Maldives National Policy On

HEALTH LABORATORIES 2020

No: Policy/23-MoH/2020/01

MINISTRY OF HEALTH
REPUBLIC OF MALDIVES

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No: Policy/23-MoH/2020/01

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Foreword

The development of the National Policy on Health Laboratories is a major step in alignment with the Ministry of Health (MoH) achieving the objectives defined in the Health Master Plan, Maldives (2015-2025). It complements the current reforms and policy making of the Ministry of Health towards the goals for continued improvement of Maldives health profile and ensuring that health care services provided are safe and of high quality. The process to develop the national policy on health laboratories was initiated by the MoH resulting in this document outlining the government`s commitment for strengthening health laboratories in Maldives.

Health laboratory services provide reliable and timely results for effective medical management and also contribute to evidence-based policy making as well as monitoring and evaluation of interventions. All three components of public health activities, viz. diagnosis, surveillance and control interventions, require substantial support from health laboratories.

In the process of developing this policy, adequate analysis of the past, current and future needs of the laboratory health service have been taken into account. The policy document provides an overview of the existing system and addresses key areas that are fundamental to ensure sustainable quality laboratory services in the country.

This policy document guides the development of a national strategy for health laboratories and a budgeted action plan to ensure coordination and further strengthening of laboratory structure, function and management. A set of strategies addressing all components are recommended for the laboratory structure and functions with key indicators defined to measure and evaluate progress. This is important as strategic decisions for strengthening and improvement of clinical and public health laboratories requires deployment of substantial funds from the government's budget for the health sector.

I sincerely appreciate the continued support of the World Health Organization in developing this policy and acknowledge all the stakeholders and individuals at different levels who contributed to the process of formulating this policy. The success of this policy and strategic plan depends on its implementation by all laboratory personnel, health care providers, stakeholders within the government, and support systems to see that the laboratory system in Maldives sustains international quality benchmarks and standards in functioning and service delivery.

Ahmed Naseem
Minister of Health

Foreword

Laboratories are an essential and fundamental part of all health systems. Reliable and timely laboratory services are also crucial to a nation's health security and economy and its ability to meet obligations, such as the International Health Regulations (IHR 2005). Strong clinical laboratories provide the foundation for accurate and timely disease diagnosis, prevention, and control to improve the health and safety of populations. WHO is proud to have recognized this essential need in the country and continues to be a prominent partner in supporting development of the health sector of the Maldives.

In Maldives, the Ministry of Health (MoH) has been striving to strengthen the existing laboratory framework through a national policy that delineates the government's assurance for strengthening health laboratories. The development of the National Policy on Health Laboratories is one of the biggest steps and a major milestone that is aligned with the MoH achieving the objectives defined in the Health Master Plan, Maldives (2015-2025). It complements the current reforms and policy making of the MoH towards the goals for continued improvement of the country's health profile while ensuring that health care services provided are safe and of high quality.

The policy has been developed keeping in mind the national health context, geography and national requirements with valuable inputs from all the stakeholders, the policy takes into account Maldives' overall health capacity while informing and emphasizing the role and directives of the government to further strengthen health laboratory services so that lifesaving aspects related to diagnosis, prevention and control of disease and overall promotion of good health are aligned with the philosophy of the Health Master Plan (2016-25). This will guide all stakeholders in undertaking operational planning and allocation of adequate and sustained resources in ways that are optimal and in line with WHO standards paving the way for a safe and reliable laboratory network in Maldives.

WHO Country Office deems itself privileged to extend technical support for development of the National Laboratory Policy. As a trusted partner to Government and people of Maldives; I assure continued technical assistance to implement the national policy, plan and strategy.

Dr. Shushil Dev Pant
WHO Representative a.i

Acknowledgement

National laboratory policy defines the vision and mission of a country's laboratory system. This ensures safety and reliability of health laboratories and consequently the quality of care. The policy will also provide a framework to coordinate delivery of quality and accessible laboratory services country-wide. This will guide government and other establishments in providing quality laboratory services through strengthened governance, organization and management structures, and supportive legal and regulatory frameworks. The focus of this national policy for Laboratory services reinforce quality and safety of the health laboratory services through improved national laboratory infrastructure and support systems. Furthermore it will also enhance coordination of laboratory services across disease control programs to promote rational use of laboratory resources. Hence, systems for monitoring and evaluating will be established which will enhance quality and efficiency of the health laboratory services and provide adequate human and financial resources to ensure effective delivery of health laboratory services.

I would like to express my gratitude to WHO country office for their continuous support and guidance in assisting to develop policies for improving the quality of care. My sincere appreciation to WHO consultant Dr Anita Desai for conducting an in-depth review of current system liaising with stakeholders and adapting the policy to local context.

I am especially thankful to all stakeholders who were involved in compiling and finalizing the policy for this to be practical and easy to adhere locally.

Quality Assurance and Regulations Division at the Ministry of Health has been the process-owner of this endeavor. The immense efforts, involvement, timely comments, collaboration and the dedication to bring make this happens was priceless and highly acknowledged.

Thasleema Usman
Commissioner of Quality Assurance

Abbreviations

AIDS: Acquired Immunodeficiency Syndrome
AMR: Anti-Microbial Resistance
ARI : Acute Respiratory Infections
CME: Continued Medical Education
CQI: Clinical Quality Improvement
ELISA: Enzyme Linked Immunosorbent Assay
EQAS: External Quality Assurance Scheme
FDA: Food and Drug administration
HBsAg: Hepatitis B Surface Antigen
HBV: Hepatitis B Virus
HCV: Hepatitis C Virus
HIV: Human Immunodeficiency Virus
HR: Human Resource
IHR: International Health Regulations
LIMS: Laboratory Information & Management System
LIS: Laboratory Information System
LT: Laboratory Technician
MDR: Multiple Drug Resistant
MoH: Ministry of Health
MTA: Material Transfer Agreement
M&E: Monitoring and Evaluation
NAB: National Accreditation Board
NGO: Non-Governmental Organization
NLCC: National Laboratory Co-ordination Committee
NRL: National Reference Laboratory
PEP: Post Exposure Prophylaxis
PHL: Public Health Laboratory
POCT: Point of Care Testing
PPE: Personal Protective Equipment
PWID: People who inject drugs
QA: Quality Assurance
QC: Quality Control
QMS: Quality Management Systems
RAHS: Regional and Atoll Health Services
SOPs: Standard Operating Procedures
STI: Sexually Transmitted infections
STO: State Trading Organization
SWOT: Strength Weakness Opportunities and Threats
TAT: Turn Around Time
TB: Tuberculosis
TOT: Training of Trainers
TWG: Technical Working Group
WHO: World Health Organization
WHO-LAT: World Health Organization – Laboratory Assessment Tool
XDR-TB: Extensively Drug Resistant Tuberculosis

BACKGROUND

An archipelago, Maldives, consists of a chain of 1192 coral islands that stretch 820 km in length and 120 kms in width covering a geographical area of approx. 90,000 square kms of the Indian ocean and with a land area of 298 square kms. The islands form 26 natural clusters (atolls) which are administratively grouped into 20 atolls and at present 188 islands are officially declared as administrative islands. In addition, there are 239 islands of which 109 are designated as tourist resorts and 128 islands are used for agriculture and industrial purposes.

Maldivian economy is largely dependent on the tourism industry and the country is recognized as a middle-income country in the region. Poverty has shown a consistent reduction from 31% in 2003 to 24% in 2010, however, the gap continues to be a concern. The census in 2014 estimated a population of 402,071, with Maldivians representing 84% of the population while 16% of the resident population is expatriates. About 38% of the population is concentrated in the capital city Male.

Many of the aspects of the country's economy with high public spending present a challenging situation of it being vulnerable to external shocks. Most of the foodstuffs, basic necessities and items for the tourism industry and the country's population are imported. This external dependence on commodities along with geo-spatial vulnerabilities of Maldives makes sustainable development a continuous challenge.

Health system

The public sector conforms to the largest share of the health system in Maldives and is supported by private health care providers for curative and diagnostic services. Another key sector are the voluntary non-governmental parties working on specific health issues. While the public system extends to all inhabited islands, private and voluntary services are concentrated in Male. The health system is also supported by external foreign development partners.

The health care delivery system is organized into a tier system with island level primary health centers, a higher level of health facilities with specialty care hospitals at atoll level and tertiary care facility at the urban level. Health policies with regard to public service delivery include establishing a public health facility either a hospital or a health centre in each inhabited island and developing tertiary services at selected urban locations. The service level is decided depending on the level of population, patient load etc. Each atoll has a hospital providing service to the population of that atoll. Kaafu atoll is an exception where Male is located and has the country's referral health facility Indira Gandhi Memorial Hospital (IGMH), Hulhumalé hospital and Villimalé hospital along with hospitals managed by National Defense Force and the Police service and an urban primary health care facility. The hospitals at atoll levels are referred to as regional or atoll hospitals graded to 3 levels based on secondary and specialists care and each atoll covers a population of 5,000 to 15,000 people. In 2016, MOH records show that there are 23 public hospitals with IGMH as tertiary hospital, 6 regional hospitals, 14 atoll hospitals and 172 primary health care centers.

Health care services including medical examination, investigations, immunization, antenatal care, drugs etc. are provided free to all Maldivian citizens. The delivery of services at primary health centers at rural level are challenged due to the geographic isolation of the islands and human resources, specialties, supplies, equipment and management. Although there is continuous training and re-training of health care personnel, ensuring quality service delivery to all inhabited islands continues to be a challenge. Added to the geographic challenges, are resource management, limited career development and professional development opportunities leading to low retention of trained staff.

Health service besides routine care has in-built systems for preparation and response to public health emergencies and disasters. Sea ambulance service has been initiated since 2014 with the aim of providing emergency transport between islands to ensure appropriate emergency care. Maldives Red Crescent was established in 2009 which actively promotes volunteerism and develops community capacity for emergency preparedness, first response including in public health epidemics and pandemics.

Since 2014, a number of reforms were brought into the public health care system. The government has entered into a partnership with the State Trading Organization (STO) in 2014 outsourcing the supply of medical supplies to the public health care delivery system. Other policy initiatives included the establishment of a national diagnostic center that can be accessed by all health care facilities.

Private and voluntary health sector in Maldives although small is vigorous and distributed widely across the islands. ADK is the main private hospital in Male. According to the MOH, out of the total 202 private health care institutions, about 50% are located in Male'. In addition, a number of non-government (NGOs) work on specific disease conditions, disability, child rights youth and human rights contributing to health outcomes.

Health Care Financing

The primary focus of the government is to provide equitable access to primary health care and sustain uninterrupted service delivery at all levels. In 2012, the social health insurance scheme was universalized and rebranded as 'Aasandha'. Under the insurance scheme, the rural population has free public health care with free referrals. Only in life threatening emergencies ambulance or air travel referrals are done to the nearest hospital including sea transport or air travel as well as treatment abroad for services not available in the country.

Quality of health care is assured through relevant health regulations (i) by licensing of health care facilities, pharmacies, health care professionals and registration of medicines and vaccines. In addition, a number of national standards and protocols are developed and implemented to ensure patient safety in the provision of care and management. However, due to high professional staff turnover and high reliance on expatriate health professionals, maintaining consistent use of the standard guidelines and protocols is a challenge.

Health situation

There is continued emphasis on universal health coverage and reducing communicable and non-communicable disease conditions and conditions resulting from exposure to environmental factors with health risks. Several factors have contributed to the increase in life expectancies such as improved accessibility to health care, improved levels of education and economic standard of living, access to safe water and hygiene technologies, increased awareness leading to increased health care seeking behavior and healthy practices at household levels.

However, challenges remain. There is emerging indication of the in-country spread of HIV in recent detected cases due to practices such as unprotected sex, commercial sex work, and needle sharing amongst PWID. Prevention of mother to child transmission of HIV infection is given special attention and women screening for HIV and other STIs is nearly universal in ANC. Hepatitis is also a significant disease that has the high risk of transmission. Although, infants are vaccinated under routine EPI and safe blood practices are maintained surveillance needs to be strengthened and a comprehensive strategy for prevention and control of hepatitis needs to be developed.

Maldives is moving from a high burden of communicable diseases towards an increasing burden of non-communicable diseases. The challenge remains of controlling non-communicable diseases and addressing social determinants of health while continuing to strengthen preparedness and control of emerging and re-emerging communicable diseases. Although progress towards combating measles, malaria and other diseases has been made, the focus needs to achieve the SDG commitment to end epidemics of AIDS, tuberculosis and other communicable diseases. Notable achievements have been made in the control of many communicable diseases. The country is malaria free and no cases have been seen since 1984. Vaccine preventable diseases have also been controlled to such an extent that diseases like polio, neonatal tetanus, whooping cough and diphtheria are non-existent. Maldives has received the Malaria free status certification in 2015 and Filaria free status certification in 2016 and. Maldives is marking towards the target of zero leprosy

However, tuberculosis is re-emerging in recent years. Prevalence of sputum positive cases per 1000 cases varying from 0.124 (2001) to 0.16 (2007) and to 0.07 (2011) is associated with poor case detection and management reflected in lowering of the success rate in treatment and the emergence of the MDR-TB and XDR-TB.

Dengue, diarrheal diseases and acute respiratory infections (ARI) continue to cause significant morbidity. In 2012, ARI, viral fever and diarrheal diseases were the communicable diseases with the highest incidence, amounting to 4748, 2120 and 694 per 100,000 population respectively. Diseases such as scrub typhus and toxoplasmosis have also emerged and continue to be endemic. Further improvements with regard to safe drinking water, improved sanitation and waste management along with public education on hygiene and disease prevention practices are required for further elimination of infectious diseases.

An emerging public health concern is that of diseases spread through animals' birds, rodents and insects. Although a mechanism for screening and quarantine of animals has been initiated, further strengthening for effective control of infectious diseases transmitted through these agents is required.

Chronic non-communicable diseases have emerged as the main cause of morbidity and mortality in the country. Cardiovascular diseases, chronic respiratory diseases, accidents and cancers are the leading causes. Other major concerns are thalassemia and other haemoglobinopathies, chronic renal diseases, congenital heart diseases as well as auto-immune diseases.

Maldives Health master Plan (2016-2025) is the main health policy document produced by the Ministry of Health. Health policy refers to decisions, plans, and actions that are undertaken to achieve specific health care goals within a society. A national laboratory policy is being proposed as a commitment of Government of Maldives to the national efforts of improving health care. It defines priority areas such as laboratory infrastructure and equipment, human resource development, bio-safety and bio-security, laboratory information systems, organization and management which includes service delivery system, service package, management structures and monitoring and evaluation. It also affirms the role of other determinants of health (food and drug safety) underlying the need for a multi-sectoral approach to health.

Delivery of high-quality laboratory services, a critical component of comprehensive health care, is essential both for clinical decision making and to measure and monitor biological and environmental markers. Emerging natural and re-emerging threats to the health of the population require development of a seamless laboratory network to address preventable health risks. Development and strengthening of laboratory services should be planned, ensuring integration with other health system components, existing policies, strategies and availability of resources.

With this background, the need for the National Laboratory policy, Strategic and Operational Plan is strongly felt. Complemented and collaborative efforts from committed laboratory personnel, the Government and support partners can result in effective measures to strengthen health laboratory services in Maldives.

INTRODUCTION

The role of laboratory services, is integral and important to both clinical and public health functions. Laboratory services provide required diagnostic support to curative and preventive health services, health promotional activities and research. Reliable laboratory investigations are critical components for clinical decision making, guiding early and appropriate treatment and rational use of essential drugs and are also essential for the surveillance and control of diseases of public health importance. Quality health laboratory services also enable evidence based policy decisions, monitoring and evaluation of impact of interventions, and health research activities. Laboratory services need to be considered as an integrated programme and not fragmented with only parts of the system strengthened to support specific disease control activities.

A national health policy, strategic planning, supported with appropriate legal regulations is required to provide comprehensive quality health laboratory services. The laboratory policy document provides guidance in key areas that are fundamental to ensuring sustainable quality laboratory services. These include coordination and management, structure and organization, regulations, quality system, laboratory information management, infrastructure, human resources, and bio-security and bio-safety management in order to standardize and strengthen the laboratory system to deliver reliable and timely services.

This policy document provides an overview of the existing laboratory system and addresses all key issues for delivery of quality laboratory services in the country. Further, the document shall provide a basis to the development of a National Strategy and an operational plan for Health Laboratories to ensure coordinated strengthening of laboratory services and to meet the goals of the national health plan and policy and requires all stakeholders to undertake operational planning and allocate adequate and sustained resources. Ministry of Health has been keen to strengthen the framework through a national policy that delineates the government's assurance for strengthening health laboratories in Maldives.

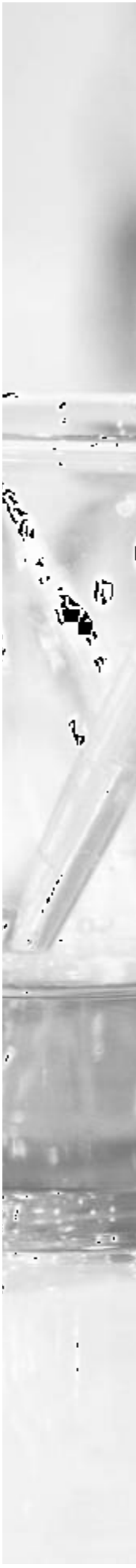
Laboratory service objectives

WHO, Health System framework comprises of six building blocks. Health laboratory services are part of one of the six building blocks. Disease surveillance, diagnosis, prevention, treatment, and health promotion largely rely on laboratory services. In addition, accurate and timely detection of emerging and re-emerging diseases, characterization of known and novel pathogens, emergence of antimicrobial resistance (AMR) in the country are necessary to direct focused interventions and bio-security measures to curtail the problem before reaching catastrophic proportions.

Laboratory services sector defines the following major objectives in execution of its mission:

(i) to provide standard packages of laboratory tests at each level of care and promote their rational use to ensure diagnosis, treatment and surveillance;
(ii) to provide the updated information and necessary knowledge, skills and competencies, to support the service;
(iii) to maintain ethics and professionalism among laboratory personnel;
(iv) to establish appropriate laboratory designs for each level of care;
(v) to provide appropriate equipment and supplies at each level of care;
(vi) to ensure excellence in laboratory services by establishing a quality assurance system;
(vii) to strengthen bio-safety practices and provide a waste management plan
(viii) to promote partnership and collaboration at local, regional, and international levels.
(ix) To digitalization of laboratory services linked with overall Health Information System (HIS)

The national laboratory policy addresses all facets of laboratory operations at all levels, including the public and private sector, with the underlying philosophy that quality services should be available and accessible to all people of Maldives. The national laboratory policy has been developed considering the national health context, geographic constraints, socioeconomic factors and in alignment with international best practices to enable laboratories to provide comprehensive support to the clinical and public health system.



Key Elements of the National Laboratory Policy

The primary aim of the national laboratory policy is to inform and emphasize the role and directives of the government to strengthen the health laboratory services in all its dimensions for the diagnosis, prevention and control of disease and overall promotion of good health in alignment with the philosophy of the Health Master Plan (2016-25).

- Strengthen the regulatory mechanism for effective networking in improving the service delivery especially referrals to deliver comprehensive service
- Upgrade the infrastructure and general management of laboratories to achieve the objectives of clinical and public health services
- Upgrade the laboratory facilities when required and in accordance with the changing health needs and technology and emerging public health concerns to meet updated international best practices
- Recruitment of qualified laboratory personnel with continuous national and international training for the upkeep of quality laboratory services
- Implement quality assurance in laboratory services at all levels supported by adequate resources
- Strengthen bio-safety and bio-security in laboratory services to ensure occupational safety and mitigate epidemics and pandemics of international concern
- Encourage periodic surveillance for execution of focused interventions and, operational and clinical research through innovative concept
- Strengthen the mandate of the National Referral Laboratory in clinical laboratory services and public health collaborating with regional and international laboratory network.
- Define the core functions – treatment and monitoring, guiding public health interventions for disease prevention and control, surveillance, rapid response to disease outbreaks, and operational research.

COORDINATION AND MANAGEMENT

Coordination

Ministry of health is responsible for coordination of health laboratory services in Maldives and provides supervision to the health laboratory network for clinical and public health purpose, under this plan or Health Master Plan or Strategic Action Plan. There are linkages with Regional and Health Services (RAHS), Quality Assurance and Regulations Division (QARD), Health Protection Agency (HPA) and disease control programmes in the provision of laboratory support for quality, surveillance, outbreak detection, preparedness and response. There is no advisory committee for technical/management support, however, oversight for regulation of laboratory services including the private sector is in place and mandated by the QARD.

Funding

Laboratory services at government health facilities are funded from the government budget. However international development partners extend their support in strengthening laboratory services

Equipment and supply management

The equipment and supply chain management have a centralized system. IGMH indents its requirement and procurement of equipment and supplies through the State Trading Organization (STO). However, areas in inventory control, forecasting, contract system especially equipment and diagnostic kit validation are still insufficient. Supplies to the laboratories at regional and health centers are provided directly by STO and pre – verification and procurement process is done by RAHS. Regulations for pre-qualifications of essential equipment and supplies exist for selection of few diagnostic kits, but not for all.

ORGANIZATION AND STRUCTURE OF THE LABORATORY SYSTEM

Structure

The Department of Laboratory Medicine at the IGMH, is the main national laboratory which works as the national referral laboratory where required. Under the overall guidance of the Ministry of Health, (i) IGMH implements laboratory services in alignment with national programs where required. (ii) functions as the central laboratory for clinical and public health services, and strengthens WHO-recognition for influenza, measles and laboratories.

There is a structure of clinical laboratories in the country designated as LI, LII, LIII, Based on criteria for HF grading arranged in a tiered structure of laboratories at different levels of the health system, depending on hospital beds, functions and the population size.

Blood transfusion services are closely integrated with the health laboratories. In addition, there are some laboratories run by NGOs as well as private laboratories.

Reference laboratories

The Department of laboratory medicine at the IGMH, is the main central/national reference laboratory providing laboratory support for clinical and public health needs where required. The hospital laboratories provide a tiered laboratory service, and tests not done at lower levels are referred to the next higher level or the central level.

Disease control programmes have laboratory diagnostic support according to the programme needs. WHO accredited and certified laboratories - the National Polio programme, National Measles and Rubella programme, Influenza Surveillance, HIV control programme and the National TB control programme provide reference facilities to the rest of the laboratories. The laboratory surveillance is a part of an early warning system for detection of outbreaks in coordination with the Health Protection Agency.

Triple packaging materials are available at laboratories for safe sample collection and hazardous materials shipping. Transportation of infectious samples between islands through courier service by sea / air is not streamlined and therefore patients are directly referred to the central laboratory. On the other hand, both government and private hospitals refer samples out of country when a particular investigation is not available within the country. The mechanism for reference is standardized

Networking

As a National Polio Laboratory, National Measles Laboratory, National referral center for AMR and Influenza Surveillance Centre, the Department of laboratory medicine, IGMH, is part of the global WHO network.

Networking of laboratories within the country is not streamlined. The feasibility of linking laboratories at Health Centers to those at the Atoll and Regional hospitals is required for improving the service delivery as well as for effective mentoring.

REGULATIONS

All clinical laboratories are mandated with a legal requirement to be registered and acquire an operating license from the Ministry of Health. This includes both public and private laboratories. Standalone laboratories are given a registration and license to operate while laboratories attached to health facilities are given approval to operate attached with facility registration.

Laboratories are issues a license to operate after an inspection by QARD based on current clinical laboratory standards. One of the criterions to issue an operating license to a laboratory is that the professionals working in that laboratory are licensed to practice by relevant councils.

QUALITY SYSTEM

The Department of laboratory medicine at the IGMH and MBS participates in EQAS in most areas and few private laboratories. However, EQAS programs are not established in both public and private sectors a mandatory requirement. A national board for management of quality of laboratory services currently does not exist.

National standards

A national standard for laboratories was prepared in 2013 based on the ISO 15189 guidelines. There is a standardized list of service package (tests) for all laboratories. Standardization of overall laboratory services, including the tests available at each level of laboratory and minimal staff requirements (numbers and qualifications) needs to be reviewed periodically and updated as per the requirement to ensure feasibility and cost-effectiveness without compromising service availability.

Quality assessment

IGMH provides kit / test validation support for kits requested from QARD, Ministry of Health Quality assessments are done for measles and influenza at IGMH. Currently there is no national board for laboratory certification or accreditation.

There is no guideline on the assay / kit to be used for a particular laboratory investigation; consequently, there is no uniformity in usage of diagnostic kits for a particular investigation/ analyte. The kits procured by the STO are CE certified, however, there is no system for in-country validation / evaluation of the batches procured for use including the private laboratories.

LABORATORY INFORMATION MANAGEMENT

Laboratories share data in a standardized format in paper form through monthly and weekly reports with health authorities. All clinical laboratories share relevant laboratory surveillance data with the Health Protection Agency. Laboratory information management system (LIMS) is not yet initiated. The government is initiating computerization to achieve information management systems which is linked with overall health information system for easy data collation to enable prompt and evidence based decision making.

INFRASTRUCTURE

The laboratory infrastructure is varied with well-designed and equipped laboratories at some levels. The national standards for clinical laboratories (2013) details the infrastructure requirements, including specifications for accommodation and environmental conditions, layout, electricity and other requirements including laboratory waste management.

HUMAN RESOURCES

The laboratory personnel in Maldives are dedicated and hardworking, and possess the requisite knowledge and skills. There is an inventory of laboratory staff in the country with their respective institutions. Although skilled staff are available at all levels, staff retention continues to remain a challenge.

Pathologists and microbiologists are medical doctors having international diplomas, degrees, under graduates or master's degrees. A number of medical professionals are expats. Medical Laboratory technologists have received diploma's, bachelor's (BSc MLT) and master's (MSc MLT) degree programmes in Medical Technology. All professionals are registered by the relevant Councils. All lab technologists trained abroad are mandated to do a competency exam to qualify for registration.

Currently, continuing professional education though considered not mandatory for registration renewal, it carries a high weightage when doing performance appraisals.

BIO-RISK AND BIO-SAFETY MANAGEMENT

The national standards for clinical laboratories (2013) detail the requirements and practices to ensure safe work environment. The international bio-safety guidelines are followed and instructions for infection prevention and control and medical laboratory waste management are documented. Dedicated occupational health services for laboratories and other workforce in the public sector are limited. Emergency treatment/post-exposure prophylaxis is provided through the hospitals. Hepatitis B vaccination is part of the national immunization programme and a policy to vaccinate all health care professionals against hepatitis B exists. A document with standard protocol for post exposure prophylaxis is available. Monitoring of private laboratory facilities for enforcing best practices in bio-safety and waste management is done during routine inspections.

Personal protective equipment (PPE) and triple packaging materials are available at laboratories for safe sample collection and shipping of biological samples and hazardous material. Transportation of clinical samples by local carriers / couriers within the country's laboratory network is not streamlined.

SWOT ANALYSIS

Strengths

- Structured Lab network.
- Dedicated skilled workforce
- Initiation of QMS
- WHO certified laboratories
- Standards for laboratories

Weaknesses

- Governance mechanisms for health laboratories
- Central Database
- Prioritization of laboratories within the health system
- Surveillance

Threats

- Emerging & re-emerging disease
- Communicable and non-communicable diseases
- Challenge to retain skilled workers

Opportunities

- Collaborations within the health sector
- Collaborations and partnerships
- E-Governance and reform initiative

Any shortcomings in the laboratory system can be overcome through a mechanism for an advisory committee within the Ministry of Health with a regulatory framework for laboratories and ensured financing of health laboratory services. A governance structure is required for periodic strengthening of infrastructure, referral management in the laboratory network, skills development and continuous professional education, retention of laboratory staff; quality assured equipment, reagents and diagnostic tests with efficient and uninterrupted supply chain management and equipment maintenance programmes. Monitoring of laboratory investigations / referrals can limit inadvertent expenditure and work load. Strengthening of surveillance programmes for communicable and non-communicable diseases including those for AMR are required. Accreditation of laboratories in a phased manner to strengthen credibility needs to be initiated.

VISION, MISSION, GOAL AND OBJECTIVES OF THE MALDIVES NATIONAL POLICY ON HEALTH LABORATORIES

VISION

Comprehensive and quality assured laboratory services, which are accessible to promote the well-being of the population

MISSION

Through government oversight strengthen laboratory services for all people to have equitable access to quality laboratory services at all levels of care

GOALS

Provide sustainable and quality assured health laboratory services to support the delivery of Universal Health Coverage at all levels

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 guiding principles: would be quality of laboratory services, efficiency, inter-sectoral coordination, community participation and integration.

KEY OBJECTIVES

- strengthen the organizational and management structures for coordination and integration of laboratory services to support health objectives.
- establish governance mechanisms for laboratory oversight, accreditation networking and information management.
- To provide the necessary knowledge, competencies, and skills and maintain professionalism among laboratory personnel; motivation and retention of adequate numbers of human resources aligned with the requirement of the laboratory.
- To review and revise national laboratory standards.
- To establish a National Reference Laboratory
- Strengthen biosafety and biosecurity in the laboratory and health system
- To promote partnership and collaboration at local (intra-sectoral and inter-sectoral), regional, and international levels to review and adapt appropriate new technologies.
- To support operational research for strengthening health laboratory services.

COMPONENTS OF THE NATIONAL LABORATORY POLICY

The policy outlines the principles and goals and provides strategic guidance and directions to the public and partners in health to further develop programs and plans for quality delivery and improvement of the laboratory services in the country.

COORDINATION AND MANAGEMENT

Governance mechanisms are necessary to ensure reliable laboratory services through effective coordination, funding and equipment and supply management. Effective coordination and management need to be in place to strengthen the functioning of laboratories in Maldives, and an oversight for implementation of the national laboratory policy, strategy and action plan.

Coordination

A National Laboratory Co-ordination Committee (NLCC) shall be established by the Ministry of Health with a designated chair and co-chair. The committee membership shall consist of representatives from the departments / divisions of medical services, public health, environment protection agency, human resource division, Maldives food and drug authority and laboratory specialists from both public and private sector.

The National Laboratory Coordination Committee shall have an advisory role for laboratory issues and should:

1. Endorse national standards, guidelines, strategies and plans for laboratory services;
2. Endorse networking of laboratories and information sharing
3. Ensure bio-security and bio-safety management in the health system;
4. Facilitate alignment of laboratory and blood transfusion services;
5. Endorse the acceptability of new developments in medical laboratory technology
6. Facilitate national/international collaboration for laboratory research

Funding

The budget for laboratory services is coordinated by the MOH as part of the overall health system budget. The Ministry of Health commits to provide budgetary and logistic support for implementing the national laboratory policy.

Equipment and supply management

The QARD of MOH shall provide a standard list and specifications for laboratory equipment to be used at all levels of the health system.

The RAHS division at MoH and IGMH shall establish guidelines on procurement procedures for laboratory equipment, reagents, and supplies.

The QARD of MOH shall ensure that public laboratory facilities are equipped according to established standards.

Procurement and donation of laboratory equipment, supplies, and reagents shall conform to nationally established standards.

A central and regional workshop on maintaining laboratory equipment shall be established to operate in accordance with national guidelines and standards.

A review of the equipment procurement and supply chain management shall be done to identify bottlenecks, ensure cost-effectiveness and to streamline the system, in collaboration with procurement agency

QARD of MOH shall strengthen the registration system for the official inventory of important equipment, test kits and other supplies. Periodic review of essential equipment, test kits, other supplies, including technical specifications, shall be organized.

Costs for routine equipment maintenance to be built-in at the time of purchase, and reliable after-sales service ensured through authorized dealers/agents.

STRUCTURE AND ORGANIZATION OF THE LABORATORY SYSTEM

The laboratory system in Maldives is well structured to provide comprehensive laboratory support for clinical and public health activities. However, the structure and organization of the laboratory system needs to be periodically reviewed to ensure delivery of people-centered laboratory services

Health laboratories must provide the following:

- Clinical diagnostic services to support management of patient care;
- Public health services to support disease control of priority diseases and manage outbreaks;
- Reference laboratory services;
- Services to coordinate training and capacity development of laboratory personnel, and monitoring and evaluation;
- Services to strengthen IQAS, EQAS and bio-safety;
- Support of operational research to improve delivery of health laboratory services.
- Surveillance to obtain national figures on disease prevalence, trends and shifts to plan interventions and prevention strategies

At the regional level and below, blood transfusion services are closely integrated with the health laboratory, and these should also be effectively supervised in collaboration with the National Blood Council.

QARD at MoH should also provide technical oversight to laboratories run by private organizations and NGOs. Information related to the general functioning of these laboratories and quality management must be shared with the QARD of the MOH.

Laboratory supervision and technical support must be provided to laboratories lower in the tiered network by upstream laboratories, with reporting mechanisms and routine flow of data/information in the opposite direction, with horizontal collaboration among laboratories. The policy recognizes the inter-relationship between communicable disease programmes and public health system strengthening. This could be through a network of well-equipped laboratories backed by tertiary care centers and enhanced public health capacity to collect, analyze and respond to disease outbreaks.

The Head of Department of Laboratory medicine at IGMH is the laboratory focal point (Technical) and QARD laboratory professional is the Administrative focal point for health laboratories. Together they steer the National Laboratory Coordination Committee. The NLCC should propose adjustments to current staffing levels to ensure that the following are carried out:

1. Implement the endorsed National Strategic Plan for Health Laboratories (and a budgeted action plan), with effective monitoring and evaluation, to strengthen clinical and public health laboratory services in the country;
2. Establish a national network of laboratories and blood banks. Develop and implement a national laboratory information system aligned with overall health information system for data sharing and analysis to monitor trends for action, forecasting and guidance of the planning process;
3. Develop national bio-safety and infection prevention and control guidelines (including guidelines for sterilization and disinfection; isolation policy; standard precautions: safe collection, transportation and storage of infectious material; and facilitate development of standard treatment guidelines and empiric antibiotic policies.
4. Review, revise and implement national standards for laboratory services.
5. Study the feasibility of adopting new developments in laboratory technology.
6. Propose collaboration and linkages with national and international partners;

Regional Reference laboratories

A review of the regional laboratories should be done to identify centers of excellence (with development of appropriate benchmarks) for official nomination and recognition as national intermediate reference laboratories.

Networking mechanisms

A national network of laboratories should be established. The department of laboratory medicine at IGMH could be recognized as the National Reference Laboratory (Apex lab), with 4-5 Regional Reference laboratories (RRLs) situated at major atoll / islands. The Atoll hospital laboratories could be linked to the RRLs within the zone for easy referral and transport of samples. The laboratories at the health centers could be linked to the Atoll hospital laboratories within the specified region / sector. Periodic meetings to facilitate mentoring and support information and experience sharing need to be encouraged.

REGULATIONS

Adherence to national standards and norms for laboratories has to be monitored and strengthened. A national accreditation system which will accredit laboratories (facilitated by the QARD) to strengthen the regulation of health laboratories in Maldives should be established. The licensing of private and endorsement of public laboratories must follow the revised national standards for laboratories. Periodic on-site visits for inspection and if required mentoring needs to be fostered. The policy advocates a positive pro-active engagement with the private sector for critical gap filling towards achieving national goals on delivery of laboratory services.

QUALITY SYSTEM

Establishment of sustainable laboratory quality management system is essential to ensure reliable and accurate laboratory results in Maldives.

National standards and laboratory packages

National standards for laboratories, including infrastructure, tests, techniques, bio-safety and equipment, must be reviewed and revised. The laboratory infrastructure should be strengthened as per the national standards.

Laboratory tests shall be selected and standardized for each level of the health care system according to the package of care defined for each level. Provision of diagnostic kits and reagents of assured quality is mandatory and must be governed by relevant national guidelines procedures. 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.

Guidelines for the rational use of laboratory tests shall be provided to all levels of the health care system. All clinicians shall be trained in the rational use of laboratory tests in accordance with the Standard operating procedures (SOPs) developed for each level of the health care system.

Standard operating procedures

Standard operating procedures shall be developed and implemented for each level of the health care system SOPs for safe collection, storage and transport of infectious materials must be developed, and implemented in coordination with the Ministry of Transportation and Communications.

Internal quality control and analysis of performance

Internal quality control practices shall be developed and strengthened in all laboratories. The practice of analyzing the performance of these internal controls as a quality indicator of the laboratory needs to be emphasized.

National External Quality Assessment Program

A National External Quality Assessment Program (NEQAP) shall be established to monitor the quality of laboratory results at regional hospitals, atoll hospitals, health centers and referral hospitals as well as at private laboratories. NRL should coordinate with MoH to establish EQAS for all commonly performed tests in all government laboratories and extend the EQAS to private laboratories. The MOH shall monitor the EQAS programmes at peripheral laboratories. A national quality manager shall be designated to provide guidance on implementation of the quality management system in the laboratories.

Reference laboratories shall be subject to external accreditation and affiliations with internationally recognized external quality assessment programs for each laboratory discipline.

National Accreditation Board for clinical laboratories

The national accreditation board to be implemented for clinical laboratories should develop the quality and accreditation standards for all laboratories. Technical assessment teams should be formed after training and skill development of experienced national staff. On-site visits should be organized and this shall facilitate the process of formal accreditation of laboratories in Maldives based on national/international standards.

LABORATORY INFORMATION MANAGEMENT SYSTEM

Laboratory information management system is required to ensure better laboratory services and aid in efficient decision-making for policy changes and interventions.

A national laboratory information management system (LIMS) aligned with overall health information system should be developed and streamlined in collaboration with the Health Protection Agency and the National Reference Laboratory. The LIMS 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). All central, regional and Atoll laboratories should be networked initially, with subsequent expansion to health centre laboratories. This would facilitate data and information sharing among laboratories and with central epidemiology unit and disease control programmes. The forms for data collection and reporting must be reviewed and updated in alignment with the planning needs. The laboratory information system should be a part of the early warning system for detection of outbreaks. It should also facilitate the detection of public health emergencies of international concern, under the International Health Regulations, 2005.

Health surveys are required for evidence based policy planning and reforms. Policy recommends periodic disease specific and anti-microbial resistance surveys to monitor the impact of public health and disease intervention using digital tools for epidemiological studies.

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. Collaborative efforts among various stakeholders involved in the control of epidemics and infectious diseases shall be strengthened.

Data collection and information sharing shall be facilitated in alignment with national needs, observing official rules and individual confidentiality at all times and levels. Dissemination of non-confidential information may be permitted only for health promotion, disease prevention and capacity building endeavors.

INFRASTRUCTURE

Laboratory Design

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. The designated authority under the MOH shall approve the design and drawings for the construction / design of a medical laboratory.

The designated authority under the MOH shall carry out annual inspections of laboratory infrastructure to ensure conformity with established standards for health facility design. The designated authority shall be mandated to close down any laboratory that does not meet the specifications and standards set for laboratories.

An electronic inventory of all health laboratories should be prepared to enable development of an infrastructure strengthening plan. National norms and standards shall be developed for laboratories at various levels. Laboratory infrastructure shall be strengthened periodically and as and when required in alignment with national standards, guided by a plan to strengthen the laboratory infrastructure in Maldives.

HUMAN RESOURCES

Education and capacity development

The policy recognises that human skills resource management is critical to the health system. To strengthen the capacity and skills development of the laboratory workforce in Maldives the Government shall upgrade and strengthen medical laboratory training institutions by providing resources (qualified teachers, equipment, and supplies) to meet the minimum standards. Training curricula shall be reviewed and updated to include emerging diseases, newer technologies, laboratory quality management systems and advances in biomedical sciences in alignment with national needs. The Government shall encourage and support the establishment of graduate and post-graduate programs in biomedical sciences. MOH shall develop a laboratory career structure and promote opportunities for continuing education to support the implementation of laboratory standards and policies. Overseas training for motivated and meritorious candidates shall be encouraged to ensure career satisfaction.

Laboratory managers and key personnel shall undergo trainings on laboratory management at different levels. Pre-service training, on-site training, e-Learning and continuous professional development should be ensured as part of the human resource (HR) development plan for laboratory staff.

Certification

The MOH shall ensure the certification of laboratory personnel and encourage the establishment of professional laboratory associations. All medical laboratory professionals shall be registered, licensed, and de-certified by a body authorized by the MOH.

Ethics

A code of professional ethics in laboratory practice including observing patient confidentiality shall be established for the laboratory staff the councils/boards under RBC of Ministry of Health shall be established to evaluate violations of the code of the ethics and recommend disciplinary actions to relevant authorities.

Human resource plan and improvement

An electronic inventory of the laboratory workforce shall be prepared. A human resource development plan for laboratory staff should be prepared in alignment with the national HR plan for health workers. Foreseeing of necessary laboratory personnel should be predicted and required budgets, teaching programme and resources development included in annual planning. Efforts should be made to facilitate a review of staff remunerations and incentives to ensure professional and personal satisfaction for better retention of the health personnel at all levels of laboratory services.

BIO-SAFETY, BIO-RISK AND WASTE MANAGEMENT

Bio-safety, bio-risk and waste management in health laboratories is one of the most essential components to safeguard the health of laboratory workers and pose no hazard to the people in Maldives. The MOH shall establish a code of bio-safety practice based on WHO recommended standards to support procedures included in the packages of care. Bio-safety committees shall be established at all levels of care to inspect the laboratories and enforce bio-safety standards and procedures.

Assessments

Bio-risk/Bio-safety assessments and evaluations must be done at various levels, and appropriate policies and guidelines must be developed to ensure containment of bio-risks and implementation of safe laboratory practices. Every hospital shall have a hospital infection control committee that audits and monitors and the laboratory must be represented on this committee.

Guidelines

Disposal of laboratory waste and biohazards shall be in accordance with relevant guidelines from relevant authorities and the national environmental protection regulations. National guidelines for bio-safety, biomedical waste management guidelines, sterilization and disinfection, isolation, infection prevention and control, safe collection, storage and transport of infectious material should be developed and needs to be reviewed periodically to include international best practices. Standard treatment guidelines for empiric and rational use of antibiotics shall be developed and implemented.

RESEARCH AND DEVELOPMENT

The Government shall promote and strengthen research in medical laboratory science / biomedical sciences. Biomedical research capacity and specialized training shall be strengthened according to national priorities.

PARTNERSHIP AND COLLABORATION

The Government shall promote and support collaboration between the public and private sectors in laboratory services. National and local biomedical ethics committees shall be established and shall work in collaboration with regional or international biomedical committees.

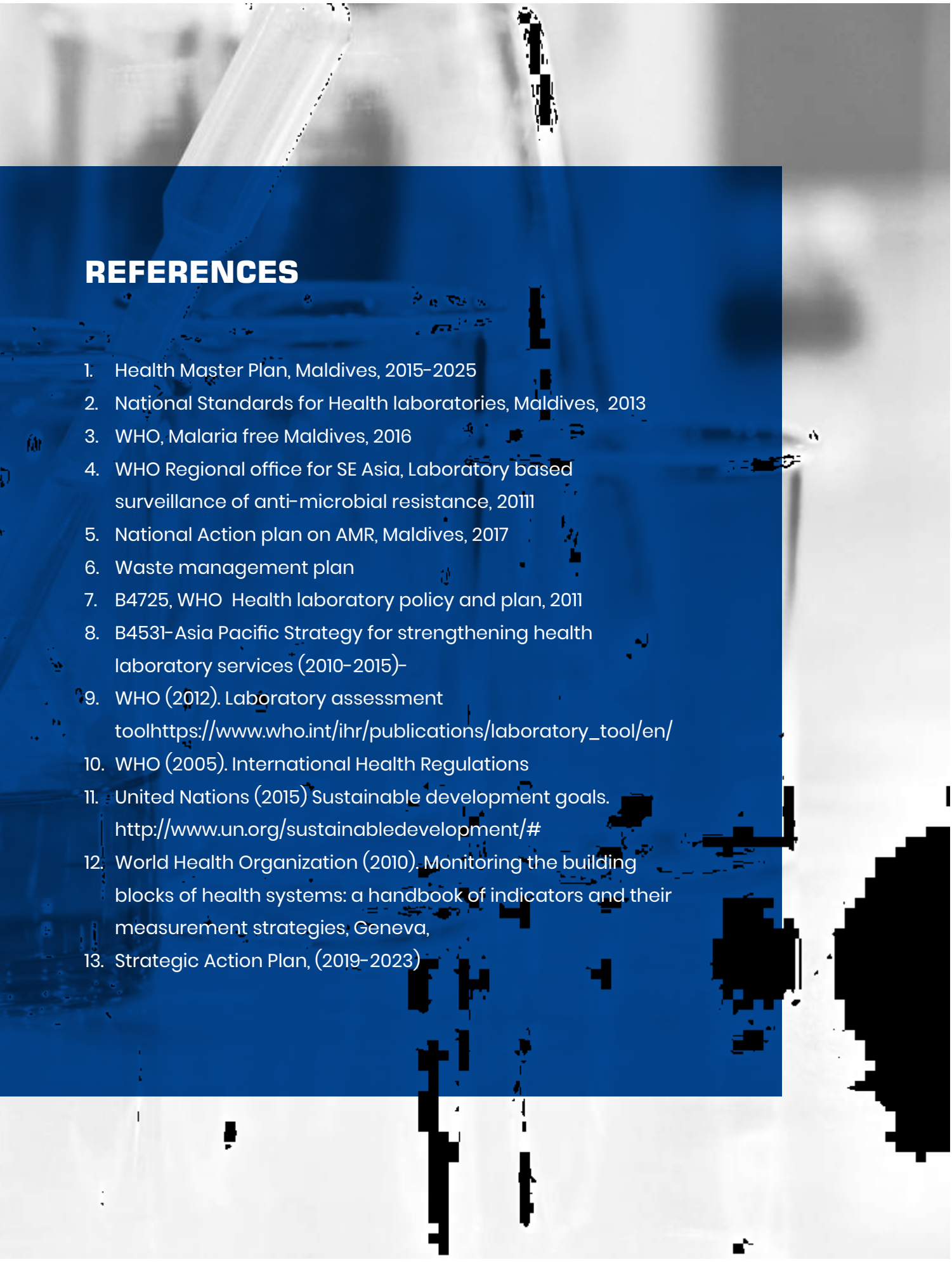
Intersectoral consultation and collaboration with ministerial partners shall be essential to implement major laboratory network strategies. The mechanisms for national and international coordination of laboratory standards and policies as initiated by the MOH and certain partners shall be put in place under the umbrella of a sector-wide approach.

IMPLEMENTATION OF THE POLICY

This policy document has been developed in alignment with the philosophy of the Health Master Plan and Strategic Action Plan and is within the context of the needs of the health system of the country. A policy is only as good as its implementation. A National Strategic Plan for Health Laboratories and a budgeted operational plan is developed facilitate the implementation of the policies and to provide detailed guidance on various actions needed to improve the laboratory systems with timelines, responsibilities, as well as with defined indicators to monitor and evaluate the progress. The operational plan will provide an insight into implementation activities, cost implications for translating the national laboratory policy into practice as well as help all stakeholders on identifying their areas of support under the directives of the MOH. The Ministry of Health shall commit to provide budgetary and logistic support for implementation of the national policy. The various administrative departments / divisions of the ministry shall guide, 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).

The national policy envisages that an implementation framework be put in place to deliver on the policy commitments. Such an implementation framework would provide a roadmap with clear deliverables and milestones to achieve the goals of the policy.

FRAMEWORK FOR NATIONAL LABORATORY POLICY



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