This document provides guidance on development of quality indicators and their use in the medical laboratory.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.
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For additional information on committee participation or to submit comments, contact CLSI.

Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org
Abstract

Clinical and Laboratory Standards Institute document QMS12-A—Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline provides guidance on development of quality indicators and their use in the medical laboratory. These indicators include measures developed in a single laboratory for local use and indicators developed by other organizations and national bodies. The document includes criteria for development of quantitative, ordinal, and qualitative indicators; it also includes procedures for gathering data, presenting and interpreting results, monitoring performance over time, and comparing performance with other laboratories or national norms.

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Foreword

With increasing awareness, the impact of medical errors can be seen on patient safety. Medical errors can result in annoyance and inconvenience such as time lost or necessitated patient revisits, but can also result in the more serious consequences of diagnostic delay or error, increased cost, inappropriate therapy, and worse, increased risk of patient illness, debility, and sometimes death. Medical errors occur throughout the health care process, in the clinical setting and also in the laboratory. An active program of quality management allows the laboratory to monitor for error with the intended goals of early detection and rapid remediation and correction, and more importantly, prevention of errors before they occur.

The process of monitoring for and addressing error does not just happen. Quality takes time to define. It requires planning of the processes and procedures that develop appropriate, measurable, interpretable information upon which action can take place in the cycle of continuous improvement. Those procedures can be referred to as quality indicators. Quality indicators are an integral component of all quality management systems, including ISO 9001,1 ISO 15189,2 and ISO 17025,3 and the system described within CLSI document HS01.4 Ideally the development of quality indicators should be based on both a risk assessment of potential errors and the frequency of observed errors.

Importantly, not all quality indicators are derived within the laboratory or are even laboratory centric. Many are recommended or required over a broader regional, state, or national network of laboratories or health care systems, based on voluntary participation, best practice recommendation, organizational mandate, or regulatory requirement. This document provides guidance in selecting and applying indicators that are developed in a single laboratory for local use and indicators developed by other organizations and national bodies.

Many organizations can benefit from guidance on selecting and developing the quality indicators they use. Experience demonstrates that poorly designed indicators can result in confusing and misleading information that leads less towards continual improvement, and more towards increased work, and often poor decision making. Others, while well designed and intended, are impractical because some laboratories do not have the resources to gather the actual information required, or do not have the capability or resources for following through with an appropriate action plan. Finally, some laboratories continue to collect information on parameters that are highly stable, rather than shift their focus, time, and energy to other indicators that may provide information that leads to change. Failure to recognize the value of information gathered is both ineffective and inefficient. The goal of this document is to highlight an effective approach to selection, development, interpretation, and application of information derived from well-designed quality indicators.

NOTE:
This document provides guidance in selecting and applying indicators that are developed in a single laboratory for local use and indicators developed by other organizations and national bodies.

IMPORTANT NOTE:
Poorly designed indicators can result in confusing and misleading information that leads less towards continual improvement, and more towards increased work, and often poor decision making.

KEY WORDS
Continual improvement
Corrective actions
Evidence-based decision making
Management review
Measurement
Metrics
Preventive action
Quality control
Quality indicator
Quality management system
Remedial actions
Introductory Chapters

These chapters include:

1. Scope
   - Document scope and applicable exclusions

2. Introduction
   - Introductory and background information pertinent to the document content

3. Terminology
   - Terms and definitions used in the document
   - Abbreviations and acronyms used in the document
Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline

1 Scope

This document provides guidance on development of quality indicators and their use in the medical laboratory. These indicators include measures developed in a single laboratory for local use and indicators developed by other organizations and national bodies. The document includes criteria for development of quantitative, ordinal, and qualitative indicators; it also includes procedures for gathering data, presenting and interpreting results, monitoring performance over time, and comparing performance with other laboratories or national norms.

This guideline is intended for use by laboratory directors, managers, supervisors, and the quality manager as a means to ensure that their laboratories implement an effective approach to selection, development, interpretation, and application of information derived from well-designed quality indicators.

Introduction

The term “quality indicator” refers to a systematic measurement process intended to provide information about the quality of a system. The concept of measurement as an essential part of quality dates back to the very beginnings of quality management as expressed by Walter Shewhart as “checking” within the “plan-do-check-act” (PDCA) cycle. The PDCA cycle in all its component parts provides a virtual never-ending process and is key for achieving the culture for quality transformation. An overview of the PDCA process is provided in Appendix A.

Commonly, performance of quality control (QC) equipment checks, such as measuring refrigerator or incubator temperatures, is considered as or is interpreted as a type of quality indicator. While it is accurate that QC measurements are a form of narrowly assessed metric, they are not considered quality indicators of a process, procedure, or outcome. The focus of this document more broadly addresses process measures, such as monitoring sample receipt to report turnaround time and sample collection errors. A variety of examples of process metrics is provided throughout the document.

Quality indicators can be designed to measure any aspect of laboratory service. It is helpful for management to take a broad view of laboratory operations, giving consideration to known risks and their potential consequences, before selecting a set of indicators to measure an aspect of the quality of operations. Many regulatory and accreditation requirements as well as laboratory guidelines and standards provide useful guidance on this matter.
The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in CLSI document HS01—A Quality Management System Model for Health Care. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are as follows:

<table>
<thead>
<tr>
<th>Documents and Records</th>
<th>Equipment</th>
<th>Information Management</th>
<th>Process Improvement</th>
</tr>
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<tbody>
<tr>
<td>Organization</td>
<td>Purchasing and Inventory</td>
<td>Occurrence Management</td>
<td>Customer Service</td>
</tr>
<tr>
<td>Personnel</td>
<td>Process Control</td>
<td>Assessments—External and Internal</td>
<td>Facilities and Safety</td>
</tr>
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</table>

QMS12-A addresses the QSEs indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on page 82.

Adapted from CLSI document HS01—A Quality Management System Model for Health Care.
Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

QMS12-A does not address the clinical laboratory path of workflow steps. For a description of the document listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

<table>
<thead>
<tr>
<th>Preexamination</th>
<th>Examination</th>
<th>Postexamination</th>
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<tbody>
<tr>
<td>Examination ordering</td>
<td>Sample collection</td>
<td>Sample transport</td>
</tr>
<tr>
<td>Sample receipt/processing</td>
<td>Examination</td>
<td>Results review and follow-up</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Results reporting and archiving</td>
<td>Sample management</td>
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</table>

GP26    GP26    GP26    GP26    GP26    GP26    GP26    GP26    GP26

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care.*
Related CLSI Reference Materials

**EP18-A2** Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009). This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for in vitro diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.

**GP22-A2** Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition (2004). This guideline considers continuous quality improvement (CQI) as five integrated quality system components, which include Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.

**GP26-A3** Quality Management System: A Model for Laboratory Services; Approved Guideline—third Edition (2004). This guideline describes the clinical laboratory’s path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements.

**GP27-A2** Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition (2007). This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.

**HS01-A2** A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004). This document provides a model for providers of health care services that will assist with implementation and maintenance of effective quality management systems.

**QMS11-A** Management of Nonconforming Laboratory Events; Approved Guideline (2007). This guideline provides an outline and the content for developing a program to manage a health care service’s nonconforming events that is based on the principles of quality management and patient safety.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.
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