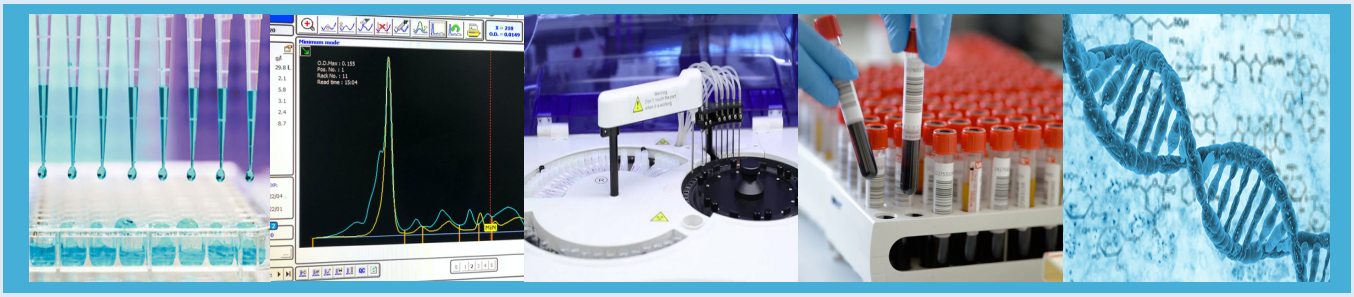
Policy and Plan for Chemical Pathology Laboratories in Sri Lanka



College of
Chemical Pathologists of
Sri Lanka

Policy and Plan for Chemical Pathology Laboratories in Sri Lanka

First edition

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College of
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Preface

Chemical Pathology is the study of the diseases by understanding the biochemical changes that occur in the body. Biochemical investigations of various body fluids such as blood, urine, cerebrospinal fluid, stool and tissue samples such as hair and nail provide valuable information on the pathology of the diseases. There are numerous chemical pathological investigations available for screening, diagnosing, and monitoring of the diseases. Chemical Pathology is the largest branch of laboratory medicine which handle more than 60% of the total number of laboratory specimens, this highlights the central role played by the field of Chemical Pathology in patient management.

The laboratory testing includes the teamwork of different categories of human resources in the healthcare service. In the laboratory, specimen processing, analysis or examination, technical and clinical validation of results and report issuing are the key functions. The Chemical Pathology laboratory staff consists of Consultant Chemical Pathologist, medical doctors including postgraduate trainees, medical laboratory technologists, orderlies and junior staff.

The Chemical Pathology testing process is a cycle which has three major phases namely pre-analytical, analytical and post-analytical phases. This cycle commences at the doctor-patient meeting and ends in the doctor again. In addition to the laboratory staff, the nurses, specimen transporters, IT providers, biomedical technicians are also involved in this cycle. They also play a significant role in providing accurate test results by the Chemical Pathology laboratory directly or indirectly.

With the establishment of the postgraduate MD in Chemical Pathology in Sri Lanka, the discipline of Chemical Pathology has developed rapidly to greater heights within a short period of time. With the increase in the number of Chemical Pathologists in the country, the College of Chemical Pathologists of Sri Lanka was established in 2015 with the aim of uplifting and setting standards of practice of Chemical Pathology in Sri Lanka. This book is compiled to fulfil a long-felt need of the country concerning Chemical Pathology services in view of providing a documented policy and a plan to develop the laboratory sector keeping with the international standards. The content of this book is based on the 2011 World Health Organization guideline on “Development of National Health Laboratory Policy Plan”.

We hope this book will be useful for the administrators as a policy and plan document, in improving standards of laboratory services in the country, thereby the quality of patientcare in Sri Lanka.

Dr B K T P Dayanath
Dr Manjula Dissanayake

Introduction

Reliable and timely results from laboratory investigations are critical elements for decision-making in almost all aspects of health care and are essential for the surveillance and control of diseases of public health importance. Improved disease recognition also improves the accuracy of health information and promotes effective national health planning. However, the laboratory services in Sri Lanka are often fragmented and accorded low priority, compounded by inadequate allocation of resources. There is no good national laboratory policy or strategic plan to deliver comprehensive and integrated quality laboratory services to those who need them in the country, at present.

The health laboratory services include all those laboratories that provide support to preventive, promotive, rehabilitative and curative health services, covering all the disciplines of laboratory medicine. The effective implementation of Health Laboratory Services requires a systematic approach to establish a coherent national framework for laboratory services.

This book addresses developing a national laboratory policy and strategic plan; defining managerial, oversight and regulatory mechanisms and establishing the required support services within the context of Chemical Pathology services in Sri Lanka.

In fact, these policies and plans can be applied in all disciplines in laboratory medicine in Sri Lanka such as haematology, histopathology, microbiology and virology in the same manner.

1

Laboratory Policy

for

Chemical Pathology

1.1

Role of the Chemical Pathology Laboratory in the Health System

Vision

Affordable, accessible, sustainable, equitable, quality Chemical Pathology Laboratory services covering the entire range of testing for the people of Sri Lanka.

Mission

Provide accessible and equitable quality health laboratory services that contribute to improved health outcomes for the people of the country, through a skilled laboratory workforce using modern technology.

Objectives

(1) To affirm government commitment and support for the institution of efficient, cost-effective and sustainable Chemical Pathology laboratory services.

(2) To strengthen the Chemical Pathology laboratory services for supporting diagnosis, treatment, surveillance, prevention and control of diseases.

(3) To establish national standards for Chemical Pathology laboratory quality management systems.

(4) To ensure the quality of the Chemical Pathology laboratory through an established quality system.
(5) To empower the establishment, implementation and monitoring of the Chemical Pathology laboratory plan.
(6) To ensure adequate financial and human resources to meet the requirements of the Chemical Pathology laboratory services.
(7) To commit to ethical values in laboratory practice, including patient confidentiality, adherence to professional codes of conduct and ethical research practices.
(8) To encourage research and collaboration to inform and improve the quality of health laboratory services.

1.2

Monitoring and Evaluation of the Chemical Pathology Laboratory Services

Implementation of the Chemical Pathology laboratory plan and annual operational plans require regular, careful monitoring to ensure that agreed activities are properly implemented, and financial expenditures are accounted for.

The following should be considered:

(1) Establish mechanisms for monitoring the implementation of activities, including identifying responsible persons, establishing regular reporting mechanisms, and holding regular review meetings with stakeholders to assess progress.

(2) Review progress through the measurement of indicators, as follows:
   (a) Activity indicators: measurement of activities conducted
   (b) Outcome indicators: measurement of outcomes and performances.

(3) Prepare timely reports addressing the review of indicators as well as challenges and constraints.

(4) Adjust activities, objectives and timelines according to the results of the review.

(5) Conduct periodic audits, both internal and external, to evaluate performance and activities, based on the essential elements.

2

Elements of the Laboratory Plan

for

Chemical Pathology

2.1

Laboratory Organizational and Management Structure

The important components of a well-organized and good management structure in a health laboratory framework includes;

A. National laboratory focal point and National Laboratory Technical Advisory Committee (NLTAC).
B. National laboratory monitoring and regulatory mechanism.
C. Laboratory structure and network.

A. National Laboratory Focal Point and National Laboratory Technical Advisory Committee

Deputy Director General-Laboratory Services (DDG-LS) is the National Laboratory Focal Point. National Laboratory Technical Advisory Committee (NLTAC) has the responsibility and accountability for steering and monitoring the medical laboratory services.

The Principal Functions of National Laboratory Focal Point

i. To ensure the development of the national health laboratory policy (NHL policy) and national health laboratory plan (NHL plan).
ii. Identification and allocation of financial and other resources for implementation of the plan.
iii. To take overall responsibility and provide guidance for implementation, monitoring and continued improvement of the laboratory services in accordance with the policy and the plan.
iv. To coordinate the establishment of national standards for medical laboratory quality systems.

v. To ensure the quality of laboratory services by monitoring and surveillance and to take appropriate measures to improve medical laboratory quality system.

Principle functions of the National Laboratory Technical Advisory Committee

I. To advise the Ministry of Health on national health laboratory policies, and relevant medical and technical developments in relation to the laboratory services.
II. To coordinate various initiatives or proposals in which the medical laboratory services can contribute to the overall health system strategy.
III. To contribute to the development of legislation and regulations related to laboratory services, as required.
IV. To regularly review and, where necessary, propose revision of the national health laboratory plan with respect to disease control.
V. To evaluate new laboratory initiatives and technologies.
VI. To provide a forum for discussion on national issues relating to the laboratory services.
VII. To provide technical inputs through expert groups on various issues concerning the health laboratory services.

B. National Laboratory Monitoring and Regulatory Mechanism

Sri Lanka Accreditation Board (SLAB) is the current monitoring body for the medical laboratories of Sri Lanka. A mechanism should be established to monitor medical laboratories through the SLAB or by a sub committee appointed by the National Laboratory Technical Advisory Committee.

The responsibility of a such a monitoring body should include

I. Guidance in drawing up appropriate legislation governing medical laboratory practices.
II. Licensing and monitoring of laboratory service providers.
III. Monitoring performance and compliance with the relevant standards, and intervening, including taking disciplinary action for non-compliance.

IV. Setting requirements for pre-service training and continuing professional development for medical laboratory personnel.

C. Laboratory Organizational Structure and Network

A well-defined laboratory structure must be established, which identifies key management and technical roles and responsibilities (job description) at each level and which establishes a functional laboratory network and referral system. The laboratory network should include a good referral mechanism, disease monitoring and response system.

These may include:

I. Identification of the roles and responsibilities, including both management, clinical & technical responsibilities, at each level of the laboratory.

II. Establishment of systems for coordination and communication, such as referral of specimens to reference laboratories within the network. The necessary guidelines and resources for specimen referral and return of results should be provided.

III. Identification of and support to national reference laboratories for specific diseases, and surveillance and response mechanisms.

IV. Establishment of mechanisms for procurement and distribution of laboratory equipment and supplies to all laboratories in the healthcare system.

2.2

National Standards for Medical Laboratory Services

National standards need to be developed as the basis for implementation of quality assured laboratory system. These standards are needed for the purpose of monitoring, regulating and accreditation of laboratory services. The standards should focus on following key elements as applied to different categories of laboratories in the network of the National Medical Laboratory System in Sri Lanka.

Key components

I. Scope of examinations (tests), testing processes, standard operating procedures (SOPs) and technologies required at different categories of laboratories. It needs to categorize the Chemical Pathology laboratories in Sri Lanka.

II. Laboratory infrastructure and facilities with essential utilities required, to provide an appropriate and safe environment for laboratory processes and procedures, staff, patients and visitors.

III. The required competency of different categories of the laboratory staff and a mechanism for competency evaluation.

IV. Selection of equipment appropriate for the tests performed at different categories of laboratories, with clear technical specifications. Such technical specifications should address geographical distribution, water quality and other factors in addition to category of the laboratory.

V. Documentation requirements including laboratory manuals describing scope of tests, specimen requirements, scope of services provided and instructions for users etc. Standard operating procedures (SOPs) in every laboratory for transportation of specimens, use of equipment, test procedures, quality management, reporting formats and guides to

interpretation, including biological reference intervals for test results and appropriate record management.

VI. Information to all laboratory users regarding the available tests, patient preparation instructions, location of testing, test indications and limitations, costs, and types of specimens required. These documents should be updated regularly.

VII. Continual review and auditing of the cost-effectiveness and appropriateness of recommended standards.

VIII. Documented procedures for clinical liaison and evaluation of customer satisfaction and complaint resolution.

2.3

Human Resource Management

Adequate number of qualified personnel are needed to implement the national medical laboratory plan. The number and types (carder) of health workers required for the optimum function of the laboratories need to be defined. Organizational structure should be taken into consideration in this process. A comprehensive national human resource plan may involve coordination with other government departments, such as the Ministry of Higher Education, and should therefore be developed to meet the projected requirements for the medical laboratory services, in conformity with the overall health workforce plan.

Key components

I. Laboratory services to be provided only by staff with recommended qualifications and relevant training.
II. Development of job descriptions for all laboratory personnel in the organizational structure.
III. Establishment of a scheme of service for laboratory workers with clear structures and opportunities for career advancement.
IV. A system of incentives to encourage staff to work in remote and underserved areas.
V. Periodic competency evaluation of staff to verify individual demonstration of necessary skills, knowledge and correct work practices.
VI. Establishment of a staff record for each laboratory worker, including personal and employment details, resume (CV), posts held and dates, authorized areas of testing, terms and conditions of employment, job description, continuing professional development, competency assessments, disciplinary actions and work injury records. This is in

addition to the personal file of the worker that is maintained in the institution.

VII. Carrying out of annual appraisals by the head of the department, using a standard appraisal tool to provide feedback to individual staff member on work performance and guide career development.

VIII. Organization of appropriate in-service training programmes for all categories of staff. Training programmes may be onsite or distance learning.

IX. Development of effective supervisory systems to monitor work performance and quality using a standard checklist. Supervision should be periodic with sufficient duration including on-site evaluation, teaching, mentoring, monitoring, quality assurance and supportive feedback. Training and evaluation programmes for supervisors should also be established.

X. Involvement in national colleges and/or regional professional association activities to promote continued professional development (CPD) and ethical medical laboratory practices.

2.4

Laboratory Quality Management System

Establishing and maintaining a quality management system for all aspects of the laboratory services are required to achieve a quality service. Monitoring and continuous improvement of quality is an essential component of a well-managed laboratory service.

Key components

I. Developing vision and mission for national medical laboratory services. These should reflect the intention and commitment of the national authorities to ensure that quality laboratory services are provided at all levels of health facilities.

II. Provision of adequate and sustainable financial resources by the government for establishing and maintaining quality laboratory systems.

III. Establishment of a network to coordinate all activities relating to the quality management of various institutions under the office of national laboratory focal point (DDG-LS) with guidance of the National Laboratory Technical Advisory Committee.

IV. Development, implementation and monitoring of quality standards in all laboratories in Sri Lanka.

V. Training of all laboratory staff on all aspects of the quality management system.

VI. Establishment, maintenance and updating of standard operating procedures(SOPs).

VII. Ensuring that a satisfactory internal quality control (IQC) program is practiced in all laboratory procedures in all laboratories in the country.

VIII. Authorization of appropriate external quality assessment schemes (EQAS) for all laboratories depending on requirements ensuring mandatory participation.

IX. Assessment of laboratory performance through internal and external audits.

X. Development of relevant quality indicators to consistently monitor and evaluate laboratory performance.

XI. Development of a national system of stepwise accreditation and support laboratories to achieve accreditation with Sri Lanka Accreditation Board (SLAB).

XII. Ensuring effective communication between laboratory staff, professional laboratory users, health administrators, technical support services, health development partners, government and other relevant stake holders.

2.5

Procurement and Supplies Management

The selection and standardization of laboratory supplies and reagents must be based on the types of tests performed and equipment used at every level of laboratory across the health care system.

Standardization promotes efficiency in inventory control, storage and distribution, quantification and procurement procedures and increases economies of scale and reduces procurement costs.

The national laboratory procurement should be in line with national procurement committee guidelines in the country. All procurement related to medical laboratory services should be under the authority of the laboratory focal point through the guidance of National Laboratory Technical Advisory Committee.

A supplies management system should be revised according to current trends.

Key components

I. Establishment of an effective national laboratory procurement and supplies management system, with appropriate storage facilities and timely distribution systems.

II. It is essential to obtain National Medical Regulatory Authority (NMRA) registration for all equipment, laboratory consumables and reagents prior to making available in the market.

III. Evaluation and validation of laboratory instrument, consumables and reagents for the first registration to be done by NMRA which is the registration authority in the country. This should be carried out by a committee consisting of well qualified Chemical Pathologists appointed by the College of Chemical Pathologists of Sri Lanka. Standard guidelines or reference to reliable evaluations and validations such as

peer-reviewed publications, WHO, USFDA, etc. should be established for this. Instrument, consumables and reagents should be subjected to regular checks thereafter. Those laboratory instrument, consumables and reagents that do not meet required standards will not be eligible to be procured.

IV. New technologies should be justified and properly placed under the concurrence of the ministry focal point.

V. Identification of national or international organizations for independent quality assurance and pre-qualification of instruments, consumables and reagents.

VI. Development of guidelines for accepting and receiving donated supplies (equipment and consumables) to ensure that they meet the required specifications and are appropriate for the laboratory and the country.

VII. Establishment of a standardized system for inventory and stock management in every laboratory

VIII. Development of appropriate systems for receipt, quality checking and storage of consumables and supplies by the laboratory and the local suppliers.

IX. Establishment of standard procedures to identify laboratory chemicals and supplies for safe disposal and prevention of biohazards.

X. A proper documentation system to be developed to record all above activities.

2.6

Laboratory equipment management

An Institutional equipment management policy must be in place. Certain institutions need to consider local requirements and facilities when purchasing equipment. This policy must address all the aspects related to such local purchase.

A national medical laboratory equipment management policy also must be in place. Major items of medical laboratory equipment are expensive to purchase, operate and maintain, and constitute the largest capital expenditure of the laboratory. This policy must address all the aspects related to bulk purchase of certain equipment in certain situations.

A medical laboratory equipment management system should be in line with the national equipment management system in Sri Lanka.

Key components

I. Preparation of specifications, evaluation and validation of new/donated equipment by institutional levels as per the standard guidelines.
II. Preparation of specifications, evaluation and validation of new/donated equipment by testing centers proposed by the National Laboratory Technical Advisory Committee, using standard guidelines.
III. Establishment of a national database of equipment including information on instrument type, operational status and service contract providers.
IV. Establishment of standard procedures for equipment purchase, using a structured checklist as required.
V. Development of guidelines for accepting and receiving donated equipment to ensure that the equipment meets the required

specifications, can be supported by local service agents, and is appropriate for the laboratory.

VI. Ensuring that all equipment is supplied with appropriate service and operation manuals in the language understood by the users, along with spare parts and service tools. Maintenance service contracts including after-sales service should be drawn up for all analytical equipment, whether purchased locally, nationally or donated.

VII. Ensuring that all major equipment is installed by suppliers, and training on equipment use, maintenance and troubleshooting is provided to relevant personnel at the time of installation or when put into use.

VIII. Development of calibration and validation protocols for all the equipment in a centrally coordinated plan.

IX. Development of SOPs for equipment use, care and maintenance and disposal of obsolete or unserviceable equipment.

2.7

Laboratory Information Management

The national laboratory information management system (LIMS) is used to generate relevant information and provide data for evaluating and planning quality medical laboratory services. The national LIMS shall be linked to the Laboratory Information System (LIS) of individual hospital / health institutes / special campaigns and must be in line with the national health information management system (HIMS) and the hospital information system and may be electronic or paper based. LIS may be customized as per the institutional requirements and the decision of link with the national LIMS should be under the authority of the administration of the particular health institution. It is recommended to use interoperability standards such as HL7 and coding system such as SNOMED and LOINC when developing LIS and LIMS

For the purpose of the document, following definitions are used;

- **Laboratory information system (LIS)**
  Comprehensive, integrated information system designed to manage all the aspects of the laboratory operations
- **Laboratory Information management system (LIMS)**
  Integrated information system designed to capture, analyze, report and view data related to management and administration of laboratory services.

Key components

I. Standardize and improve the existing paper-based laboratory information system in view of transforming to computer based comprehensive LIS - Establishment of standard record-keeping systems

and recording and reporting tools, data collection forms, reporting formats, registers, logbooks, etc.

II. Establishment of reporting process from the laboratory up to the Ministry of Health depending on the organizational structure and the laboratory network structure.

III. Establish a mechanism for utilizing laboratory information for evidence based administrative and management decision making.

IV. Establish an electronic information system for laboratory-based disease surveillance

V. Establish a laboratory equipment database

VI. Develop a policy for comprehensive LIS for medical laboratories (some of the components of the LIS; Sample management, workflow management, instrument integration, inventory management, quality control, enforcing SOP, decision support, and reporting)

VII. Establish national laboratory test coding system based on international standards.

VIII. Integrate LIS with LIMS and health information system (HIS) for sharing data.

IX. Establish system to manage laboratory human resource information related to laboratory services (e.g. training) and share data with hospital human resource (HR) system.

X. Establishment of an Information Technology Department at the Ministry of Health to address any technical issues related to infrastructure and implementation of HIMS/ LIS.

2.8

Laboratory Safety and Waste Management

Safety and Waste Management

Laboratory safety is of paramount importance to environmental health & human health. Laboratory management needs to ensure that appropriate safety measures are applied in all laboratory practices. Laboratory safety procedures should be developed in line with national health and safety guidelines, and in collaboration with health facility infection control teams.

Key components

I. Appointing a laboratory safety officer for institution.
II. Establishment of national safety policies and guideline.;
III. Provision of adequate protection to laboratory personnel to prevent occupationally acquired diseases, and management in cases of exposure, including post-exposure prophylaxis (PEP).
IV. Establishment of appropriate cleaning, disinfection and sterilization procedures in all laboratories.
V. Establishment of a biological waste management program including cleaning, disinfection, sterilization, and disposal of sharps and contaminated material.
VI. Establishment of standard procedures for the safe disposal of chemicals and supplies.
VII. Disposal of laboratory waste in accordance with national environmental protection regulations.

2.9

Laboratory Financing

The financing of health laboratory services must be a part of the overall health financing plan and all national, subnational and institutional budgeting processes.

Key components

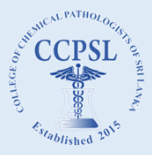
I. Provision of adequate financial resources to sustain all costs associated with quality and reliable laboratory services.

II. Streamlining of provision of resources from different sources of funding, including the government, global health initiatives, and multilateral and bilateral donors through the National Laboratory Focal Point.

III. Development of national health budgets based on the laboratory needs and evidence-based priority areas.

IV. Continuous monitoring and regular updates of financial expenditure.

V. Establishment / strengthening of an efficient, effective, user-friendly and transparent system of financial record-keeping and reporting, in which lines of accountability are established.



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