

<b>CONTINUAL IMPROVEMENT</b>			
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## 1.0 Purpose

To provide a description of the processes used for support and implement continuous quality improvement (CQI) programs at Case Medical Centre Laboratory. It also describes all aspects of CQI, and how each part relates to the other to create a functioning quality system.

## 2.0 Scope

The scope of CQI includes the continual improvement processes for identifying improvement activities, developing, recording, implementing action plans and communication to all laboratory personnel. This SOP is applicable to all laboratory personnel.

## 3.0 Terms, Definitions and Abbreviations

### 3.1 Terms and definitions

**Continual improvement:** Change that is focused on increasing the effectiveness and efficiency of the laboratory QMS to fulfil its policy and its objectives.

### 3.2 Abbreviations

CQI Continual Quality Improvement

Proteus Laboratory

SOP Standard Operating Procedure

N/A Not Applicable

QMS Quality Management System

QA Quality Assurance

QC Quality Control

EQA External Quality Assurance

PT Proficiency Testing

PDCA Plan Do Check Act

### 4.0 Tasks, Responsibilities and Accountabilities

<b>Task</b>	<b>Responsible</b>	<b>Accountable</b>
Identify areas of improvement	Laboratory personnel	Quality manager
Implementation of continual improvement	Laboratory personnel	Quality manager
Reporting of deviations	Laboratory personnel	Quality manager
Reporting concerns of complaints related to quality and safety	Laboratory personnel	Quality manager

5.0 Safety and Environment

N/A

6.0 Quality Assurance and Quality Control

N/A

## 7.0 Procedure

The Continual Improvement processes support the following efforts.

- a. Improve the quality of results or patient care by identifying problems in a timely manner and confirming, by documentation of corrective action, that such problems have been resolved.
- b. Provide continuous medical education and training to include competency assessment and verification. In addition, personnel records kept documenting all continuing education.
- c. Compliance with established policies and standards.

**Note:** Improvement plans are developed depending on the identified nonconforming work or areas that have been deemed necessary to be taken up as Quality Improvement projects.

### 7.1 Identification of improvement activities within the QMS

Continual improvement of the effectiveness and efficiency of the laboratory quality management system is accomplished through the review of the quality policy, documents and records, customer complaints, quality objectives, audit results, corrective and preventive actions, management review amongst others.

The laboratory Quality manual embodies the organizational commitment to continually improve the laboratory processes. Even after the QMS is developed, established, and implemented, continual improvement activities remain continuous. To identify future areas of improvement in the laboratory processes, the process continues to be analysed carefully through systematic oversight and feedback received from users and stakeholders to identify new areas of improvement and solutions to these identified areas.

The laboratory has created an environment that encourages and enables all participants to actively seek opportunities for improvement of performance in

processes, services, and products to improve user satisfaction. These processes include:

- Audits
- Customer complaints and suggestions
- Corrective actions and preventive actions
  
- Management reviews
- PT performance
- Quality indicators
- Risk assessment
- Weekly meeting amongst others.

Results from continual improvement activities are used to generate quality indicators, quality objectives, risk assessment activities, reviewer processes and other activities as required by the laboratory.

### **7.1.2 Quality Indicators and quality objectives**

#### **7.1.2.1 Collection of data, interpretation, and analysis**

Laboratory management has established quality indicators that are used to monitor and evaluate performance throughout the entire testing processes in all aspects of pre-examination, examination, post- examination, and management. The laboratory has developed an indicator matrix for planning, setting objectives, methodology, interpretation, limits, action plans and duration of measurements.

Quality indicators are monitored and reviewed quarterly to ensure continued appropriateness.

Key quality indicators monitored include:

- Errors at logging
- Critical /Urgent results not phoned out.
- Stock out
- EQA/PT performance

The laboratory, in consultation with its users has established turnaround time for each of its examinations. The laboratory evaluates whether it is meeting the set turnaround time monthly.

#### **7.1.2.2 Collection of data**

Reports of all key indicators as decided by the laboratory management are submitted to the quality manager at the end of every month.

#### **7.1.2.3 Outcome**

Based on the reports received, trend analysis is done and reported during the annual management review meeting

#### **7.1.3 Corrective and preventive action**

These actions relate to the laboratory management process, both administrative and specific laboratory requirements (i.e., result reports, equipment maintenance, QA/QC, safety/accident reports, etc.).

Both preventive and corrective actions are addressed and documented as soon as possible. Corrective and preventive action forms are used whenever possible to document incidents requiring corrective or preventive actions. Both records of CA and PA are reviewed quarterly, signed, and dated, to verify the status of all CA and PA.

### **7.2 Approaches to continual improvement**

Each identified area of improvement is considered as a continual improvement project. Staff are assigned individual projects that are implemented jointly as a team and documented in the quality improvement project plan form. The PDCA cycle is adopted in the development and implementation of these projects.

#### **7.2.1 Plan**

- Identify the problem,
- state the problem,
- collect baseline data,
- analyse the baseline data,

- Identify possible causes,
- Develop action plans,
- define overall goal,
- Brainstorm and document action plans,
- Select parameters for measurement,
- Document accepted results and then define how the data will be collected, reviewed, and analysed.

#### 7.2.2 Do

- Implement and monitor how the plan is being executed.

#### 7.2.3 Check

- Determine and document whether the change was effective
- Document unexpected observations

#### 7.2.4 Act

- If successful, develop and implement plans to standardize the process, communicate changes and train staff if necessary
- If unsuccessful, repeat PDCA cycle.

### 7.3 Implementation of Action plans

All action points recommended during continual improvement activities are included in an Action plan for easy monitoring during implementation. The Quality/ Laboratory manager is responsible for ensuring that all actions included in the action plan are implemented within the specified time frame.

#### **Communicating improvement plans to staff.**

Improvement plans are communicated to staff during quarterly meetings. Records of continual projects are available in the laboratory.

### 8.0 References/Related Documents

- Quality Manual (**PRL MAN 001**)
- Corrective Action and Preventive Action (**PRL MGT 009**)
- ISO 15189:2012

## Key Quality indicators

Quality indicator	Objective	Methodology	Targets	Action Plan
EQA	To ensure accurate reliable results	EQA reports	≥ 80% acceptable performance per analyte per survey	Corrective/ Preventive action when target is not met
Errors at logging	Capture Patient details accurately	Request form checks	≤ 3% errors per logger per month	Corrective/ Preventive action when target is not met
Critical / urgent Results not phoned out	Timely treatment is given to patients	Reviewing of results	0% results not phoned out	Corrective/ Preventive action when target is not met
Stock out	Meet the stated TAT	Stock- sheet	0% stock out within a month	Corrective/ Preventive action when target is not met

**Quality indicators Matrix**

Quality Indicator	Quarter 1			Quarter 2			Quarter 3			Quarter 4		
	Jan	Feb	Mar	APR	May	Jun	July	Aug	Sep	Oct	Nov	Dec
<b>EQA</b>												
<b>Errors at logging</b>												
<b>Stock out</b>												
<b>Critical/urgent Results not phoned out</b>												
<b>Comments</b>												

**Review history table**

<b>Version No</b>	<b>Date of next review</b>	<b>Date reviewed</b>	<b>Action taken/Remarks</b>	<b>Reviewed by</b>

