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

PLEASE

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This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute (CLSI) consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (ie, candidate for advancement) for 60 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

Comment period ends

27 April 2009

The subcommittee responsible for this document will assess all comments received by the end of the comment period. Based on this assessment, a new version of the document will be issued. Readers are encouraged to send their comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; Fax: +610.688.0700, or to the following e-mail address: standard@clsi.org.

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COMMENT

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

Advancing Quality in Health Care Testing

Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related health care issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and health care services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the health care community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the health care community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (ie, that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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

Michael A. Noble, MD, FRCP(C)
Maureen E. Ahler, MSQA, MT(ASCP)
Bette Bennett
Julie Coffey, CQA, CMQ/OE(ASQ), ART, MLT
Kathryn Connolly, CQA (ASQ), MT(ASCP)
Judy A. Daly, PhD
Christine Fleming, BA, MLT
Sonia C. Giribaldi, MT(ASCP)
Elizabeth Kenimer Leibach, EdD, MS, CLS, MT
John J. Mahoney
Barbara Parsons, MA, MT(ASCP)
Charles D. Reynolds, MS
Paul Valenstein, MD

Abstract

Clinical and Laboratory Standards Institute document GP35-P—*Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Proposed 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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Proposed Guideline

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Committee Membership

Area Committee on Quality Systems and Laboratory Practices

Sheila M. Woodcock, MBA, FCSMLS(D)
Chairholder
QSE Consulting
Rose Bay, Nova Scotia, Canada

Carl D. Mottram, BA, RRT, RPFT, FAARC
Co-Vice-Chairholder
Mayo Clinic
Rochester, Minnesota

Albert Rabinovitch, MD, PhD
Co-Vice-Chairholder
NovoMetrics, Inc.
Mountain View, California

Eric Arendash, MT(ASCP)
Centers for Medicare & Medicaid Services
Philadelphia, Pennsylvania

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ) CQM
Laboratories Made Better!
Broomfield, Colorado

Theresa Billups, MBA, MT(ASCP)DLM
Remel, Inc.
Lake Charles, Louisiana

Margaret M. Grimes, MD
Medical College of Virginia Campus
Richmond, Virginia

Devery Howerton, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia

Peter L. Minetti, CQA, CQE, CQMgr(ASQ)
Fujirebio Diagnostics, Inc.
Malvern, Pennsylvania

Bruce D. Tually, BAppSc, MAppSc
Hunter Area Pathology Service
New South Wales, Australia

Advisors

Kay M. Creed
Bon Secours Health Partners Laboratories
Richmond, Virginia

Dennis J. Ernst, MT(ASCP)
Center for Phlebotomy Education
Ramsey, Indiana

Steven I. Gutman, MD, MBA
FDA Ctr. for Devices/Rad. Health
Rockville, Maryland

Stephen J. Sarewitz, MD
Valley Medical Center
Renton, Washington

Jennifer Schiffgens, MBA, MT(ASCP)
California Pacific Medical Center
San Francisco, California

Daniel W. Tholen, MS
American Association for Laboratory Accreditation
Traverse City, Michigan

Subcommittee on Development and Use of Quality Indicators

Michael A. Noble, MD, FRCP(C)
Chairholder
University of British Columbia
Vancouver, Canada

Kathryn Connolly, CQA (ASQ), MT(ASCP)
COLA
Columbia, Maryland

Judy A. Daly, PhD
University of Utah-Primary Children's Medical Center
Salt Lake City, Utah

Christine Fleming, BA, MLT
Quality Management Program-Laboratory Services
Toronto, Canada

John J. Mahoney
LifeScan, Inc.
Milpitas, California

Barbara Parsons, MA, MT(ASCP)
Johns Hopkins Medical Institutions
Baltimore, Maryland

Charles D. Reynolds, MS
Centers for Medicare & Medicaid Services
Boston, Massachusetts

Paul Valenstein, MD
Pathology and Laboratory Management Associates
Ann Arbor, Michigan

Advisor

Lee Hilborne, MD, MPH, FASCP
RAND Corporation
Santa Monica, California

Staff

Clinical and Laboratory Standards Institute
Wayne, Pennsylvania

Lois M. Schmidt, DA
Vice President, Standards Development and Marketing

Jennifer K. McGeary, MT(ASCP), MSHA
Staff Liaison

Melissa A. Lewis
Editor

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Maureen E. Ahler, MSQA, MT(ASCP), Kaiser Permanente Medical Care
Bette Bennett, LifeLabs Medical Laboratory Services
Julie Coffey, CQA, CMQ/OE(ASQ), ART, MLT, Quality Management Program – Laboratory Services
Sonia C. Giribaldi, MT(ASCP), Alfred I. DuPont Hospital for Children
Elizabeth Kenimer Leibach, EdD, MS, CLS, MT, Medical College of Georgia

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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 9000,[1] ISO 15189,[2] and ISO 17025,[3] and the system described within CLSI/NCCLS document HS01.[4]

Importantly, not all quality indicators are derived within the laboratory. Many are recommended or required over a broader regional, state, or national network of laboratories, based upon voluntary participation, best practice recommendation, organizational mandate, or regulatory requirement. This document provides guidance in selecting and applying indicators that are derived from outside the laboratory.

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 in some laboratories because they 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.

Invitation for Participation in the Consensus Process

An important aspect of the development of this and all CLSI documents is the consensus process. Within the consensus process, CLSI members and other interested parties (1) have the opportunity to review and comment on CLSI publications in development; and (2) are assured that their comments will be given serious consideration. All CLSI documents evolve, as does the technology affecting laboratory and health care procedures, methods, and protocols; and therefore, through the operation of the consensus process, CLSI documents are expected to undergo cycles of evaluation and modification. CLSI documents are expected to undergo cycles of evaluation and modification.

The Area Committee on Quality Systems and Laboratory Practices has attempted to engage the broadest worldwide representation in the committee deliberations to develop this document. Consequently, it is expected that issues may still remain unresolved when the proposed-level document is published. Review and comment within the CLSI process is the mechanism for resolving such issues.

The CLSI voluntary consensus process depends on the expertise of worldwide reviewers whose comments add value to the final document. At the end of a 60-day comment period, each subcommittee is obligated to review all comments and to respond in writing to all substantive comments. Where

appropriate, modifications will be made to improve the document, and all comments along with the subcommittee's responses will be included in an appendix when the document is published at the next consensus level.

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; Proposed 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] When used in this document, "quality indicator" refers to a measurement process that addresses how well a laboratory is meeting a defined aspect of its customers' needs. This includes providing information about the quality of clinical laboratory services or services where clinical laboratory findings are integral to other components of the care process (eg, the use of data from the microbiology laboratory to measure the quality of hospital infection control practices).

Commonly, performance of quality control 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 quality control measurements are a form of narrowly assessed metric, they are not considered a quality indicator 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 before selecting a set of indicators to measure an aspect of the quality of operations. The requirements described by the International Organization for Standardization (ISO),[1-3] the requirements described by Clinical Laboratory Improvement Amendments (CLIA),[6] the guidance of Clinical and Laboratory Standards Institute (CLSI) (see CLSI/NCCLS documents HS01 and GP26),[4,7] and the domains described by Institute of Medicine[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 must 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 quality control (QC) monitoring of analytic systems and external proficiency testing [PT]). When not required by external agencies, quality indicators are chosen by leadership based on organizational goals, strategic planning, review of data and complaints, and subjective assessment.