.14 The MOH shall develop a laboratory career structure and promote opportunities for continuing education to support the implementation of laboratory standards and policies.
- 4.15 Laboratories shall be represented at all meetings for the planning and development of health sector budgets.
- 4.16 All medical laboratory professionals shall be registered, certified, and decertified by a body authorised by the MOH.
- 4.17 A code of professional ethics shall be established for the laboratory staff. An ethics committee shall be established to evaluate violations of the code of the ethics and recommend disciplinary actions to relevant authorities.

Laboratory Design (Infrastructure)

- 4.18 The location and design of the laboratory within a health facility at each level of care shall conform to the established minimum standards and specifications for design and safety.
- 4.19 The MOH or another authority approved by the MOH shall approve the design and drawings for the construction of a medical laboratory .
- 4.20 The MOH or another authority approved by the MOH shall carry out annual inspections of laboratory infrastructures to ensure conformity with established standards for health facility design.
- 4.21 The MOH or another authority approved by the MOH shall be mandated to close down any laboratories that do not meet the specifications and standards set for laboratories.

Laboratory Packages

- 4.22 Laboratory tests shall be selected and standardised for each level of the health care system according to the package of care defined for each level.
- 4.23 Standard operating procedures (SOPs) shall be developed and implemented for each level of the health care system.
- 4.24 Guidelines for the rational use of laboratory tests shall be provided to all levels of the health care system.
- 4.25 All clinicians and laboratory personnel shall be trained in the rational use of laboratory tests in accordance with the SOPs developed for each level of the health care system.

- 4.26 The MOH shall establish a code of biosafety practice to support procedures included in the packages of care. Biosafety committees shall be established at all levels of care to inspect the laboratories and enforce biosafety standards and procedures. Disposal of laboratory waste and biohazards shall be in accordance with relevant guidelines from relevant authorities.

Quality Assurance Systems

- 4.27 Quality laboratory services shall be promoted through the setting and implementation of standards and procedures according to packages of laboratory services at each level of care.
- 4.28 Internal quality control practices shall be developed and strengthened in all laboratories.
- 4.29 A National External Quality Assessment Program (NEQAP) shall be established to monitor the quality of laboratory results at public health centre, district, and referral levels, as well as at private laboratories.
- 4.30 Reference laboratories shall be subject to external accreditation from and affiliation with internationally recognized external quality assessment programs (QAP) for each laboratory discipline.
- 4.31 Laboratory management information systems (LMIS) shall be developed for each laboratory system. The LMIS will be based on the service and planning requirements of each level of the health care system and shall be integrated into the National Health Management Information System (NHMIS). The NHMIS shall be strengthened for better, more informed decision making in the laboratory.
- 4.32 Data collection and information systems shall be improved to facilitate good surveillance practices which, in turn, will facilitate timely responses to epidemics as well as tracking of reportable and emerging diseases.
- 4.33 Collaborative efforts among various stakeholders involved in the control of epidemics and infectious diseases shall be strengthened.
- 4.34 The MOH shall put in place mechanisms to supervise, monitor, and evaluate the implementation of the laboratory policy with a focus on specified input and process indicators (such as human and financial resources and utilization of services). Evaluation will be conducted both internally and externally in collaboration with the MOH's partners.
- 4.35 The MOH shall provide adequate resources to the NRL to provide technical support visits to peripheral laboratories.

Research and Development

- 4.36 The Government shall promote and strengthen research in biomedical sciences.
- 4.37 Biomedical research capacity and specialized training shall be strengthened according to national priorities.
- 4.38 The Government shall mobilise resources for research activities from public funds or partners.

Partnership and Collaboration

- 4.39 National and local biomedical ethics committees shall be established and shall work in collaboration with regional or international biomedical committees.
- 4.40 The Government shall promote and support collaboration between the public and private sectors in laboratory services.
- 4.41 Intersectoral consultation and collaboration with ministerial partners shall be essential to implement major laboratory network strategies.
- 4.42 The mechanisms for national and international coordination of laboratory standards and policies as initiated by the MOH and certain partners shall be put in place under the umbrella of a sector-wide approach.

5. IMPLEMENTATION STRATEGIES

- 5.1 Implementation of the laboratory policy requires local and external resource mobilisation based on the policy guidelines. This will be done in collaboration with partners.
- 5.2 The short-term priorities will focus on the improvement of human resources, infrastructure, equipment, and supplies.
- 5.3 The five-year implementation plan outlines required activities, targets, indicators, responsible parties, and time frame.
- 5.4 In order to monitor and evaluate the implementation of the laboratory policy, the Government shall establish an integrated system of monitoring and evaluation.

6. FIVE-YEAR IMPLEMENTATION PLAN

| Activity | Responsible Party | Time Frame | Indicator |
|--|-------------------|---------------|---|
| 1. Develop a National Medical Laboratory Policy | | | |
| 1.1 Adopt the National Medical Laboratory Policy | MOH and NRL | July 2005 | Policy approved in August |
| 2. Develop and implement national guidelines in priority areas | | | |
| 2.1. Develop, disseminate, and implement laboratory test profiles and standard operating procedures (SOPs) at various levels of care | NRL and MSH | December 2006 | At least 75% of laboratories performing the most critical tests using SOPs |
| 2.2 Train personnel in use of SOPs | NRL and MSH | June 2006 | 75% of laboratory personnel trained in the use of SOPs |
| 2.3 Develop integrated clinical treatment guidelines and train in rational use of laboratory investigations | NRL and MSH | December 2006 | At least 75% of facilities using integrated clinical treatment guidelines with laboratory standards |
| 3. Address standardisation and management of laboratory equipment | | | |
| 3.1 Develop and implement standardized minimum equipment lists and specifications for each level of care | NRL | December 2006 | 50% of facilities with functioning equipment from the standard essential list 75% of equipment meets national standards and specifications |
| 3.2 Develop and implement guidelines on laboratory equipment | NRL and ACM | December 2006 | Laboratory equipment guidelines developed, disseminated, and implemented |
| 3.3 Develop and disseminate maintenance requirements for essential laboratory equipment | | December 2006 | 75% of laboratories with fully honored maintenance contracts |
| 3.4 Increase budget for laboratory equipment and source funds to bring laboratories to minimum critical standards | MOH and MINECOFIN | December 2006 | 80% of laboratories with functioning critical equipment from the standard essential list |
| 4. Improve availability and management of supplies | | | |
| 4.1 Improve laboratory supply levels | MOH and NRL | December 2006 | 90% of facilities with 80% of key critical supplies in stock |
| 4.2 Establish a national authority for laboratory supplies and equipment | MOH | March 2010 | Regulatory authority formed |
| 4.3 Increase minimum allocation for laboratories in the national drug budget and create a separate cost code for laboratory supplies | MOH and MINECOFIN | January 2006 | 30% of drug and medical supply budget figures allocated to laboratories as a separate cost code |

| Activity | Responsible Party | Time Frame | Indicator |
|--|-----------------------|---------------|---|
| 4.4 Create a cost code for laboratories at district and reference levels | MOH and MINECOFIN | January 2007 | Cost codes available for each level of care |
| 4.5 Allocate percentage of district grant as a contingency sum for emergency laboratory supplies | MOH and MINECOFIN | January 2007 | District budget for supplies increased by 3% |
| 4.6 Integrate logistics and supply management (e.g., quantification, procurement, storage, and distribution) | MOH, CAMERWA, and NRL | December 2006 | Integration guidelines developed and implemented |
| 4.7 Develop and implement cost-sharing mechanisms and guidelines (e.g., percentage of retention by user, exempt investigation, etc.) | MOH and NRL | December 2006 | Cost-sharing guidelines developed and implemented |
| 5. Set and enforce standards of design for laboratory infrastructure | | | |
| 5.1 Develop and implement standards of design for laboratory infrastructure | MOH and MININFRA | December 2007 | 30% of existing laboratories conform to set standards of design |
| 5.2 Ensure all new laboratory designs conform to nationally set standards | MOH and MININFRA | December 2007 | 75% of new laboratories conform to standard designs |
| 5.3 Inspect laboratory building against set standards annually | NRL and MININFRA | December 2007 | Inspectorate bodies in place and functioning Evaluate annually before budget submissions and submit written reports to MOH through NRL |
| 6. Address staffing levels and qualifications (human resources) | | | |
| 6.1 Achieve and retain minimum levels of qualified staff | MOH | | 30% of facilities with required number of qualified staff in five years and 60% in 10 years 50% of newly qualified staff retained in the public sector |
| 6.2 Rationalise existing staff through redeployment, training, and development of standards | MOH | December 2006 | 80% of health centres and district hospitals staffed with laboratory technicians 80% of laboratory staff employed at health centre and district-level holding diplomas or higher |

| Activity | Responsible Party | Time Frame | Indicator |
|---|---|---------------|--|
| 6.3 Upgrade and strengthen existing laboratory certificate schools to diploma level and increase output to 40 students per annum from 2006 | MOH, MINEDUC, and Kigali Health Institute (KHI) | December 2006 | Certificate course discontinued by January 2005. Diploma course introduced in current certificate schools. Training facilities staffed to 60% capacity; at least 40% of training staff with recommended minimum qualifications |
| 6.4 Establish a degree course in Biomedical Sciences at KHI | KHI | December 2008 | Degree course introduced and first intake of students |
| 6.5 Develop career structure for laboratory personnel | MOH | December 2008 | Proposed career structure adopted |
| 7. Introduce and monitor quality assurance methods at all levels | | | |
| 7.1 Establish laboratory quality assurance programs | NRL | December 2006 | Quality assurance programs established in 80% of facilities |
| 7.2 Develop a National External Quality Assessment Program (NEQAP) laboratory and affiliate with international external quality assessment laboratory | NRL | December 2006 | NEQAP centre established with the participation of 75% of laboratories |
| 7.3 Affiliate all reference laboratories with internationally recognized external quality assessment schemes | NRL | December 2006 | Designate reference laboratories participating and meeting standards of external quality assessment schemes |
| 7.4 Introduce internal quality control procedures through the development of procedures and staff training | NRL | December 2006 | 90% of facilities conform to internal quality control guidelines |
| 7.5 Integrate laboratory data information monitoring systems | MOH and NRL | December 2006 | Standard system of data collection established and operational |
| 7.6 Develop and implement integrated monitoring and supervisory guidelines | MOH and NRL | December 2006 | 80% of facilities receiving quarterly visits |
| 8. Establish safety standards for laboratory health workers | | | |
| 8.1 Appoint safety committees at all levels | NRL | December 2007 | 75% of laboratories with safety committees or safety officers |
| 8.2 Develop and disseminate safety guidelines and appoint committee | NRL | December 2007 | Safety guidelines in use in 80% of facilities |
| 8.3 Upgrade storage facilities to set standards of safety | MOH and NRL | December 2007 | 80% of facilities meet national requirement of safety standards |

| Activity | Responsible Party | Time Frame | Indicator |
|--|-------------------|---------------|---|
| 9. Establish ethics guidelines | | | |
| 9.1 Develop and adopt national code of ethics | NRL | December 2006 | Code of ethics developed and adopted by the Biomedical Council |
| 9.2 Establish national and local ethics committees | MOH and NRL | December 2009 | National ethics committee established National ethics guidelines in place and disseminated to local ethics committees |
| 10. Increase capacity to perform research | | | |
| 10.1 Establish medical research agency/institute to promote research and develop guidelines | MOH/MINEDUC | December 2009 | Agency/institute established and funded |
| 10.2 Develop national guidelines for research and development | MOH/MINEDUC | December 2009 | Guidelines developed and implemented |
| 10.3 Establish funding mechanism for researchers and human resource development strategy | MOH/MINEDUC | December 2010 | A minimum of 20 research posts established |
| 10.4 Move from demand-driven to commissioned research | MOH/MINEDUC | December 2010 | Number of commissioned research studies increased by 100% |
| 10.5 Create a budget line for research and development in MOH/NRL | MOH | December 2006 | Budget line created for research and development |
| 10.6 Fund laboratory-based research and researchers | MOH | December 2010 | Number of researcher posts increased to 10 Laboratory-based research projects increased by at least 50% |
| 11. Improve Partnership and Coordination | | | |
| 11.1 Coordinate implementation of standards through appropriate national committees | NRL | December 2009 | Existence of various bodies established and documentation for work completed |
| 11.2 Establish a multidisciplinary laboratory policy implementation team | NRL | December 2006 | Implementation committee appointed with multidisciplinary and multisectoral representation Quarterly progress reports submitted to MOH |
| 11.3 Advocate for donor participation and mobilize funds in the implementation of the National Medical Laboratory Policy | MOH | January 2006 | Donor support for components funds sourced |
| 11.4 Estimate cost of priority areas | NRL | December 2005 | Costing available |

APPENDIX 1. COMPOSITION OF WORKING GROUPS

1. Mr. Emmanuel RUSANGANWA, National Reference Laboratory
2. Dr. Justin WANE, National University of Rwanda
3. Dr. Laetitia GAHIMBARE, Centre Hospitalier Universitaire de Kigali
4. Ms. Emma NGOGA, King Faycal Hospital
5. Ms. Grace KAHENYA, MSH/Zambia
6. Mr. John Gatabazi, National Reference Laboratories
7. Mr. Cyprien BUTARE, Kigali Health Institute
8. Dr. Alphonse KARAGIRWA, Biomedical Centre
9. Mr. Antoine GATERA, MSH/RPM Plus
10. Ms. Christine ONYANGO, MSH/RPM Plus
11. Mr. Lawrence KALIHUNGU, Kanombe Military Hospital lab in charge
12. Mr. Elisaphan MUNYAZESA, Kigali Health Institute
13. Mr. Felix HITAYEZU, MSH/RPM Plus
14. Mr. Charles SASITA RWABUKERA, MSH/RPM Plus
15. Dr. Vianey NIZEYIMANA, Planning Ministry of Health
16. Mr. Alisen NYANGABYAKI, Centre Hospitalier Universitaire de Kigali
17. Mr. Anthere MURANGWA, Kanombe Military Hospital Laboratory
18. Mr. Pierre RUGIMBANYA, National Reference Laboratory
19. Mr. Emmanuel KAMONYO, Legal Advisor, Ministry of Health
20. Mr. Roman NTARE, Kigali Health Institute

