MINISTRY OF HEALTH, NUTRITION
& INGENIOUS MEDICINE
SRI LANKA

GUIDELINES

STRENGTHENING LABORATORY SERVICES IN PRIMARY HEALTH CARE INSTITUTIONS

REVISION 1.0 JUNE 2019

STRENGTHENING LABORATORY SERVICES IN PRIMARY HEALTHCARE INSTITUTIONS

Concept Note and Guidelines

Prepared by

Division of Laboratory Services

Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka

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This document will be subject to revision, as needed during the implementation of the programme.

Strengthening Laboratory Services in Primary Healthcare Institutions

Concept Note and Guidelines

First Edition: 2019 May

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MESSAGE FROM THE DIRECTOR GENERAL OF HEALTH SERVICES

Laboratory services are an essential component in the healthcare delivery system nowadays. Clinicians routinely rely on accurate laboratory results in their day to day practice. Firstly, investigation reports are important for accurate diagnosis of a disease. For instance, the availability of Blood Glucose Levels in primary care intuitions will allow medical officers to manage Diabetes patients effectively. Secondly, investigations are necessary to monitor the progression of a disease. For example, the availability of inflammatory makers will aid clinicians to evaluate the response of medications in the primary healthcare setup without transferring patients to higher level institutions. Therefore, strengthening laboratory facilities in primary care institutions has become an integral part of the Primary Healthcare Strengthening Project.

Strengthening laboratory services in primary healthcare brings many economic benefits, and aids in the development of the country. At present, the country saves a large sum of capital by early detection of diseases and preventing their complications.

Therefore, expanding the diagnostic services to the grassroots level of healthcare will undoubtedly strengthen the people centered primary healthcare services in Sri Lanka.

Dr. Anil Jasinghe,
Director General of Health Services,
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FOREWORD

In the modern world, laboratory services are instrumental in carrying out evidence-based patient care services in order to achieve a better health outcome, and also provide crucial information for epidemiologists in the surveillance of diseases. Furthermore, investigation data enables relevant authorities to plan the provision of healthcare services and to evaluate their effectiveness. Therefore, a strong laboratory service is an essential element in sustaining a healthy population in Sri Lanka.

Despite a strong MCH service base, there is limited capacity in the primary care system to provide adequate laboratory facilities for primary healthcare services (PHC), making the country less prepared for the changing burden of diseases and potential health emergencies. This leads to an overcrowding of larger healthcare facilities while primary care institutions are being underutilized. This in turn results in an inequity in services and does not achieve the best value in healthcare funding.

Strengthening laboratory services at primary care institutions is a strategy to reduce out of pocket spending, and reduce financial risk through providing diagnostic services including medical laboratory investigations, within public facilities. This will also contribute to the SDG 3 target for universal health coverage—ensuring that all people have access to the necessary promotive, preventive, curative, and rehabilitative health services, while also ensuring that people do not suffer financial hardships when paying for these services—by increasing the availability of essential investigation facilities for medical diagnosis.

Guidelines on Strengthening Laboratory Facilities in Primary Healthcare Institutions, developed by the Laboratory Division of the Ministry of Health will enable primary care institutions to perform recommended investigations for managing patients with common communicable and none-communicable diseases at the primary care level.

With the guidance provided in this document, provincial and regional directors will be able to implement strategies to provide basic investigation facilities to the population according to the locality of the region, thereby achieving island-wide coverage of laboratory care services.

I wish to place on record my deep appreciation and gratitude to all the Technical Expert Committees comprised of professional colleges, under the preview of the Laboratory Services of the Ministry of Health, PDHSS, RDHSS and their expert teams for their valuable contributions to different chapters that helped make the exercise a reality. I also offer special thanks to the Director, Primary Healthcare System Strengthening Project for the coordination of this activity, and to the World Bank team for their contribution to this important national initiative.

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CRP	C-Reactive Protein
DDGL/S	Deputy Director General of Laboratory Services
DGH	District General Hospital
ESR	Erythrocyte Sedimentation Rate
FBC	Full Blood Count
FBS	Fasting Blood Sugar
HLC	Healthy Lifestyle Clinic
JICA	Japan International Cooperation Agency
MCH	Maternal and Child Health Clinics
MLT	Medical Laboratory Technologist
MP	Malaria Parasite
MRI	Medical Research Institute
NCD	Non-Communicable Disease
NHSL	National Hospital of Sri Lanka
PDHS	Provincial Director of Health Services
PGH	Provincial General Hospital
PMCI	Primary Medical Care Institution
PMCU	Primary Medical Care Unit
PSSP	Primary Health Care System Strengthening Project
RDHS	Regional Director of Health Services
UFR	Urine Full Report
WWC	Well Woman Clinic
SLCM	Sri Lanka College of Microbiologists
TQM	Total Quality Management
EQA	External Quality Assessment
HbA1c	Haemoglobin A1c
MP	Malarial Parasite
SOP	Standard Operating Procedure
PT	Proficiency Testing
GS	Gram Stain
AFB	Acid-fast Bacillus
HIV	Human Immunodeficiency Viruses
AIDS	Acquired Immunodeficiency Syndrome
TB	Tuberculosis

INTRODUCTION

Laboratory services are not only essential to patient care but also provide critical and relevant information for epidemiology and surveillance, allowing government and other agencies to plan the provision of health care services and monitor their effectiveness. The availability of investigations leads to accurate early diagnosis of diseases which reduces the number of hospital days reducing the opportunity costs as well as reducing mortality and morbidity. For instance, early diagnosis of Myocardial Infarction will lead to a better outcome, reducing complications of the disease. Moreover, patients can be discharged early reducing the burden on families. Strong laboratory facilities are therefore crucial to national well-being and the maintenance of health, and economic development.

Sri Lanka has a well-established, tiered state-sector hospital system that has extensive island wide coverage. At present, all tertiary care institutions, 98 percent of secondary care institutions and 5.4 percent of primary care institutions have functioning laboratories. This means a large number of patients who access primary care institutions are referred to larger hospitals or private facilities for basic investigations.

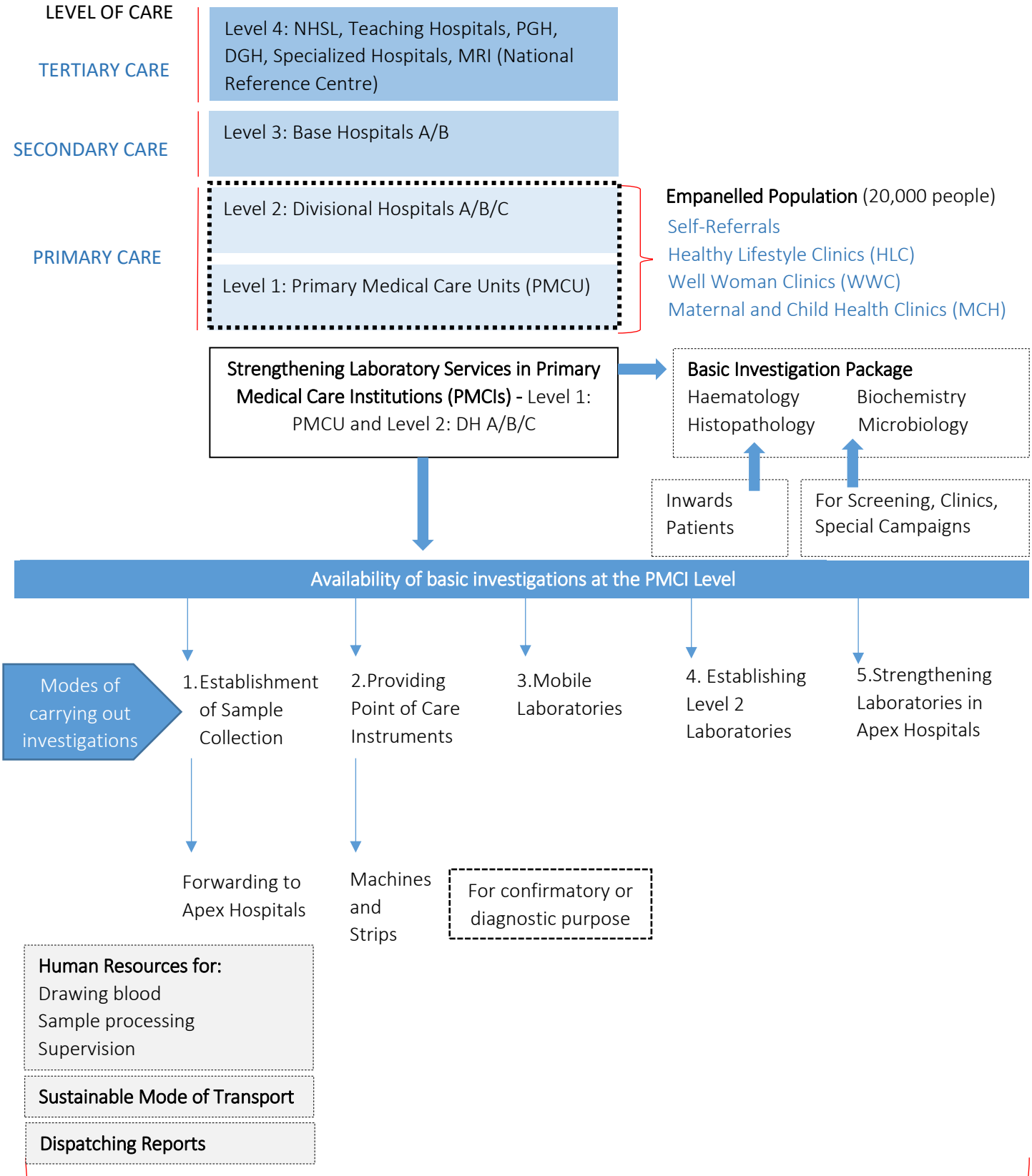
There are 1,118 health institutions providing primary, secondary, and tertiary care in Sri Lanka. Around 1,000 of these have been categorized as primary care institutions (90 percent), and are located in distant areas to serve the rural and estate populations of the country. Primary care institutions are not supported with specialized care facilities, and the majority of them are maintained by provincial health authorities.

In this regard, the Ministry of Health, Nutrition and Indigenous Medicine, with assistance from the World Bank, has taken necessary steps to ensure the availability of basic laboratory tests for all levels of healthcare institutions in the country.

OBJECTIVE

Currently, most of the Primary Medical Care Institutions (PMCI) have been underutilized due to the limited availability of basic investigation facilities, as well as the unavailability of medicines. The objective of this effort is to provide the highest possible laboratory facilities at the primary care level and to reduce the number of patients visiting secondary care institutions, bypassing the PMCI level. This will prevent overcrowding of higher-level healthcare institutes while bringing convenience to the patient.

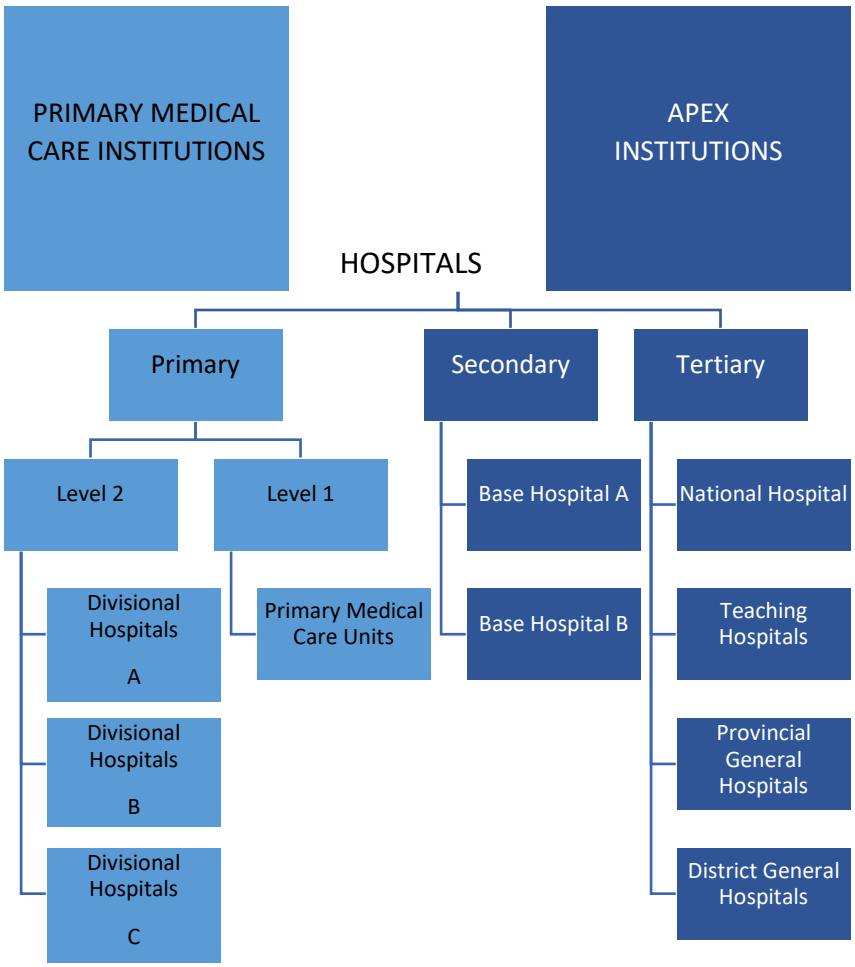
CONCEPTUAL FRAMEWORK



THE MODES OF PERFORMING INVESTIGATIONS

This guideline defines the minimum investigation package which should be available in the primary healthcare setup. In order to carry out investigations in the package, local health authorities should decide the optimal mode of performing the investigation (forwarding samples/ using POCI/ utilising a mobile laboratory/ developing level 2 laboratories/ strengthening laboratories in apex hospitals) considering the locality of the institution, resource availability and the cost-effectiveness. The mode of performing investigations should be sorted out for individual tests. For instance, a Blood Glucose Level can be done more feasibly as a POCT, while carrying out the lipid profile may be more feasible by forwarding the sample to the nearest institution where laboratory facilities are readily available.

CLASSIFICATION OF PRIMARY HEALTHCARE INSTITUTIONS



Primary care includes Level 1 institutions which consist of Primary Medical Care Units (PMCU) and Level 2 which consists of Divisional Hospitals type A, B and C. These four types of institutions are collectively known as Primary Medical Care Institutions (PMCI).

KEY STRATEGIES

1. To make **basic investigations** available at the PMCI level.
2. To establish **sample collecting centres** where laboratory facilities or the particular test is not available.
3. To deploy **point of care equipment**.
4. To utilize **mobile laboratories.**
5. To develop Level 2 new laboratories in Divisional Hospitals for analysis of samples collected from Primary Medical Care Institutes (PMCI).
6. To strengthen laboratories at **Apex Institutions**.

The PSSP project will focus primarily on establishing a laboratory service network to enable the state health system to offer localized laboratory testing services (e.g. FBS, FBC, urine tests etc.) to patients. **Through this network, primary care institutions will be able to send samples for testing to the nearest referral hospital with laboratory facilities and treat patients based on the test results.** This way, institutions will no longer need to request patients to arrange such tests on their own, thereby reducing out-of-pocket expenses for patients. In addition, this will prevent patients from being unnecessarily referred to a higher-level institution.

Establishing this network requires an efficient system within which blood samples and test results are transported back and forth between feed-in institutions and a designated referral hospital with laboratory facilities. The guidelines provided in the publication "**A Guide for Establishing a Laboratory Service Network"** compiled by the Ministry of Health in collaboration with JICA provides all necessary guidelines as well as technical details with regard to establishing sample collecting centres, choosing the right mode of transport, and dispatching results. The booklet could supplement this document as a useful reference guide which is freely available to download from the Ministry of Health website. (*Please visit http://www.health.gov.lk, click Staff Access Menu, click Projects, click JICA, Click NCD Management Project)*

To conduct the laboratory tests listed in the basic investigation package (see section 1.1)**, PMCIs will be equipped with sample collecting centres where the samples will be forwarded to apex hospitals for analysis.** Where feasible, point-of-care equipment (strips or machines) can also be used for investigations. Furthermore, PMCIs with laboratories and an MLT/MLTT in place can cater to the requirements of the "Basic Investigation Package," and where necessary laboratories can utilize the above-mentioned strategies to ensure the availability of required investigations. In order to implement these strategies to deliver the required laboratory services within regions, discussions must be held between the PDHS/RDHS and relevant stakeholders, and necessary action must be taken. The process should be closely monitored and regulated by the PDHS/RDHS, and the DDGL/S and other relevant national authorities shall be kept informed during all stages of the process, in order to facilitate national-level monitoring by the Ministry of Health.

STRATEGY 1: Establishing Minimum Investigation Facilities at the PMCI Level

1.1 The Basic Investigation Package

To ensure maximum benefit to the community, basic investigations pertaining to haematology, microbiology, biochemistry and histopathology should be available at PMCIs. In keeping with the main focus of this programme, investigation requirements were discussed with the relevant professional colleges. The following investigation package includes some special investigations which are required for special clinics as well as for campaigns against specific communicable and non-communicable diseases. PMCIs should be able to provide the following investigations to their local population.

The table below illustrates the investigations pertaining to the basic investigation package grouped according to speciality with the technical methods which could be used to carry out the investigation. A few tests can be performed with Point of Care Test strips while majority of the investigations can be performed with the help of machines which can be analysers, equipment such as microscopes or Point of Care Instruments that are cartridge based.

CATEGORY	NAME OF THE INVESTIGATION	STRIPS (POCT)	Machines[1]
Haematology	ESR	No	Yes
	FBC	No	Yes
	MP	No	Yes
	Blood picture	No	Yes
Microbiology	Urine/Stool Direct Microscopy	No	Yes
	AFB stain	No	Yes
	Forward specimens for culture		

Biochemistry	Lipid Profile	No	Yes
	Total Cholesterol	Yes	Yes
	Serum Creatinine	No	Yes
	Blood Glucose	Yes	Yes
	HbA1C	No	Yes
	Troponins (I/T)	Yes	Yes
	ALT/AST	No	Yes
	CRP	Yes	Yes
	Urine for bilirubin	Yes	Yes
	Urine for glucose	Yes	Yes
	Urine for ketone bodies	Yes	Yes
	Urine for proteins	Yes	Yes
	Urine for reducing substances	Yes	Yes
	Urine for urobilinogen	Yes	Yes
	Urine for β - HCG (qualitative)	Yes	Yes
	Urine Microalbumin to Creatinine ratio	No	Yes
Histopathology	PAP-Smear		

Tests to be Done for Screening Purposes

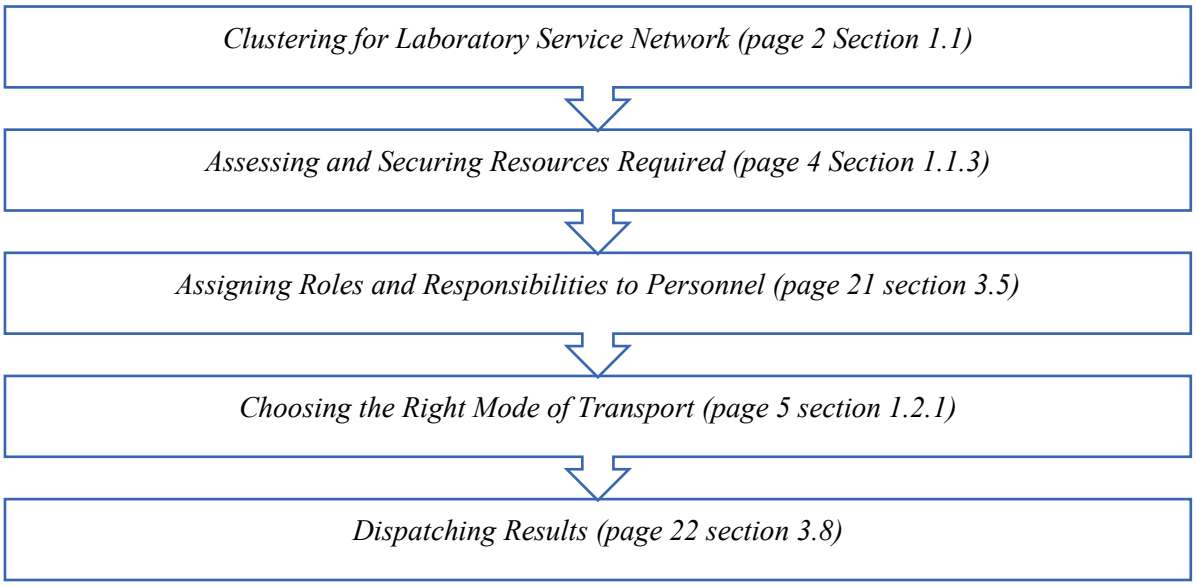
Healthy Lifestyle Clinic	FBS	Yes	Yes
	Urine Albumin	Yes	Yes
	Total Cholesterol	No	Yes
	Serum Creatinine	No	Yes
Well Woman Clinic	Blood sugar	Yes	Yes
	PAP-Smear	No	Yes
Antenatal Clinic/ Maternal and Child Health Clinic	Full Blood Count	No	Yes
	VDRL/HIV (sample to be sent district STD Clinics)	No	Yes
	Urine Full Report	No	Yes
	Blood Glucose	Yes	Yes
	Oral Glucose Tolerance Test	Yes	Yes
	Blood Grouping and Rh (sent to blood bank)	No	Yes
	* Plus, any other tests required by the clinicians		

Thalassemia Screening Tests	FBC *Details to be discussed with nearest Thalassemia centre	No	Yes
Tests Relevant to Public Health			
Dengue	FBC Dengue Antigen and Antibody tests	No Yes	Yes Yes
TB Malaria	Sputum for AFB (Forwarding samples only) Blood film for MP (Rapid Diagnostic Test or Malaria available in Base hospital and above)	No No	Yes Yes

[1.] Machines: Analysers, equipment such as microscopes, POCIs which are cartridge based.

STRATEGY 2: Establishing Sample Collecting Centres (Laboratory Service Network)

Sample collecting centres can be established in PMCIs, to collect blood samples and forward them to Apex Hospital laboratories for analysis. The final reports should then be sent back to the PMCIs in a timely and coordinated manner. Some of the key challenges which need to be addressed are listed below, and the technical details pertaining to each topic are elaborated in the book "A Guide for Establishing a Laboratory Service Network."



Source: Ministry of Health, Nutrition and Indigenous Medicine and JICA. A Guide for Establishing a Laboratory Service Network.

2.1 Clustering for Laboratory Services

The laboratory service network will take one laboratory at a referral hospital and several feed-in institutions in its catchment area as one “network cluster,” and within this cluster, primary care institutions can benefit from the laboratory services extended by the referral hospital.

2.2 Assessing and Securing Required Resources

While defining the scope of this system, the PDHS/RDHS will have to verify the feasibility by looking at the human resources (HR) available in each network cluster, as well as the financial resources (FR) at hand.

2.3 Assigning Roles and Responsibilities

When a feed-in institution is required to deliver the samples, a transporter needs to be assigned. It is the responsibility of the head of the institution to make necessary arrangements to handle key tasks including the following:

- ✓ Drawing blood
- ✓ Preparing blood samples.
- ✓ Record keeping: Staff for maintaining the laboratory register.
- ✓ Transporting samples and reports (if pick-up is not arranged by the referral hospital): One staff member from the feed-in institute should be assigned for delivery of the samples and receiving the test results, either using public transport or a vehicle stationed at the institution.

As per General Circular Letter No 02-17/2006 "Duties of Medical Laboratory Technologist", when there is a requirement, a Medical Laboratory Technologist can be employed to perform the collection of blood specimens if there is no medical officer in attendance for the task.

When establishing sample collection centres at PMCIs (former Central Dispensaries), it is necessary to provide the required number of Nursing Officers. Cadre revisions as well as the required deployment of the officers must be considered.

2.4 Choosing the Right Mode of Transport

MODE >>	Pick-up by Referral Hospital	Delivery by Feed-in Institutions	Hybrid
Responsibility for collection /delivery	Referral hospital assigns a transporter to collect samples from primary care institutions on fixed day(s) of the week	Each institution assigns a transporter to deliver samples to the hospital	Referral hospital collects samples from some institutions while others deliver them on their own
Transport	Own transport	Own and/or public transport	Own and/or public transport
Conditions required in the network cluster	• PDHS issues permission to the staff transporter to work outside the assigned place of work*	• Public transportation/ access to roads that enable transportation of samples without	• Public transportation/ access to roads that enable transportation of

		compromising their quality • Authorisation from PDHS (same as *)	samples without compromising their quality • Authorisation from PDHS (same as *)
Resources to maintain the delivery system (Cold chain)	• Staff transporter with a valid driver's license at the hospital • Means of transport assigned for the pick up of samples at the hospital • Fuel and repair costs (operations and maintenance) at the hospital • Allowances/incentives for staff • Cool box and ice packs at the hospital • Refrigerator at each institution	• Staff transporter with a valid driver's license in each institution • Means of own or public transport available at each institution • Fuel and repair costs (O&M) at institutions with own transport • Allowances/incentives for staff • Fees for public transport for staff transporter • Cool box and ice packs at each institution • Refrigerator at each institution	• Staff transporter with valid driver's license at the hospital and some institutions • Means of own or public transport available at the hospital & at some institutions • Operations and maintenance of the hospital and at • institutions with own transport • Fees for public transport for staff transporter • Cool box and ice packs at the hospital and at some institutions • Refrigerator at each institution

Source: Ministry of Health, Nutrition and Indigenous Medicine and JICA. A Guide for Establishing a Laboratory Service Network. 2017

Selecting the most appropriate mode of transportation for each network cluster is essential for the successful functioning of the network. If the specimens cannot be transported to the laboratory, and the results dispatched to the feed-in institutions in good time, the entire network will fail. Thus, it is crucial to select a suitable mode of transportation that will work in the conditions of each respective cluster. The feasibility of the mode of transport needs to be verified before beginning the process. Electronic methods should also be considered according to availability.

2.5 Dispatching Results

- ✓ Reports should be issued only to authorized persons.
- ✓ Timely release of provisional and final reports should be ensured.
- ✓ Any value which exceeds the normal limit must be clearly documented, understood and conveyed verbally, electronically or in printed form.
- ✓ Reporting can be done in three forms:

1. Electronically
2. Verbally (over the phone)
3. Hard copy

Once patient information management systems are developed and in place, the reports can be retrieved by the patient using electronic devices. When purchasing laboratory equipment, they should be compatible with integrating with a Laboratory Information Management System.

Once the reporting of results is done at the laboratory (after the completion of the post-analytical component in the laboratory)

- ✓ If electronic facilities are available, data entry operators or trained staff can enter results into the system, and a Medical Officer at the care point can access the results. If required, results can be printed for further action.
- ✓ In case of urgent reports or an alert level report, an authorized person in the reference laboratory should verbally inform the Medical Officer at the institution where the sample originated.
- ✓ In case of routine tests done for screening by NCD clinics, Well Woman Clinics, and Maternal and Child Health Clinics, a hard copy can be issued and delivered through the courier/ transport service.

Laboratory Information Management Systems (LIMS) that are used should adhere to “National eHealth Guidelines and Standard”, “The National Policy on Health Information” as well as the Laboratory Manual developed by the Ministry of Health which are available as publications in the Ministry of Health website. (http://www.health.gov.lk/)

STRATEGY 3: Providing Point of Care Equipment

Point of Care Testing (POCT) facilities will be provided to conduct basic screening tests/confirmatory tests (depending on the need, or level of institution) including blood glucose, total cholesterol, urine sugar, urine albumin and haemoglobin levels etc. The Devices Regulatory Authority of Sri Lanka and end users will decide on the purpose of the device.

It is the responsibility of the head of the institution and the relevant staff to ensure the reliability of the results by conducting regular calibrations and other quality assurance measures (required reference material and guidance according to internationally accepted standards should be provided by the relevant authorities from the Ministry of Health).

All places where POCT (strip or another method) is established with or without an MLT, a periodic quality assurance process (according to ISO 22870: 2016) has to be established. For that purpose, a consultant chemical pathologist \ relevant laboratory consultant from apex hospitals and supervising MLT are required. Periodic assessments should be carried out with an unknown specimen and its statistical analysis and report should be provided (EQAS) to the relevant institution while adhering TQM guideline.

Point of care tests can be done in two ways:

Strips	Machines
1. Blood sugar 2. Serum cholesterol 3. Dengue Detection Test 4. Urine analysis tests strips for sugar, protein, reducing substances, HCG. 5. Troponin I (Conventional)	1. Blood sugar 2. Blood cholesterol 3. Electrolytes 4. Serum Creatinine 5. Troponin I (Highly Sensitive) 6. UFR 6. FBC 7. HbA1C 8. Malaria Parasite (Microscope) 9. Stool full report (Microscope)

These are some of the investigations which should be made available at the primary care level as decided by discussions with the relevant experts in developing this guideline. HOWEVER, a particular hospital may decide to include additional investigations or omit some of these investigations. In addition, the national guidelines developed by the Ministry of Health (available currently or new guidelines developed in the future) should be adhered to in making decisions with regard to the level of care.

**Strips should be made available at any level of PMCI. However, machines should be made available at the referral hospital of the cluster.*

If a machine has been provided to conduct these tests the services of an MLT should be made available.

In consultation with the national committee managing the epidemic situation, special test methods may be introduced even at the PMCI level.

The advantages of POCT in primary health care

1. Simpler sample collection
2. Simpler pre-analytical processes
3. Rapidity of results

However, the following disadvantages need to be noted in the primary healthcare setting.

1. Errors due to lack of expertise and insufficient quality control
2. Problems of comparability of results of different methods (laboratory versus non-laboratory)
3. Increased cost (equipment and reagents are expensive)
4. Cost of quality control high
5. Inadequate documentation of results

Total Quality Assurance/ Management of POCT

It is very important that POCT must be conducted within a framework of quality standards. Arrangements, supervisions of Total Quality Management/Assurance of Laboratories established in PMCI should be under the authority of head of the institution where the laboratory is located and under the supervision of Consultant Chemical Pathologist/ Relevant Laboratory Consultants of the Apex Hospital. POCTs are usually carried out by healthcare workers, who do not have formal training in quality control and testing principles. Therefore, they do not have the expertise to assess the quality of results produced by the POCT.

The users shall have

I. Appropriate training and competency assessment.
II. Support network inclusive of standard operative procedures.
III. Access to training.
IV. Experts available for advice.

In addition to POCT, Total Quality Assurance/Management should cover the entire laboratory system (see the chapter on Quality Assurance on page 22).

Supervision of Total Quality Management/ Assurance Program

Relevant Laboratory Consultant will establish Total Quality Management\Assurance program for the cluster with the Senior MLT in consultation with Regional Director, Provincial Director and head of the respective institution.

Steps in Implementation and Ongoing Performance

I. Establishment of the need - type of POCT needed
II. Evaluation and validation
III. Preparation of SOP
IV. Training and competency evaluation
V. Implementation
VI. Quality control and calibrations
VII. Coordination and review of EQA programs
VIII. Periodic comparison with laboratory methods
IX. Provision of assistance
X. Record keeping

Quality Control

- Internal quality control – the number of samples and tests shall be decided considering the stability of POCT device, type of test, frequency of testing, frequency of lot changing, etc.
- External quality control – Depending on available find funding. Assistance could be obtained to get the help from the MRI.
- Calibrations – Need to be documented, according to the frequency given by the manufacturer of the device. Best method – periodic comparison with the main laboratory.

Frequency – decided according to test type, number, type of POCT, technology.

Range – close to medical decision levels, normal, high and low.

Number of samples – to be decided.

STRATEGY 4: Utilization of Mobile Laboratories

Each PDHS division should have a minimum of one mobile laboratory, with a view of expanding this service by allocating one mobile laboratory for each district in the future.

Mobile laboratories are recommended in the following situations:

1. Where there is a severe dearth of human resources with a limited number of MLTTs.

2. Where there is a shortage of reagents.

3. During sudden unexpected failures in established laboratories such as equipment failure or reagent shortage.

4. Where there are poor transport facilities to forward samples to Apex Hospitals.

5. During epidemics and disaster situations.

6. During special screening campaigns.

STRATEGY 5: Developing Level 2 Laboratories (Divisional Hospital Laboratories) for Analysis of Samples Collected from PMCIs

5.1 Level 2 Laboratories (Divisional Hospital Laboratories)

Level 2 laboratories will be facilitated with above-mentioned laboratory investigations including biochemical tests, haematological tests, and histopathological tests except for microbiological tests and immunoassays (Example: TSH, T4, T3 and Hb A1C).

5.2 Required Infrastructural Facilities

Infrastructural facilities will include laboratory space, instruments and equipment, reagents, specimen and reagent storage facilities, waste disposal facilities and quality assurance facilities.

5.2.1 Space:

Space should be available to carry out biochemical investigations, haematological investigations and microbiological investigations.

5.2.2 Instruments and Equipment:

The following is a list of essential instruments and equipment:

Haematology	Five-part full blood count analyser ESR racks Micropipettes Staining racks
Biochemistry	Biochemistry analyser
Microbiology	Bunsen burner
Other	Centrifuge Refrigerator Microscope Water bath

5.2.3 Storage:

Specimens may require storage facilities, and in order to manage the workload sufficient specimen storage facilities are required. In addition, separate storage is required for reagents and culture media.

5.2.4 Waste Disposal:

It is recommended to adhere to the common waste disposal protocols.

5.3 Required Staff Facilities

5.3.1 Consultant Pathologists / Relevant Laboratory Consultants

The responsibility of clinical management and total quality management processes should be streamlined through Consultant Pathologists/Relevant Laboratory Consultants, Medical Technologists and MLT assigned for Quality Control **(Refer letter DDG(LS)/OS/2017-02 dated 2018 February)**. Every step in setting up laboratory processes should be carried out under the supervision of consultants relevant to the discipline.

5.3.2 Medical Laboratory Technologists

All Divisional Hospitals will be developed on a phase basis as level 2 laboratories in order to strengthen the primary healthcare system and support NCD control. As such, all Divisional Hospital laboratories should employ at least one MLT at the initial stage and gradually increase to two MLTs so as to ensure the sustainability of the process.

STRATEGY 6: Strengthening Laboratories in Apex Hospitals

Medical care facilities above the level of a Divisional Hospital could be selected as an Apex Institution where the samples from peripheral hospitals will be referred. In order to accommodate the extra number of samples existing laboratories in the base hospitals and above should be strengthened with the human resource and other facilities.

The following measures should be taken to improve the capacity of laboratories in Apex Hospitals.

- Allocating sufficient personnel to the laboratory, and assigning tasks.
- Installing new laboratory equipment
- Managing an adequate stock of consumables and other supplies.
- Maintaining the quality of laboratory tests
- Defining the criteria for accepting the specimens from feed-in institutions if the capacity of the laboratory is limited.

Quality assurance represents a set of policies and procedures that are designed to monitor and evaluate the ongoing and overall quality of the total testing process: pre-analytical, analytical (testing), and post-analytical processes. Quality control represents techniques and procedures designed to detect, reduce, and correct deficiencies in the analytical process prior to the release of patient results, in order to improve the *quality* of the results reported by the *laboratory*.

Internal and external quality control is an essential aspect of ensuring that data released from a laboratory is fit for the purpose. If properly executed, quality control methods can monitor the various aspects of data quality on a run-by-run basis. In runs where performance falls outside acceptable limits, the data produced can be rejected, and after remedial action on the analytical system, the analysis can be repeated. The correct procedures for feedback, remedial action and staff motivation must also be documented and acted upon. There should be a genuine commitment by the staff of a laboratory towards quality for a quality control program to succeed.

Proficiency testing or external quality assurance schemes should be carried under the guidance of Consultant Pathologists/Relevant Laboratory Consultants. The head of the institution is responsible for liaising with relevant consultants. The services of medical officers and medical laboratory technologists shall be obtained for quality assurance. All these processes shall be coordinated through PD and RD of the province.

Quality Management

Quality management systems related to POCT and Medical Laboratories, specifically ISO 22870:2016 and ISO 15189:2017 should be adopted in order to ensure the quality of the testing process in primary healthcare laboratory services.

Internal Quality Control

Internal quality control (IQC) is monitoring of the test procedure performed in the laboratory on a daily basis. It includes analysis of specially prepared materials with known concentrations of analytes and statistical analysis day-by-day of data obtained. There is continuous evaluation of the reliability of the work of the laboratory. IQC primarily checks the precision of the testing process.

External Quality Assessment (EQA) or Proficiency testing (PT)

The term external quality assessment (EQA)or proficiency testing (PT) is used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory. This comparison can be made to the performance of a peer group of laboratories or to the performance of a reference laboratory. Although important, participation in EQA/PT schemes is not a substitute for IQC measures or vice versa.

EQA/PT can be regarded as a routine, but relatively infrequent, check on analytical errors and it measures bias or accuracy of the testing process.

The primary intention of participating in an EQA program is to improve the quality of the services provided by participating laboratories for the benefits of the patients.

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1. Julei A Hammeling, A review of medical errors in Laboratory Diagnostic and where we are today, Laboratory Medicine, volume 43, issue2 February 2012.
2. Dacie and Lewis Practical Haematology. [Philadelphia]: Elsevier Limited, 2017Editors: Barbara J. Bain, Imelda Bates, Mike A. Laffan; editor Emeritus S. Mitchell Lewis.
3. "A Guide for Establishing a Laboratory Service Network" compiled by the Ministry of Health in collaboration with JICA.

1. Investigations to be performed at laboratories of different levels

Investigations to be performed in a Microbiology Department

		BH A	BH B	DH
A. Bacteriology				
01. Microscopy, Culture & ABST				
a)	Blood Culture	Yes	Yes	
b)	Urine Culture	Yes	Yes	Direct Microscopy
c)	CSF Culture	Yes	Yes	GS/AFB
d)	Body fluid Culture	Yes	Yes	GS
e)	Stool Culture	Yes	Yes	Direct Microscopy
f)	Sputum Culture	Yes	Yes	Direct Microscopy
g)	Pus/Swab Culture	Yes	Yes	

i) For Part c & d, if the microscopy result is required urgently but there is no culture facilities available on site, it is advisable to send a separate specimen for microscopy, while timely dispatching the separate sample to culture and ABST in order to prevent contamination, that can lead to a false positive results.

ii) For Part f, Direct microscopy would indicate for AFB, but there is no significant impact on patient management as a stand-alone test in general bacteriology.

2. Packaging and transport conditions (Microbiology specimens):

a. According to the international standards, clinical materials coming under category B (UN3373) are human and animal material such as, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts. These must be packed to Packing Instructions PI650.

b. When packaging samples for transport to Microbiology:

1. All samples should be sent in a plastic bag with an attached request form.
2. All sample bags MUST be sealed to avoid contamination in the event of leakage during transit.
3. The request form should not be folded up and placed in the bag with the sample. This causes several problems;
   – If the sample leaks the request form is contaminated which is a health and safety issue.

– Lab reception cannot see the test requested or the clinical details without opening the sample bag. This is particularly a problem for high-risk samples

c. High-risk samples

All high-risk samples and accompanying request forms must be labelled with a 'danger of infection' sticker. High-risk samples are defined as coming from the following groups:

- Those known to be Hepatitis B surface antigen, Hepatitis C positive or HIV antibody positive
- Those whose HIV or Hepatitis B status is unknown but who have evidence of AIDS or HIV disease or who are jaundiced.
- Those who fall into the known high-risk groups for HIV and/or Hepatitis B
- Those with known or suspected CJD
- Those with known or suspected typhoid fever
- Faeces from patients with known or suspected typhoid, E coli 0157, dysentery
- Sputum or bronchial washing/lavage from suspected or known TB
- Unfixed or incompletely fixed tissue samples and smears from such patients.

3. Delivery of Specimens

- Any delay in the transport of samples to the laboratory increases the likelihood of misleading or negative results. In specimens such as sputum and urine (in a non-boric acid container) they can multiply to significant levels so the validity of the result may be compromised.
- If any delay is unavoidable urine samples should be held at 4 Celceous, other samples should be held at room temperature.
- All fluids, e.g. CSF, pleural fluid, joint fluids and pus require culturing without delay. Specimens should preferably be taken during normal laboratory opening hours and sent immediately to the microbiology laboratory.
- Ideally, all bacterial swabs should be placed in transport medium and kept at room temperature until delivery to the laboratory.
- The Microbiology laboratory reception should be warned of the arrival of urgent and important, unrepeatable specimens.

For a microbiological point of view, specimens that are necessary to collect at the primary care level would be;

i) Urine
- UFR to be done onsite (does not come under microbiology laboratory test directly)
- Urine for culture should always be collected in the sterile universal container, to prevent bacterial overgrowth a screw-capped universal container, containing boric acid is preferable.

ii) Sputum – AFB to be done onsite.

iii) Specimens of clotted blood (“serum” tubes) are suitable for most serological tests. Refrigerate until delivery: Do not freeze.

iv) Blood culture – to be arranged by discussing with the consultant microbiologist at relevant laboratory level.

Please note that performing cultures are not advisable in the laboratories where a consultant microbiologist's coverage is not available.

4. Sustainable mode of transporting specimens
    a. Staff

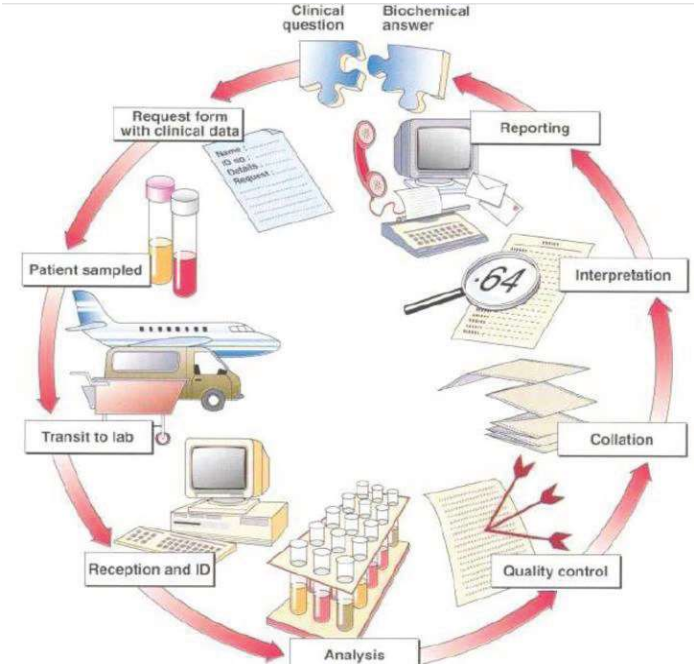
        Following are suggestions

        i. Motorbike/ Three-wheeler with a porter category staff level.
        ii. Utilize hospital ambulance in an organized manner i.e. transport every day/another day at a scheduled time.

5. Health issues
    a. Transporter
        i. Should be checked for his health, pre-blood born virus assessment for the basal level and documented and records are to be kept with an allocated infection control nurse.
        ii. All new personnel should get the pre-training on blood born viruses and other infection control practices including hand hygiene, spill management and competency assessed and documented. Repeated training and documentation in every 6 months are recommended.
        iii. Always carry specimens in a safe manner and deliver them as soon as possible to the relevant laboratory or reception.
        iv. Handle specimen containers as little as possible. Wash the hands afterwards if do handle them.
        v. If a specimen is broken or leaking in the carrier, should not remove it. Take it to the laboratory who will deal with it appropriately.
        vi. After any spillage, need to wash the hands. Contaminated clothing should be removed and cleaned. Contact the Infection Control Team of the nearest hospital where there is a service, (Transporter need to have a pre-determined Infection control nurse's coverage and their contact number), if unsure of what to do.
        vii. All accidents, spillages etc. must be reported to the originator and recorded.
        viii. Wash hands frequently while on duty, especially before refreshment breaks and when finishing work.

6. Following are examples of specimen transport containers.

Request – Test – Report Cycle



The reporting of results involves four stages:

(i) Technical validation of results
(ii) Results recording – laboratory
(iii) Interpretation & clinical validation — laboratory
(iv) Reporting to the right person - end user (Medical Officer)

Communication of Results

- The release of reports should be done only to authorized persons (Medical Officer)
- The timely release of provisional and final reports must be ensured
- Any value which exceeds the normal limits must be clearly documented, understood and conveyed verbally, electronically or in printed form.

Critical and Alert Value Listing and Reporting

- The critical values should be decided by agreement of clinicians and consultant chemical pathologists/ consultant haematologists etc. Critical and alert values should be listed by individual laboratories and communicated down to care receivers.

- All critical alert value reporting should be recorded with information such as the name of the patient, unique number, test, results, to whom information is given, date and time and the informing officer.

Reporting can be done in three forms.

1. Electronically
2. Verbally (over the phone)
3. Hard copy

Once results reporting is done at the laboratory (after completion of the post-analytical part in the laboratory):

- If electronic facilities are available, data entry operators can enter results into the system and the Medical Officer at the care point can access the results. This is the most efficient method.

If necessary, they can print out results:

- In case of urgent reports or alert level report detected – verbal communication should be carried out to the Medical Officer at the care point.
- In case of routine tests (done for screening NCD clinics) hard copies can be issued and delivered through a courier/transport service.

Documentation to be done in the laboratory

When, where, what and to whom were the results reported.
Ex: Results released at 3 pm.

Documentation to be done at the point of care (PMCI)

When, what and to whom were the results informed:

- Turn Around Times (TAT) should be decided for all categories of tests (responsibility of relevant professional body/college)
- Documentation should be done for all levels of communication between the laboratory and end user
- Time of informing the results- register to be maintained at both stations
- Time and date of dispatching a hard copy of results

- Mode of regular communication (meetings once in two months should be arranged to exchange ideas of both ends) should be established
- Register to be maintained at the receiving station of reports (a responsible person should be appointed to receive reports – namely, the phlebotomist, midwife in charge or suitable person)
- The Medical Officer should authorise the receipt of reports
- A system should be developed to trace delayed results/ results exceeding established TAT

- Authorization should be carried out according to Gen Cir No: 02-17/2006

ANNEX 3:
Establishment of Pathology Sample Collection Centers

Every PMCI should have a Pathology Sample Collection centre. *The closest draining (referral) laboratory must be situated in such a distance from the PMCI, that the blood sample drawn at 8 a.m. should be able to reach the referral laboratory before 12 noon on the same day through a recognized mode of transportation.* In areas (PMCIs) where this criterion cannot be achieved it is recommended to consider the establishment of basic laboratory clustering of two or more PMCIs.

Guidelines for the Establishment of Pathology Sample Collection Centres at PMCIs

There are minimum requirements and best practices for specimen collection to assure the safety, quality and efficacy of the collection of pathology specimens for testing. Errors in pathology specimen collection can be a major risk to patient safety in the pathology testing process. The integrity and identification of patient specimens to be tested depends on the correct collection.

Standard sample collection procedures must be followed to ensure quality test results. In chemical pathology, the common causes of incorrect results are errors in the pre-analytical phase and post-analytical phases rather than analytical errors.

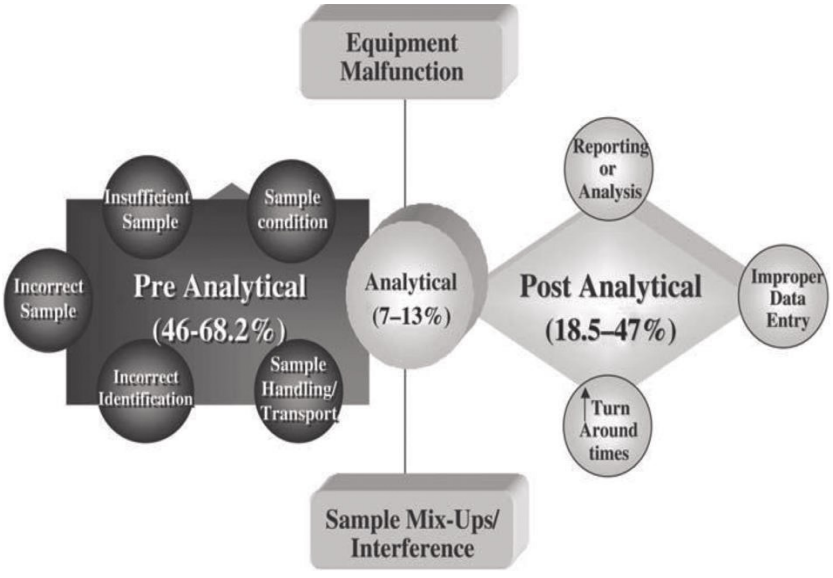


Figure 1 Sources of Laboratory Errors

Factors Influencing Quality

Pre-Analytical	Analytical	Post-Analytical
Right patient preparation	Laboratory professionals	Recording
Right patient identification		
Right specimen		
Right collection	Reagents	Interpretation
Right labelling	Equipment	Turnaround time
Right quantity	Selection of test (SOP)	Report to the right user
Right transport	Records	
Right storage	Biosafety	
Right sample preparation/processing before testing		

Guidelines for Pathology Sample Collection Centers.

There are six main factors to be considered:

1. Premises
2. Equipment
3. Personnel
4. Documentation/Instruction
5. Collection procedures
6. Transport and storage of specimens

1. Premises

The collection premises must comply with the following requirements:

(i) It should be situated in an easily accessible area for all (staff and patients - including disable access)

(ii) If blood testing is done in the same premises access to the testing area should be given only to authorized personnel, the test area should be separated from the sample collection area and with restricted entry only to authorized personnel.

(iii) The blueprint should be as illustrated in Figure 1.

(iv) Easily cleanable surfaces must be available for clerical work, specimen collection and specimen handling.

(v) A suitable and secure storage area for supplies must be available and accessible only to staff.

(vi) Floor coverings in the immediate collection and storage areas must have a non-porous surface.

(vii) There should be a provision to accommodate waiting for patients and bystanders as required.

(viii) Toilet doors should be lockable from the inside and unlockable from the outside in case of an emergency. The doors should be removable or open outward for access

purposes. Furthermore, doors should accommodate disable- wheelchair access. Preferably disability provisions inside as well.

(ix) Hours of operation should be displayed in the collection centres. Information pertaining to patient preparation should also be displayed for the public.

(x) Collection areas should have adequate space for furniture to enable patients to be seated or to be recumbent according to medical requirements. There should be a work surface for the collection staff. Collection area should be separated from the waiting area to assure privacy.

(xi) Sample collection centre should provide a comfortable environment, dust free and ensure the safety of all. Adequate handwashing facilities, basic first aid, couch to accommodate emergencies etc.

2. Equipment.

(i) Ideally, evacuated tubes should be used for the collection of blood. However, different methods should not be mixed such as vacutainer tubes filled using a syringe without removing the stopper as well as mixing pediatric vacutainer with the adult device.

(ii) Syringes, needles, tourniquet, disinfectant, common latex gloves and at least one box of latex-free gloves (in case of latex allergy) and a pair of goggles and appropriate grade masks when collecting blood from high-risk patients etc. must be available.

(iii) Resuscitation equipment must be available for use by trained personnel. Additionally, appropriate first aid facilities should be available.

(iv) There must be dedicated specimen storage areas at ambient or refrigerated temperature.

(v) There must be documentation detailing which specimens require controlled temperature storage. Suitable, secure refrigerators must be available. Where refrigeration is required, the storage temperature must be maintained between 2-8^{0}C.

(vi) A Centrifuge should be available if the collecting centre separate and forward samples.

(vii) Spill management kits should be available for managing spillage of biological fluids.

(viii) Blood drawing stations should be equipped with comfortable chairs with arms to rest the hand. (Figure 2)

(ix) Specimens must not be stored with food, drink or pharmaceuticals. Specimens should be stored for the least possible time prior to transport to the testing laboratory. **The maximum allowable storage time should be specified in the collection instruction manual, where applicable.**

3. Personnel

(i) Overall supervision is by the head of institution & Medical Officers of the centre.
(ii) Designation and identification of the correct personnel for the drawing of blood is a must
(iii) Recommend personnel include the following:
- Phlebotomist (Training guidelines have to be developed. WHO guidelines are available.)
- Nurses

(iv) Identification must be worn by all staff. First name or surname or identification number (or any combination of the three) should be used as a minimum.
(v) Suitable attire must be worn by staff in accordance with health authority regulations.
(vi) The use of linking staff is encouraged to assist patients.
(vii) There must be policies regarding sample collection services, privacy, confidentiality and informed consent available to staff, and all staff must be aware of and comply with the policies.

The specimens must be collected in accordance with the following policies:

Regarding pathology (blood) tests:

- Laboratory test requests should be written by the Medical officer
- A Medical Officer or Phlebotomist must ensure a written informed consent is obtained from the patient.
- Staff must be trained to ensure knowledge of basic first aid measures to deal with situations likely to be encountered in the course of patient specimen collection.

4. Documentation/ Instruction

Instructions should be available in languages or formats relevant to the patient population.

5. Collection Procedures

(i) The patient must be informed of the procedure about to take place.

(ii) Collection staff must wash hands or use an alcoholic hand rub, together with glove use during the collection procedure.
(iii) Patients must be instructed on post-procedure care in accordance with the collection instructions manual.

6. Transport and Storage of Specimens

(i) Specimen dispatching procedures must be double checked before drawing blood from the patient (responsibility of the MO and Phlebotomist)
(ii) In the case of screening clinics (NCD clinics), collection centres can have defined times and dates for sample collection and dispatch.
(iii) In case of OPD or inward patients, the Medical Officer should decide the requirement of laboratory tests (i.e. suitability to do basic investigations or necessity to transfer the patient). If the Medical Officer decides to do basic tests, then blood can be collected and dispatched immediately/ can develop daily blood collection process depending on the requirement of the centre (past statistics can be used to adopt the practice)
(iv) In case of patients who are referred back from tertiary centres for follow up at PMCIs, blood collection for blood tests can be arranged on an appointment basis (e.g. renal diseases, diabetics, IHD etc.)
(v) If Specimens are to be retained within the collection centre for a certain period of time, safety, specimen stability and security requirements must be addressed and appropriately documented.

7.Patient and Staff Safety.

Training of the collecting centre staff regarding workplace safety and coverage from Infection Control Nurse in the situations of;

- Needle Prick Injury
- Blood and body fluid spill
- Waste management including sharps

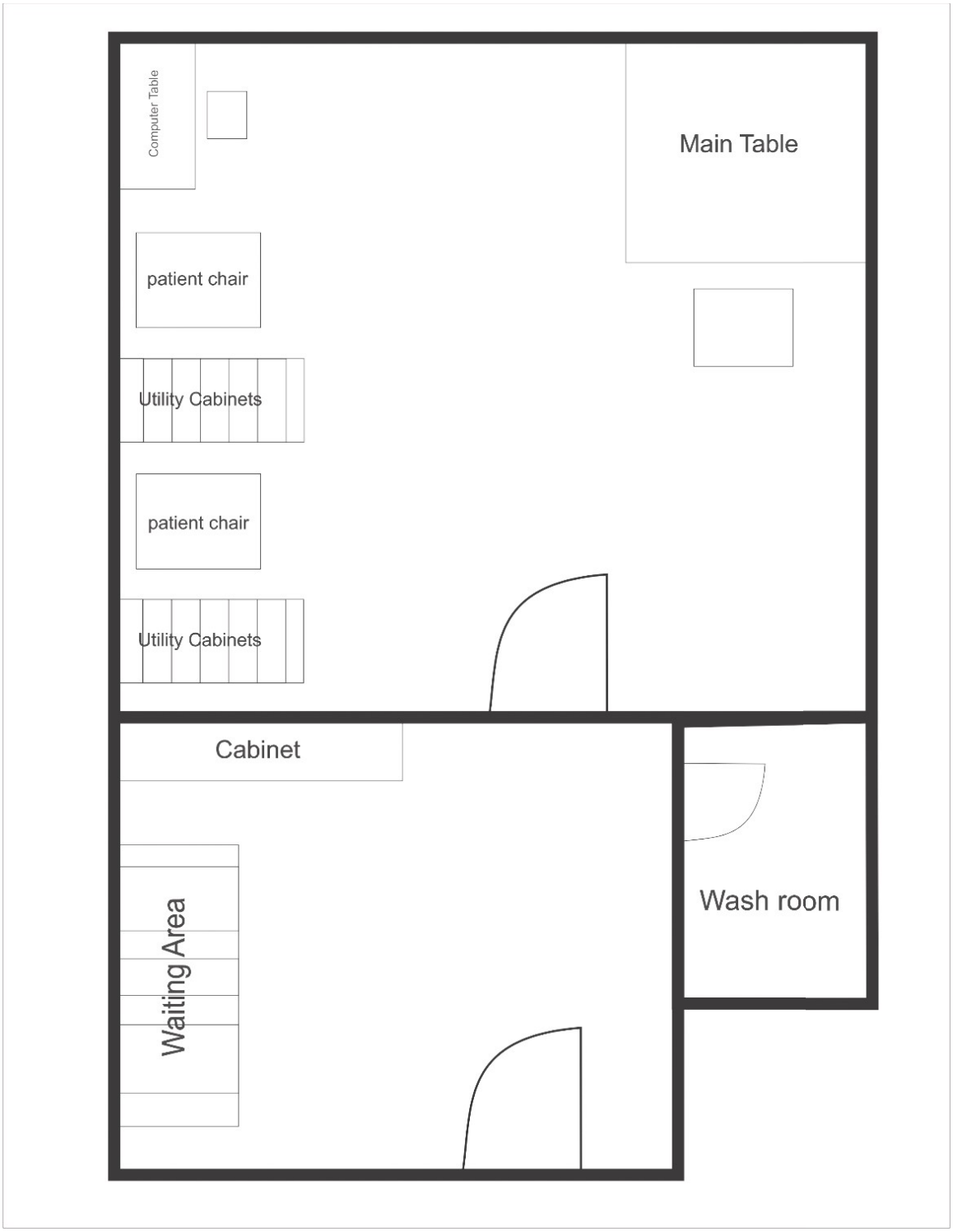


Figure 2 Floor plan.

Figure 3 Blood drawing stations

Figure 4 Waiting area of a sample collection centre

ANNEX 4:
Transportability of Investigations

Category	Investigation	Transportability to Apex Institution		Availability in Propose Level 2 Labs	Existing availability		
					DH A	DH B	DH C
Haematology	ESR	YES	EDTA bottle 4-22 C Preferably with in 4hrs (Samples should NOt directly contact with the ice pack in the container)	YES	YES	YES	YES
	FBC	YES		YES	YES	YES	YES
	Blood grouping	YES	Done at the nearest Blood Bank available				
	MP	YES	A slide should be prepared and sent with a blood sample and relevant clinical history	YES	YES	YES	YES
	Blood picture				NO	NO	NO
Biochemistry	Cholesterol (total)	YES	Transport within 2-4 hours as blood at 2-8 C, if more than that serum has to be separated and frozen.	YES	YES	YES	YES
	Serum Creatinine	YES		YES	YES	YES	YES
	Blood Glucose	YES		YES	YES	YES	YES
	HbA1C	YES		NO	NO	NO	NO
	Troponin I/T	YES		YES	YES	YES	NO
	ALT/AST	YES		YES	YES	YES	NO
	CRP	YES		YES	YES	YES	NO
	Urine for bilirubin	YES	Transport within 2-8 hours at 2-8 C	YES	YES	YES	YES
	Urine for glucose	YES		YES	YES	YES	YES
	Urine for ketone bodies	YES		YES	YES	YES	YES
	Urine for proteins	YES		YES	YES	YES	YES
	Urine for reducing substances	YES		YES	YES	YES	YES
	Urine for urobiliNOgen	YES		YES	YES	YES	YES
	Urine for β - HCG (qualitative)	YES		YES	YES	YES	YES
Histopathology	PAP-Smear	YES	A slide should be prepared and sent with relevant clinical history	YES	YES	YES	YES
Microbiology	Urine/Stool Direct Microscopy	YES	Sterile screw cap container and send within 2 hours in room temperature. If delayed: For universal (Non preservative added container) transport within 24h in refrigerator temperature. For boric acid (preservative added) container can be transported in room temperature within 48-96 hours. ** For UFR Non-sterile container is sufficient	YES	YES	YES	YES
	AFB stain	YES		YES	YES	YES	YES
	Blood Culture	YES	Preferably within 2 hours of collection, If delayed Keep at room temperature. Do NOt refrigerate. Automated Blood culture bottles should NOt be exposed to light. For suspected cases of septicaemia, antibiotics may be started after obtaining a blood culture before referring the patient to a higher level institution. Arrangements to keep a stock of blood culture bottles should be arranged liaising with the consultant microbiologist at the refferal/Apex hospital.	YES	YES	YES	NO
	Urine Culture	YES	Preferably within 2 hours of collection, If delayed Keep in the refrigerator. Preferably Boric acid added containers if delaying in transport those can be kept at room temperature for 48h	YES	YES	YES	Direct Microscopy
	Stool Culture	YES		YES	YES	YES	Direct Microscopy
	Wound Swab Culture	YES	Preferably within 2 hours of collection, Storage: Room Temperaturedelayed Keep in the refrigerator.	YES	YES	YES	NO
	Sputum Culture	YES	Preferably within 2 hours of collection	YES	YES	YES	Direct Microscopy
*Please reffer to the National Guidelines on Specimen Collection and Transport SLCM for details.							

CONCEPT NOTE AND GUIDELINES
PREPARED BY THE DEIVISON OF LABORATORY SERVICES OF THE
MINISTRY OF HEALTH, NUTRITION AND INDIGENOUS MEDICINE SRI LANKA

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