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Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline

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.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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Advancing Quality in Health Care Testing

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Abstract

Clinical and Laboratory Standards Institute document GP35-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.

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

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.

2 Introduction

The term “quality indicator” refers to a systematic measurement process intended to provide information about the quality of a system.[5] 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,[1-3,6] as well as laboratory guidelines and recommendations,[4,7,8] provide useful frameworks for identifying aspects of laboratory service that are candidates for quality indicators.

Ideally, every aspect of laboratory services is objectively and regularly monitored (eg, all 12 quality system essentials [QSEs] and all phases of the path of workflow). Unfortunately, universal monitoring is impractical. Decisions need to be made about which processes to monitor and how frequently measurements should be made. Typically, clinical laboratories are managed using a set of indicators that provide information about only a fraction of laboratory functions at specific points in time.

Some quality indicators are required by law, regulation, accrediting organizations, or contractual arrangements (eg, requirements for internal QC monitoring of analytical systems and external proficiency testing [PT]). When not required by external agencies, quality indicators are chosen by leadership based on organizational goals, risk management, strategic planning, review of data and complaints, client recommendations, and subjective assessment.