

# A Summary of Deliberations on Strategic Planning for Continuous Quality Improvement in Laboratory Medicine

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**Key Words:** Quality; Strategic planning; Laboratory medicine

DOI: 10.1309/AJCP4M9UYBVMHTKC

## Abstract

*On September 24-26, 2007, the Centers for Disease Control and Prevention convened the 2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health to develop an action plan for change for the immediate and long-term future. A wide variety of stakeholders, including pathologists, pathologist extenders, clinicians, and researchers, examined means to improve laboratory service communication, quality parameters, and potential future laboratory contributions to health care. In this summary document, we present the identified gaps, barriers, and proposed action plans for improvement for laboratory medicine in the 6 quality domains identified by the Institute of Medicine: safety, effectiveness, patient centeredness, timeliness, efficiency, and equity. Five major recommendations emerged from concluding discussions and included focusing on preanalytic and postanalytic processes as areas of potential quality improvement and recruiting a multidisciplinary group of nonlaboratory stakeholders to work with laboratory personnel to achieve improvement goals.*

The Centers for Disease Control and Prevention (CDC) 2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health (2007 Institute) was designed to bring together national leaders in laboratory medicine, experts on health care policy and quality, and representatives from multiple stakeholder groups for high-quality laboratory services to develop an action plan for change. An underlying assumption motivating the 2007 Institute was that the current state of laboratory medicine practice may be viewed as supporting less than optimal patient care. It is well recognized that pathologists and other laboratory medicine personnel work extremely hard and have produced remarkable achievements, although the potential for further improvement is still present.

The 2007 Institute focused on three themes: (1) advancing collaborative care, or ways to enhance communication and collaboration of providers of laboratory services and consumers, other providers and users of laboratory services, and payers; (2) measures of quality, or ways to define quality parameters that will link laboratory service performance with patient outcomes; and (3) preparing for the future, or ways that laboratory medicine is expected to contribute to the future of health care. The goals of the 2007 Institute were to lay the foundation for strategies not only to identify and plan immediate actions to optimally use laboratory medicine to improve services but also to develop a 5- to 10-year strategic plan to actively address the broader roles that laboratory medicine must assume to ensure safe and effective care and improved patient outcomes for all Americans. The key outputs of the 2007 Institute were designed to be the collective recommendations of the theme groups for a multiyear strategic plan for the field of laboratory medicine.

## Prior Work Used to Inform the 2007 Institute

The 2007 Institute was the most recent in a series of CDC initiatives aimed at investigating the state of laboratory medicine and exploring means of improving practice. During the 1980s and 1990s, the CDC convened 5 meetings to build stakeholder coalitions, to facilitate strategic planning, and to formulate recommendations on laboratory-related issues.<sup>1</sup> These meetings focused on the impact of alternative reimbursement methods on laboratory practice (1984), public health laboratory safety management (1985), quality management of laboratory test results in a changing health care environment (1986), quality improvement of health management through clinician and laboratory teamwork (1989), and evaluation of the frontiers of laboratory practice research (1995).

The CDC convened the Quality Institute Conference 2003 that targeted a number of quality and patient safety issues. Other CDC initiatives in 2005 included the evaluation of quality indicators and an inventory of laboratory patient safety initiatives with input from the Clinical Laboratory Management Association and the Institute for Quality in Laboratory Medicine.

## 2007 Institute Structure

The 2007 Institute was convened on September 24-26, 2007, in Atlanta, GA, and was structured as an invitation-only meeting, composed of information presentation sessions that all invitees attended ■Appendix 1■ and 3 breakout groups, each group composed of approximately one third of all invitees.<sup>2</sup> For each of the 3 themes, 2007 Institute participants defined the current and ideal states of laboratory service practice, identified gaps between the current and ideal states, and suggested action plans necessary to address the gaps currently separating participants' perceptions of the current and ideal states of laboratory medicine practice.

A total of approximately 100 invitees and CDC staff attended the 2007 Institute, and these participants represented a variety of stakeholders, including pathologists, multiple other laboratory personnel, laboratory medicine personnel representatives from particular professional organizations (eg, American Society for Clinical Laboratory Science), nonpathologist physicians (mostly primary care clinicians), representatives from funding agencies (eg, Agency for Healthcare Research and Quality), representatives from payer organizations, patient advocates, health information technology experts, health services researchers, laboratory administrators, and representatives from nationally recognized health care quality organizations.

## Methods and Materials Used to Synthesize the Summary

The ideal outcomes to be developed by Institute attendees participating in discussion groups focused on each of the three Institute themes: (1) identification of unmet challenges, (2) identification of steps to meet challenges, and (3) launching an agenda for change. The following is a summary of the information relevant to these outcomes presented in tabular form. Four major information sources were used to synthesize this summary: (1) written background and Institute syllabus materials provided to invitees before or at the 2007 Institute (eg, the Lewin Group and National Quality Forum reports),<sup>3,4</sup> (2) transcripts of audiotapes obtained by researchers funded by the CDC to actively participate in the 2007 Institute as a first step in development of a laboratory medicine research agenda, (3) handwritten field notes written by the 2 of us (D.M.G. and S.S.R.) during the course of the Institute, and (4) examination of all written notes from the breakout groups.

In alignment with a desire to present the information emanating from the Institute in a nationally meaningful context, the laboratory medicine quality gaps and potential action plans were classified into one of the 6 Institute of Medicine (IOM) health care domains: safety, effectiveness, patient centeredness, timeliness, efficiency, and equity. It is evident that many of the gaps articulated during the Institute could fit under more than one of the IOM characteristics. It also is evident after examining the quality gaps and suggested action plans to address the gaps ■Table 1■, ■Table 2■, ■Table 3■, ■Table 4■, ■Table 5■, and ■Table 6■ that either or both of the stated gaps and correlating action plans at least imply root causes for quality failures. However, it was not an explicit charge of 2007 Institute invitees to perform formal root cause analysis on the identified quality gaps. Some root causes may have been relatively evident, and they appear in the following summary. However, some of the quality gaps articulated during the 2007 Institute were complex, involving organizational, economic, and political causes that could not be sufficiently explored during the discussion sessions.

The summary information was validated independently by all authors attending the 2007 Institute and by CDC project members and 2007 Institute staff.

## Summary

A subgroup of the 2007 Institute attendees was invited by the CDC to participate in a discussion aimed at articulating feasible "next steps" that attendees, others in the laboratory community, and other stakeholders may and should pursue, based on the information obtained and discussed

**Table 1**  
**Safety**

Quality Gap	Theme Group*	Action Plans for Improvement
Insufficient integration of LISs with clinical information systems (lack of interoperability)	C	Meet at the table with industry and business IT professionals to collaborate on the adoption/integration of applications already being developed, tested, and/or used (potential good model: pharmacy)
No standardized measurement of error or quality in anatomic pathology	M	Investment of necessary financial and human resources for development of standardized performance measures
Lack of data on POLs and/or POC testing	F	Creation of funding opportunities for research or demonstration projects aimed at gathering evidence about the performance of POLs and/or POC testing
High workforce vacancy rates	F	Provision of increased education resources and opportunities focused on laboratory careers (starting at the high school level); recruitment of professional educators into all health science programs; willingness by public and private funding agencies, professional organizations, and academic institutions to invest in new/additional training programs, especially for histotechnology
Lack of direct verbal communication between laboratory professionals and all other health care practitioners	C	Development of health care teams that integrate a pathologist in the day-to-day discussion and/or planning of patient care
Lack of longitudinal tracking of currently measured quality assurance measures	M	Increased education related to methods and the value of use of process control charts, etc
Lack of adoption of QI systems/methods from industry or business (eg, Lean, Six Sigma)	F	Increased education and leadership from pathologist champions to initiate adoption of potentially beneficial, evidence-based QI systems from business and industry

IT, information technology; LIS, laboratory information system; POC, point-of-care; POLs, physician office laboratories; QI, quality improvement.

\* C, collaborative care; F, futures; M, measures.

**Table 2**  
**Effectiveness**

Quality Gap	Theme Group*	Action Plans for Improvement
Insufficient HIT coding/language standardization for seamless laboratory-clinical information sharing at user-friendly interfaces	C	Need to engage programmers/systems analysts <i>first</i> to develop what is needed, then engage LIS and HIT personnel to integrate, implement, and pilot test what has been built. Basic science informatics leaders must decide on a standardized HIT coding/language (eg, HL7, LOINC)
Insufficient or nonexistent integration of public health LIS and public and private LIS at the POC	C	Same as above with provision of public health resources for development of interoperable system
Lack of communication with nonlaboratory health care colleagues and other stakeholders about laboratory processes and the value of laboratory services	C	Development of interdisciplinary health care teams that include pathologists and other diagnostic testing experts
Lack of evidence-based performance measures	M	Investment of financial and human resources to develop evidence-based performance indicators using previously used and well-described health services research methods (including protocols developed by the CDC)
Pervasive and continuous “black box” laboratory and pathologist culture	F	Investment of financial and human resources supporting behavioral research related to organizational culture and physician behavior using well-established quantitative and qualitative methods
Lack of cost analyses providing evidence for the economic value of laboratory services	M	Investment of financial and human resources supporting economic research
Lack of laboratory community willingness to partner with multiple and diverse stakeholders for broader political goals potentially benefiting all physician/provider groups and practice types (ie, lack of team players)	F	Active search, identification, and recruitment of pathologist champions to advocate and lead proposed action plans, with acknowledgment of creation of some incentives for recruitment and retention of leaders
Lack of proactive pathologist leadership	F	Active search, identification, and recruitment of pathologist champions to advocate and lead proposed action plans, with acknowledgment of creation of some incentives for recruitment and retention of leaders

CDC, Centers for Disease Control and Prevention; HIT, health information technology; HL7, Health Level 7; LIS, laboratory information system; LOINC, logical observation identifiers names and codes; POC, point-of-care.

\* C, collaborative care; F, futures; M, measures.

during the 2007 Institute. Four major recommendations and suggestions emerged from this discussion:

1. Further work should first focus on processes in the preanalytic and postanalytic phases of the total testing process.

2. Recruitment of a multidisciplinary group of nonlaboratory stakeholders with whom to work is critical in achieving goals for improvement. Funding agencies apart from the CDC and professional educators were thought to be particularly critical partners.

**Table 3**  
Patient Centeredness

Quality Gap	Theme Group*	Action Plans for Improvement
Intrapatology community contentiousness about quality and safety issues	C	Increased pathologist education and enforcement of accountability policies regarding disruptive physician behavior (eg, JCAHO January 1, 2008, reporting policy on disruptive physician behavior)
Little to no direct communication with patients about tests and results	F	Increased patient education about laboratory processes and services and development of a patient education tool focused on providing a mechanism for dialogue between patients and laboratory personnel (including pathologists) about laboratory tests and the meaning of test results
Lack of information about patient preferences regarding laboratory services and diagnostic testing	F	Investment of financial and human resources into patient preference research related to laboratory services and diagnostic testing
Few and fragmented consumer education resources about laboratory professionals, laboratory services, and the value of the laboratory to patient care	C	Increased patient education about laboratory processes and services and development of a patient education tool focused on providing a mechanism for dialogue between patients and laboratory personnel (including pathologists) about laboratory tests and the meaning of test results
Lack of quality indicators based on evidence showing an impact on patient outcomes	M	Investment of financial and human resources into quality indicator development research
Lack of education and awareness by all laboratory professionals about health services research and the current generally accepted goal of making patient centeredness the aim of all quality improvement efforts	F	Increased educational programs, including continuing medical education programs, with possible continuing medical education requirements for a certain amount of this educational content

JCAHO, Joint Commission on Accreditation of Healthcare Organizations.

\* C, collaborative care; F, futures; M, measures.

**Table 4**  
Timeliness

Quality Gap	Theme Group*	Action Plans for Improvement
Chronic workforce vacancies	F	Provision of increased education resources and opportunities focused on laboratory careers (starting at the high school level); recruitment of professional educators into all health science programs; willingness by public and private funding agencies, professional organizations, and academic institutions to invest in new/additional training programs, especially for histotechnology
Lack of evidence for many turnaround time quality assurance measures related to their impact on clinically significant outcome measures	M	Investment of financial and human resources into quality indicator development research
Lack of specific data on reporting of critical values	C	Investment of financial and human resources into quality indicator development research
Variability in reporting of significant public health and genetic test results	C	Provision of public health resources for development of interoperable systems
Lack of communication between laboratory personnel and clinicians about real needs and the rationale for test turnaround times	C	Development of interdisciplinary health care teams that include pathologists and other diagnostic testing experts
Pathologist lack of education about need for shift from individual to team work efforts	F	Increased pathologist education and enforcement of accountability policies regarding disruptive physician behavior (eg, JCAHO January 1, 2008, reporting policy on disruptive physician behavior)
Cultural resistance to change with lack of adoption of QI systems/methods from industry or business or new technologies impacting timeliness	C	Increased education and leadership from pathologist champions to initiate adoption of potentially beneficial, evidence-based QI systems from business and industry

JCAHO, Joint Commission on Accreditation of Healthcare Organizations; QI, quality improvement.

\* C, collaborative care; F, futures; M, measures.

3. Build partnerships with health information technology experts and commercial laboratory information system vendor staff with the programming and systems analysis expertise to generate what is needed to solve the perceived information technology barriers and problems first, before engaging application experts to implement and test the tools developed initially.
4. Bring laboratory medicine professionals of all types up to speed on current knowledge and thought regarding health services research, quality improvement, and patient safety.

**Table 5**  
Efficiency

Quality Gap	Theme Group*	Action Plans for Improvement
Chronic workforce vacancies	F	Provision of increased education resources and opportunities focused on laboratory careers (starting at the high school level); recruitment of professional educators into all health science programs; willingness by public and private funding agencies, professional organizations, and academic institutions to invest in new/additional training programs, especially for histotechnology
High level of interpractice and intrapractice variability with no process standardization at any level	M	Investment of resources into national initiatives aimed at standardization of laboratory processes and identification of best practices
"Discontinuity of care" within the laboratory	C	Investment of resources for studying intralaboratory communication and work processes to provide evidence for root cause analyses and further research
No measurement for overuse, underuse, or misuse of tests	M	Investment in the performance of resource utilization research relating to laboratory testing use
No mechanism for dissemination of best practices	C	Development of an education and informational tool for dissemination of laboratory-related information, including evidence-based best practices
No indicators of efficiency that are broadly accepted and measured	F	Investment in research on efficiency measurement
Cultural resistance to change with lack of adoption of QI systems/methods from industry or business or new technologies impacting efficiency	F	Increased education and leadership from pathologist champions to initiate adoption of potentially beneficial, evidence-based QI systems from business and industry

QI, quality improvement.

\*C, collaborative care; F, futures; M, measures.

**Table 6**  
Equity

Quality Gap	Theme Group*	Action Plans for Improvement
Variable use of defensive practice owing to malpractice concerns	C	Educate pathologists about evidence related to transparency related to errors and open physician-patient communication and decreased risk of litigation
Lack of financial incentives for laboratory consultative services	F	Pathologist leadership working with political leadership to modify pathologist and laboratory reimbursement based on the collection and presentation of evidence demonstrating the value of laboratory consultative services
Lack of national standardization of practice	M	Investment of resources into national initiatives aimed at standardization of laboratory processes and identification of best practices
Lack of accountability for laboratory/pathologist performance	M	Pathologist leaders need to work with government regulatory agencies and other professional organizations (eg, American Medical Association) and with a relevant group of nonpathologist scientific experts to participate in the ongoing processes of identifying and developing performance measures and processes to use on a national level for pathologist accountability.
Lack of development of a national agenda for laboratory performance indicators	M	Investment of financial and human resources into quality indicator development research

\*C, collaborative care; F, futures; M, measures.

## Appendix 1 Institute Planners, Presenters, and Participants

### Session Presenters

2007 Institute: Managing for Better Health: Welcome Keynote Address: Managing for Better Health at Intermountain Healthcare	Joe Boone, PhD, and Anne Haddix, PhD Brent C. James, MD, MStat
Report on the Status of Laboratory Medicine Laboratory Medicine and Quality in the 21st Century The Future of US Healthcare	Clifford Goodman, MD Raj Behal, MD, MPH Gail Wilensky, PhD

### Breakout Groups

Advancing Collaborative Care	Paul Epner, MEd, MBA, coleader, Institute committee representative; Elissa Passiment, EdM, coleader, Institute committee representative; John Hickner, MD, MSc, Work Group; Linda McKibben, MD, DrPH, Work Group, CDC Consultant
Invitees	Nancy Elder, MD, MSPH; Daniel J. Fink, MD, MPH; M. Hall Gregg, PhD; Mark Johnston; Brian F. Keaton, MD, FACEP; Joseph Kelly; Michael Laposata, MD, PhD; Douglas Lowery North, MD; William H. Mitchell, MD, FACS; Viola Naylor; James Pearson, PhD, BCLD; Michael Ross, MD; Alan Simon, MD; Connie Slayton; Neil Wenger, MD, MPH; Emily S. Winn-Deen, PhD
Measuring Quality	Rick Panning, MBA, CLS (NSA), coleader; Ana Stanković, MD, PhD, coleader, Institute committee representative; Larry J. Kricka, DPhil, FACB, Work Group; Mario Plebani, MD, Work Group; Devery Howerton, PhD, Work Group, Institute committee representative; Linda McKibben, MD, DrPH, Work Group, CDC Consultant
Invitees	Raj Behal, MD, MPH; Helen Burstin, MD, MPH; Robert H. Christenson, PhD, DABCC, FACE; Julie A. Gayken; Lee Hilborne, MD, MPH, FASCP, FCAP, DLM(ASCP); Verlin Janzen, MD, FAAFP; Patricia Maloney; Stephen T. Mennemeyer, PhD; Lisa Nern, MSW; Mary P. Nix, MS, MT(ASCP)SBB; Margaret Peck, MS, MT(ASCP); Daniel Marques Périgo, RPh; Stephen Raab, MD; Neysa R. Simmers, CLS (NCA), MEd, MBA; Susan South, MT(ASCP)SBB; Dan Tholen, MS; Elizabeth (Liz) A. Waggar, MD; Maxfield L. Williams
Preparing for the Future	George D. Lundberg, MD, coleader; Robert Michel, coleader, Institute committee representative; D. Joe Boone, PhD, Work Group; Linda McKibben, MD, DrPH, Work Group, CDC Consultant
Invitees	Peter Basch, MD, FACP; Ian Barnes, PhD, FRCPath; Sophia Chang, MD, MPH; Paul M. Fischer, MD; Marc D. Grodman, MD; Cyril Michael Hetsko, MD, FACP; Richard E. Horowitz, MD; Richard S. Johannes, MD; Daniel H. Johnson, Jr, MD; Brian R. Klepper, PhD; Michael Laposata, MD, PhD; Karen Linscott, MA, PT; Janet M. Marchibroda, MBA; Diana Mass, MA, MT(ASCP), CLS (NCA); Thomas M. Sodeman, MD, FCAP; Kenneth Thorpe, PhD; Ann M. Vannier, MD; Gail R. Wilensky, PhD; Tom Williams, MBA, MPH

Information on past Institutes is available at the DLS Quality Institute abstracts Web site ([http://www.cdc.gov/mlp/QIConference/Abstracts/abstract\\_21.aspx](http://www.cdc.gov/mlp/QIConference/Abstracts/abstract_21.aspx)).

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*Supported by cooperative agreement (C107-708) from the CDC.*

*Based on the 2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health, convened by the CDC.*

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### References

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