

Quality Assurance of laboratory test results at the Medical Research Institute

“We maintain quality and others to follow”

Quality is the degree of congruence between expectation and realization. It is the matching of expectations versus fulfillment. In other words quality means meeting the pre-determined requirements to the satisfaction of the users for a particular substance or a service. The three important cornerstones in health care are quality, access and cost which are interdependent. Quality is achieved when health services are accessible to the users and are provided in an efficient and cost effective way.

Accurate and reliable laboratory test results are required for the diagnosis and effective management of patients carried out by the clinicians. Unreliable laboratory results could have serious consequences. It could lead to inappropriate actions such as mistreatment of patients. Conversely, it could also lead to inappropriate inaction such as under-investigation of a disease when actually indicated or not instituting any treatment when required. The laboratory tests carried out at Medical Research Institute are reliable and accurate so that the clinicians are able to diagnose and treat patients effectively.

The Ministry of Health develops important policy decisions based on the laboratory test results generated from the national surveys and population studies done at the Medical Research Institute. Appropriate mass scale interventions are planned and carried out by the Ministry of Health to improve the health status of people in Sri Lanka. Internationally accepted laboratory based research depends on the reliable laboratory test results.

Quality Assurance is the sum total of all activities that are undertaken to ensure the generation of reliable and accurate results or data. This is equated with good laboratory practice and starts from test selection through obtaining a satisfactory sample from the right patient, analyzing it and recording the results promptly and correctly, to appropriate interpretation of and action on the result with all procedures being documented for reference.

Quality assurance has two components namely, Internal quality control programme(IQC) and External Quality Assessment (EQA). Internal quality control programme is a set of procedures undertaken by the healthcare professionals in their day to day activities to ensure the release of reliable results.

The three phases of Internal Quality Control programme are pre-analytical phase, analytical phase and post- analytical phase. The staff of Medical Research Institute is committed to establish and maintain an efficient internal quality control programmes in their respective specialities. The pre-analytical phase includes patient preparation, sample collection and transportation. The guidelines for the above procedures has been documented on “Diagnostic services available at Medical Research Institute“ published in 2010 and distributed to all the state sector hospital laboratories in Sri Lanka. This document describes the type of sample, the volume required, transport conditions and the turnaround time to ensure a quality test report. The sample receiving counter is open for 24 hours and appropriate documentation/ records are maintained at key points to ensure the traceability of the samples.

Documented validated analytical methods from the World Health Organization (W.H.O.) and the Food and Drugs Authority (F.D.A.) of USA are used in the laboratories at M.R.I to conform to the international standards. Documented standard operation procedures developed based on the above methods have been distributed to the state sector hospital laboratories through the Ministry of Health. It will be made available at www.mri.gov.lk for national and international reference. The chemicals, reagents and equipment used in analytical procedures are approved by the Cosmetics Drugs and Devices Authority of

Sri Lanka. The appropriate grades of chemicals and reagents (analytical, chromatographic, molecular biologic) with “CE” mark, are used in the analysis.

The reliability of the test reports depends on the performance of the equipment that is being used in the analysis. The periodic calibrations and maintenance of equipment are carried out to the maximum capability.

Quality control represents the procedures that monitor the performance parameters which will detect the source and magnitude of any possible errors and alert the laboratory personnel before releasing the results. Quality control is achieved by using internationally accepted standards, calibrators and quality control material. All the materials that are used for analysis are maintained in appropriate temperatures and are used well within the expiry dates.

The post analytical phase includes technical validation followed by clinical validation. The medical laboratory technologists perform the technical validation considering the documented raw data, calibrator and quality control results, performance of equipment and other contributory factors such as sample collection. The clinical validation followed by the authorization to release the results is performed by the specialist medical officers of the relevant field. The final test reports prepared by the medical laboratory technologists are released by the authorized signatories.

The main objectives of the external quality assessment (EQA) schemes include the evaluation of the Internal Quality Control programme of a participating laboratory. Majority of the laboratory specialties at MRI are participants of internationally accepted EQA programmes run by the World Health Organization and Centre for Disease Control, Atlanta, USA. Therefore, the laboratory analysis is being monitored at defined regular intervals by independent external bodies confirming the reliability of test results issued from the MRI.

The Medical Research Institute function as the national organizers of external quality assessment schemes in the areas of clinical chemistry, bacteriology and haematology.

NEQAS (National External Quality Assurance Scheme) in clinical chemistry covers 9 provinces including 75 state sector hospital labs. EQA samples are distributed bimonthly to cover 13 routine biochemical tests that are done in peripheral laboratories. This EQA sample is a “blind”, freeze dried QC with established traceability to international standards. The stability is maintained and transported in ambulances to the relevant destinations. The performance of each participating laboratories is assessed by a scoring system and appropriate technical advices are given to improve the test performance in these hospital laboratories.

NEQAS in Bacteriology covers 9 provinces including 40 state sector hospital labs and 15 private sector laboratories. EQA sample comprises of 3 pure bacterial cultures distributed quarterly. The participants perform the identification of the bacteria and antibiotic sensitivity test. The performance is evaluated by a scoring system and an annual evaluation report is given for overall performance of the laboratory.

The recently commenced NEQAS in Haematology covers 10 state sector labs with a quarterly distribution. The components of a full blood count are sent to the participants and their performance is assessed by consensus results.

Our goal is to achieve accreditation in compliance with the ISO 15189 standard in the near future with the assistance of the Ministry of Health.

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Dr Meliyanthi M. Gunatillaka,

Consultant Chemical Pathologist

Head, Department of Biochemistry, Medical Research Institute, Colombo