NQF

NATIONAL QUALITY FORUM

LABORATORY MEDICINE

Preferred Practices for Measuring and Reporting Patient Safety and Communication in Laboratory Medicine

A CONSENSUS REPORT

LABORATORY MEDICINE STEERING COMMITTEE

Charles R. Denham, MD (Co-Chair)
Texas Medical Institute of Technology
Austin, TX

Paul Valenstein, MD (Co-Chair)
St. Joseph Mercy Hospital
Ann Arbor, MI

Rhonda Bruxvoort
Iowa Foundation for Medical Care
West Des Moines, IA

Nancy Elder, MD
University of Cincinnati
Cincinnati, OH

Frank Federico, RPh
Institute for Healthcare Improvement
Cambridge, MA

Paul Griffey, MBA, MT
LifeBridge Health
Baltimore, MD

Myla Lai-Goldman, MD
Laboratory Corporation of America Holdings
Burlington, NC

David Mongillo, MPH
American Clinical Laboratory Association
Washington, DC

Rick Panning, MBA
Allina Hospitals & Clinics
Minneapolis, MN

James Pearson, DrPH
Division of Consolidated Laboratory Services
Commonwealth of Virginia
Richmond, VA

Joanne Simpson
Children's Hospital and Medical Center
Seattle, WA

Milenko Tanasijevic, MBA, MD
Brigham and Women's Hospital and Dana Farber Cancer Institute
Boston, MA

Ann Watt, MBA
The Joint Commission
Oakbrook Terrace, IL

Judith Yost
Centers for Medicare & Medicaid Services
Baltimore, MD

Richard Zarbo, MD
Henry Ford Health System
Detroit, MI

Liaison Members

Joe D. Boone
Centers for Disease Control and Prevention
Atlanta, GA

Susan Snyder
Centers for Disease Control and Prevention
Atlanta, GA

PROJECT STAFF

Nicole W. McElveen, MPH
Program Director

Robyn Y. Nishimi, PhD
Senior Advisor

Fatema Salam, MPH
Senior Program Director

Helen Burstin, MD, MPH
Senior Vice President, Performance Measures

Stacy Melanson, MD, PhD
Clinical Consultant
Brigham and Women's Hospital and Dana Farber Cancer Institute
Boston, MA

Foreword

FOR MOST PATIENTS, THE CLINICAL LABORATORY is an integral part of care. Laboratory charges occur for virtually all hospital admissions, and laboratory medicine affects nearly all patient care in all clinical settings.

Not only are essentially all patients touched by laboratory work, but the results of those analytics are an essential component to informed decisionmaking. Many care decisions are based directly on information gleaned from laboratory results.

Successful quality improvement efforts have focused on the analytic phases of laboratory testing, but efforts at continued quality improvement have focused less on the time directly before testing (preanalytic) and after testing (postanalytic). The pre- and postanalytic phases of laboratory testing are especially critical points upon which to focus patient safety improvements. Evidence indicates that errors occur in those windows at an uncommonly high rate—with preanalytic error rates as high as 75 percent and postanalytic error rates as high as 31 percent. These errors pose a direct threat both to patient safety and to consumers' confidence in the healthcare system—for example, improper patient identification can lead to misdiagnosis or wrong treatment.

In order to foster quality improvement in the healthcare laboratory, healthcare stakeholders require a foundation for the development of performance measures in laboratory medicine. Thus, the National Quality Forum (NQF), which was established in 1999 to facilitate widespread healthcare quality improvement, sought to endorse a set of preferred practices that focus on patient safety and communication for laboratory services. This report represents the culmination of that project. The resulting set of preferred practices is an important step in improving patient safety and engagement.

NQF thanks the Laboratory Medicine Steering Committee and its members for their efforts in ensuring that laboratory medicine is safe and trustworthy.

Janet M. Corrigan, PhD, MBA
President and Chief Executive Officer

The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.

Support for this project has been provided by the Centers for Disease Control and Prevention (www.cdc.gov).

The findings and conclusions in this report have not been formally disseminated by the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry and should not be construed to represent any agency determination or policy.

Recommended Citation: National Quality Forum (NQF). *Preferred Practices for Measuring and Reporting Patient Safety and Communication in Laboratory Medicine: A Consensus Report.* Washington, DC: NQF; 2009.

ISBN: 978-1-933875-31-6

Table of Contents

Executive Summary

PATIENT SAFETY CONTINUES to be one of the most important aspects of improving healthcare quality, and the National Priorities Partnership has made safety a priority area—specifically to "improve the safety and reliability of America's healthcare system."

Clearly, safety within individual sectors of the healthcare system is essential. One important part of the system, however, touches the diagnosis and treatment of thousands of patients each day across all care settings—laboratory medicine service. Thus, safety improvements in this area have the potential for widespread impact. Today, laboratories strive to address quality and safety at every stage of laboratory testing. Still, errors within laboratory testing services continue to have a significant effect on patient safety, despite the efforts of several initiatives, regulations, and programs. Furthermore, most studies indicate that laboratory errors occur either before testing (preanalytic phase) or directly after testing (postanalytic phase) is performed; preanalytic errors range from 32 percent to 75 percent, and postanalytic errors range from 9 percent to 31 percent.

In 2006, the National Quality Forum (NQF) began efforts to define laboratory medicine measurement and reporting. Collaborating with the Centers for Disease Control and Prevention (CDC), a workshop was held with 23 key stakeholders to promote a dialogue among participants with diverse backgrounds. The emerging themes from this workshop were the challenges laboratories face in implementing standards, particularly because many factors that span the preanalytic, analytic, and postanalytic phases are beyond the control of the laboratory. A commissioned paper analyzing existing guidelines also revealed that identifying evidence-based practice and care guidelines for the pre- and postanalytic laboratory phases was critical to move the quality agenda forward in the laboratory community.

This NQF report, *Preferred Practices for Measuring and Reporting Patient Safety and Communication in Laboratory Medicine,* is the follow-up effort to that initial workshop and paper. It highlights six preferred practices that have been endorsed as national voluntary consensus standards to drive quality improvement within the pre- and postanalytic laboratory phases. These practices are intended to serve as a foundation to focus on

improved patient safety and communication of diagnostic services during the pre- and postanalytic phases. They also are intended as the starting point for the development of performance measures in laboratory medicine communication and patient safety. The NQF-endorsed® practices are organized along six domains and are suitable for widespread implementation; they also are applicable and generalizable to multiple care settings and populations. Specifically, the practices address:

- **Laboratory Leadership**
  Preferred Practice 1: Leaders of organizations that participate in test ordering and leaders of clinical laboratories should collaboratively ensure that specific expectations regarding communication to and from the laboratory are met.
- **Patient/Specimen Identification**
  Preferred Practice 2: Standardized policies, processes, and systems should be implemented to ensure the accurate and legible labeling of laboratory specimens.
- **Sample Acceptability**
  Preferred Practice 3: Collection and processing facilities should ensure that acceptable specimens are collected using appropriate techniques.
- **Test Order Accuracy**
  Preferred Practice 4: Organizations should implement systems to ensure that all test orders are accurately communicated to laboratory staff in a timely manner.
- **Verbal Communication**
  Preferred Practice 5: For verbal or telephonic reporting of critical test results, verify the test results by having the person who is receiving the information record and read back the complete test result.
- **Critical Value/Result Reporting**
  Preferred Practice 6: Communicate critical laboratory values/results to the individuals who require them and appropriately document them in a secure, confidential, accurate, and timely manner.

Implementation of these practices will improve patient safety and communication processes. Furthermore, as laboratories adopt a more standardized approach for test orders and critical value/result reporting, as well as accelerate the implementation of interoperable electronic information systems, significant quality improvement can be achieved. Laboratory medicine quality and safety is of key importance to furthering the goal of high-quality healthcare for every American.

Preferred Practices for Measuring and Reporting Patient Safety and Communication in Laboratory Medicine: A Consensus Report

Background

THE LABORATORY IS AN INTEGRAL PART of the continuum of care, extending across clinical (i.e., diagnosis, treatment), public health, and research settings.[1] According to data from the Centers for Medicare & Medicaid Services' Medicare database, laboratory charges occur for 98 percent of hospital admissions.[2] Because laboratory medicine affects nearly all patient care across the spectrum of healthcare settings, assuring quality and safety at every stage of laboratory testing is of key importance to furthering the goal of providing high-quality healthcare for every American.[3]

Efforts to define and achieve consistent quality in laboratory testing have been ongoing, including programs such as Lean Six Sigma,[4] Q-Tracks, and Q-Probes.[5] Federal regulations were put in place in 1992—specifically, the Clinical Laboratory Improvement Amendments (CLIA)—to set minimum quality standards for clinical laboratory testing.[6] Currently, more than 200,000 U.S. laboratories are certified under the CLIA regulations.[7] Professional organizations such as The Joint Commission, the College of American Pathologists (CAP), and the Clinical and Laboratory Standards Institute have developed guidelines, policies, and standards to ensure patient safety and better quality within the laboratory setting. Most recently, the Centers for Disease Control and Prevention (CDC) has embarked on an effort to develop an evidence-based review process to identify effective best practices in the pre- and postanalytic phases of laboratory medicine.[8] Although these initiatives are noteworthy, there is still a need for a common set of practices that will encourage systematic quality improvement and patient safety and communication in laboratory medicine.

In the past, quality improvement strategies have focused on the analytic phase of laboratory testing, have included proper testing techniques and appropriate instruments, and have ensured that quality control procedures are used for every test administered.[9]

However, most studies indicate that laboratory errors occur either before testing is performed (during the preanalytic phase) or directly after testing is performed (during the postanalytic phase); preanalytic error rates range from 32 percent to 75 percent, and postanalytic error rates range from 9 percent to 31 percent.[10]

Continuing changes in clinical laboratory procedures directly affect the increase in error rates in both the pre- and postanalytic phases. For example, specimens are now collected in a variety of settings, the types of tests have increased, and samples are often sent to a reference laboratory for complete testing.[11] A lack of medical technologists and high turnover rates also add a layer of complexity to the process of laboratory services and quality assurance. Often, preanalytic errors contribute to errors made during the postanalytic phase; for example, patient misidentification can lead to a misdiagnosis and/or wrong treatment. Therefore, emphasis is needed on the development of performance measures to drive quality improvement for both phases.

This project aims to provide the foundation for the development of performance measures in laboratory medicine by endorsing a set of preferred practices that focus on patient safety and communication for laboratory diagnostic services. The National Quality Forum (NQF) notes that for significant improvements to occur in patient safety and communication processes, a more standardized approach for test orders and critical value/result reporting must be adopted. This standardized approach will contribute toward the development of efficient electronic information systems within the laboratory setting. As with all NQF-endorsed® standards, these preferred practices will be reviewed and revised as the evidence base and the field of laboratory medicine evolves.

The work encompassed by this report is a follow-up of a previous NQF project on quality in laboratory medicine. In January 2006, NQF and CDC brought together 23 key stakeholders in laboratory medicine to participate in a workshop focused on defining laboratory quality and value. The workshop was designed to facilitate a rich dialogue among a diverse group of participants, including providers, purchasers, researchers, and consumers. The workshop revealed that there is little agreement regarding where the initial focus on national laboratory medicine measurement and reporting efforts should be. Issues noted during the workshop included the vast number of areas that laboratory medicine covers, the difficulty of implementing standards because of the interface among the preanalytic, analytic, and postanalytic phases, and concerns about implementing a standard that may span many factors that are not within laboratories' control. Workshop participants generally agreed that more research is needed to identify measures in priority areas within laboratory medicine and that focus is needed in these areas as places to begin quality measurement and reporting. Some participants believed that measurement and reporting efforts should focus initially on the process of specimen identification and on laboratory tests in a few areas where a strong link to evidence-based practice and care guidelines exists.

In late 2006, a research paper commissioned for NQF analyzed existing guidelines.[i] Such an analysis was an important next step in pushing the quality movement forward in the laboratory community. The paper included an analysis of 1) measures currently in practice for laboratory medicine, 2) measures included in the 2005 Institute of Medicine's (IOM's) performance measurement report, *Performance Measurement: Accelerating Improvement,*[12] and 3) measures presented at the April 2005 Institute for Quality in Laboratory Medicine conference. The commissioned paper provided a crosswalk between performance measures for laboratory medicine and those included for healthcare organizations and the healthcare system in the IOM report. Additionally, the paper reviewed guidelines currently in practice to establish a comprehensive framework for measuring laboratory medicine quality that accommodates the needs of laboratories, providers, purchasers, and consumers.

Purpose of This Project

As noted earlier, both the workshop and the commissioned paper served as background for the development of this project and informed its early development and the deliberations related to it. The specific purpose of this project was to:

- identify a framework for organizing practices in the pre- and postanalytic laboratory phases;
- endorse a minimum set of preferred practices for laboratory medicine based on this framework. These practices were to be both specific and overarching—that is, covering all settings; and
- identify high-priority research areas to advance the evaluation of laboratory medicine and its impact on care.

The NQF-Endorsed Preferred Practices for Patient Safety and Communication in Laboratory Medicine

Individual initiatives to spur quality improvement in laboratory medicine have been ongoing, and the need for systematic, effective practices that have demonstrated improved quality outcomes in this field is urgent. The fact that the pre- and postanalytic components of the testing process—critical leverage points for patient safety and quality of care—involve care providers and systems outside the laboratory requires effective communication and collaboration among all providers involved in the testing process. By focusing on the pre- and postanalytic components of laboratory testing, all stakeholder interests will be addressed, including those of patients, providers, laboratory professionals, health information technology professionals and vendors, and other ancillary staff who routinely deal with test specimens and test results. The principle of shared accountability is reinforced by examining the full continuum of the testing process and soliciting input from multiple disciplines. Nationally endorsed practices in laboratory quality can serve as a road map for the identification of performance measures and set a research agenda to advance the field.

[i] The commissioned paper, *Identification of Performance Measures of Importance for Quality in Laboratory Medicine,* can be accessed at www.qualityforum.org/pdf/projects/lab-med/txlabpaper_behal_final%2005-21-07.pdf.

This report endorses a set of six preferred practices that are suitable for widespread implementation and that address the domains that make up the framework. The practices are intended to be applicable and generalizable to multiple care settings and populations. The practices and many of the implementation examples are based on published studies or widely accepted experimental or consensus information. The preferred practices developed for this project were evaluated for their adequacy using NQF-endorsed standard evaluation criteria for all practices, presented in detail in Box A:

effectiveness – clear evidence must be presented that indicates the practice would be effective in improving outcomes;

generalizability – the practice should be able to be utilized in multiple care settings and/or for multiple types of patients;

benefit – it must be clear how the practice would improve or increase the likelihood of improving patient outcomes; and

readiness – the training, technology, and staff required for implementation of the practice are available.

Box A: Criteria for Evaluation of Practices

Evidence of Effectiveness

There must be clear evidence that the practice (if appropriately implemented) would be effective in improving outcomes (e.g., reduced substance use). Evidence may take various forms, including:

- research studies (syntheses) showing a direct connection between the practice and improved clinical outcomes;
- experiential data (including broad expert agreement, widespread opinion, or professional consensus) showing the practice is "obviously beneficial" or self-evident (i.e., the practice absolutely forces an improvement to occur) or organization or program data linking the practice to improved outcomes; or
- research findings or experiential data from other healthcare or non-healthcare settings that should be substantially transferable.

Generalizability

The practice must be able to be utilized in multiple applicable clinical care settings (e.g., a variety of inpatient and/or outpatient settings) and/or for multiple types of patients.

Benefit

If the practice (determined to be effective) were more widely utilized, it would improve or increase the likelihood of improving patient outcomes (e.g., improved patient function). If an effective practice already is in near universal use, its endorsement would lead to little new benefit to patients.

Readiness

The necessary technology and appropriately skilled staff must be available to most healthcare organizations. For this project, opportunity for measurement also was a consideration.

Preferred Practices for Patient Safety and Communication in Laboratory Medicine

As noted earlier, the pre- and postanalytic phases of laboratory testing are especially critical areas of focus for patient safety improvements. Accordingly, the following framework domains served to organize the practices:

Preanalytic Domain: Patient/Specimen Identification

Preanalytic Domain: Sample Acceptability

Preanalytic Domain: Test Order Accuracy

Postanalytic Domain: Verbal Communication

Postanalytic Domain: Critical Value/Result Reporting

Additionally, one overarching practice for the domain of Laboratory Leadership was identified.

NQF specifically notes that to achieve optimal communication between the laboratory and ordering entities for test orders and follow-up, it is recommended that laboratories seek to adopt a standardized order code set/ nomenclature. The lack of a generally accepted code set for specifying laboratory test orders may slow down the process and affect the adoption of a universal electronic test ordering system. Accordingly, NQF makes the following recommendation:

> An organization should adopt, at a minimum, a standardized order code set. No industry-standard nomenclature for orderable tests exists, which creates the potential for miscommunication when orders are placed in one information system and sent to another. SNOMED CT, LOINC, or some other recognized public domain code set should be modified to provide a usable industry standard.

Domain: Laboratory Leadership

The Problem

The strategies for improving patient safety and communication within laboratories often extend beyond the walls of the laboratory and involve a strong commitment from leadership. For an organization to reflect a culture of quality and patient safety, its leaders who operate and interact with clinical laboratories must be engaged with the organization's quality improvement efforts. These leaders represent the first line of defense in protecting patients from adverse consequences that may result from poor laboratory practices.[13] Additionally, laboratory leadership must play a central role in educating patients and other care providers on the aspects of patient safety that relate to the laboratory.

It is essential for patient care and patient safety to ensure that test ordering is appropriate, that specimens are acceptable, and that test results are communicated effectively among healthcare staff and to patients. Successful communication requires collaboration and procedures that extend throughout an entire organization and across organizations.[14] But more important, within a laboratory, efficient delegation of duties is critical, because quality and safety often are at risk when duties are not delegated properly.[15] CLIA defines the duties of the laboratory director to include taking responsibility for the overall operation and

administration of the laboratory along with "ensuring that quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur."[16] One study indicated that 1.4 percent of the laboratories inspected by CAP were cited for not specifying who should perform duties on behalf of the laboratory director.[17] Economic and other institutional constraints require that communication is completed as efficiently and effectively as possible.[18] And, if a laboratory's internal quality control system is lacking, the risk to patient safety increases.

Organizational commitment to policies and procedures helps ensure compliance.[19] Among the policies and procedures that should be in place is a system that tracks errors in communication. Quality improvement initiatives may include a variety of approaches, such as a comparison of practices among other similar organizations,[20,21] the use of satisfaction surveys,[22] or the development and monitoring of process indicators. It is ultimately the efforts of the leaders and a focus on effective communication among all parties that interact with the laboratory that ensure quality control and patient safety.

Preferred Practice 1: Leaders of organizations that participate in test ordering and leaders of clinical laboratories should collaboratively ensure that specific expectations regarding communication to and from the laboratory are met.

Specifications:

- The laboratory and ordering entities should strongly encourage the use of electronic communications for all data exchange, test orders, and critical test reporting.
  - When electronic communications and data interchanges are utilized, a secure electronic system should also be incorporated.
  - When electronic communications and data interchanges are utilized, they should be provided to all HIPAA-compliant entities involved directly or indirectly in patient care so that physicians, hospitals, and other providers utilizing electronic health records have access to downloadable data.
- The laboratory and ordering entities should coordinate their activities to ensure that established processes and measurements are in place that optimize the transmission of critical test results to individuals at all times.[23]
- The laboratory and ordering entities should coordinate their activities to develop systems to ensure that results are ultimately transmitted to the patient's provider in a timely manner so that appropriate patient care occurs.
  - The laboratory and ordering entities should collaboratively focus on the implementation of secure electronic communication systems within their available resource capabilities.
- The laboratory and ordering entities should coordinate a process to reconcile all laboratory orders by checking them electronically or manually against the corresponding test results.
- The laboratory and ordering entities should collaboratively investigate instances in which orders for critical tests or critical values/results are not properly communicated or not communicated in a timely manner and implement corrective action for those instances.

- Clinical consultants should be available to assist clinicians who order nonwaived testing.[24]
- The laboratory and ordering entities should coordinate access to available historical laboratory results at the time of new test ordering.
- The laboratory and ordering entities should coordinate processes to ensure that appropriate action is taken in a timely manner after the receipt of critical test results, and the ordering entity should ensure that the action is documented in the patient's medical record.
- The laboratory and ordering entities should coordinate to establish systems to monitor verbal and electronic communication of laboratory results and to enhance process improvement.
- Pathologists and laboratory administrators should meet on a regular basis with medical staff and clients (as appropriate to the care setting) to review the list of critical test results, the format and availability of electronic results, and the critical test communication process.
- The laboratory administration should have a central role in educating patients and care providers on the key aspects of patient safety within the laboratory setting.

Example Implementation Approaches:

- Communication failures between a laboratory and a licensed care provider are documented and investigated by the appropriate member of the organization and should result in process improvements to prevent reoccurrences.
- Laboratories generate letters to caregivers or organizational leadership detailing individual particular communication failures. Periodic review of documentation may reveal patterns amenable to systemic correction (e.g., failure to communicate with particular individuals, failure at a particular time of the day or on a particular day).
- Laboratories generate training materials of certain reoccurring laboratory issues and incorporate this training into corporate education modules. In addition, monthly laboratory newsletters highlight common issues between the laboratory and other care settings and open new lines of communication.

Opportunity for Measurement:

- Communication can be demonstrated in several ways—by showing that documents have been exchanged, that information has been noted in the patient's chart, that meetings have been held, or that sign-offs have been provided that demonstrate the test ordering and the result. These actions also can demonstrate that the communication expectations of each party have been defined, that outliers have been agreed upon, that time expectations have been documented and evaluated, and that corrective action has been taken.

PREANALYTIC LABORATORY PHASE

Domain: Patient/Specimen Identification

The Problem

Ensuring improvements to patient safety and quality for laboratory medicine must begin with the accurate identification of patients and laboratory samples.[25] There is great potential for laboratory samples and pathology specimens to be mislabeled, or incompletely labeled, and consequently misinterpreted.[26] One study found that there is a greater risk to a patient of his or her blood samples for transfusion being miscollected and mislabeled

than of succumbing to viral infection. Failure [27] to correctly identify patients contributes to medication errors, transfusion errors, testing errors, wrong-person procedures, inappropriate or delayed treatment, and missed diagnoses.[28]

Errors in labeling patient specimens or in patient identification also can lead to misinterpretation of results and to a wrong diagnosis and the development and use of inappropriate treatment plans.[29] Estimates are that more than 160,000 adverse medical events result each year from the misidentification of laboratory specimens.[30] Data reported for transfusion medicine indicate that mislabeled specimens accounted for 35 percent of high-severity events and that about 25 deaths per year occur as a result of hemolytic transfusion reactions caused by patient/specimen identification errors.[31]

Most identification errors result from human factors; therefore, case finding in a normal laboratory practice underestimates the true frequency of such errors.[32] Contributing to the inaccuracies of frequency and quality measurement is the variation of identification practices among institutions.[33] This may also explain why many identification errors go undetected.[34] Such errors can result in patient fatalities and also can affect the accuracy of reports by government and private regulatory agencies.[35]

Practices have been implemented to reduce the frequency of identification errors. Patient wristbands have become common in hospitals to help with correct patient identification.[36] CAP has introduced Q-Probes, a time-limited voluntary modular quality improvement program aimed at identifying and describing indicators of quality for anatomic pathology and laboratory medicine. In 1999, CAP introduced Q-Tracks, an ongoing program for quality improvement requiring annual renewal.[37]

The CAP Laboratory Accreditation Program requires that specimen collection and handling policies and procedures are defined and implemented, including verifying the identification of each patient from whom a specimen is collected.[38] Data from this program indicate that errors can be systematically identified and subsequently reduced with appropriate interventions.[39] One Q-Tracks study was conducted to investigate whether continuous monitoring of wristband errors by participants in the CAP Q-Tracks program results in lower wristband error rates. During this two-year study, wristband error rates decreased significantly from 7.40 percent to 3.05 percent ($p<.001$), demonstrating the importance of error-reduction programs.[40]

Several institutions have implemented electronic systems for positive patient identification and have experienced a reduction in error rates, particularly related to the safety of blood transfusion.[41,42] Such systems also help ensure accurate and legible specimen labeling.[43,44] One year after the implementation of an electronic bar-coding system, a pediatric hospital noted a significant decline in the mislabeled specimen rate from 0.03 percent to 0.005 percent ($p<0.001$).[45] And some organizations have estimated cost savings after they implemented a new electronic system.[46]

Improvement processes related to patient/specimen identification also have received attention from accreditation and regulatory organizations. But, despite this awareness, organizations are unsure of the best approach to take to address errors and to view poorly

monitored rates as a measure of patient safety.[47] Such errors can be prevented through the use of appropriate quality assurance practices.

Preferred Practice 2: Standardized policies, processes, and systems should be implemented to ensure the accurate and legible labeling of laboratory specimens.

Specifications:

- If possible, the patient should identify him- or herself verbally.[48]
- At least two patient identifiers, such as a medical record number, name, or date of birth (neither of which should be the patient's room number or physical location), should be used when labeling blood samples or other specimens for clinical testing. Labels containing two unique identifiers should be legible.[49,50]
  - The patient's payer identification should be included on blood samples and other specimens for clinical testing.
- Specimen collection containers should be labeled or identified at the time of collection and in the presence of the patient.[51]
- Labels should be readable by humans and/or technology, as applicable.

Example Implementation Approaches:

- Check-digit technology is used for institution-assigned patient identifier numbers (self-contained second identifier).
- Bar-coding and radio frequency identification (RFID) systems are used to assist with positive patient identification.
- Organizations adopt a policy to uniformly utilize only a patient's legal name, as one of the two patient identifiers.
- Labels are printed at the bedside during the collection procedure, or other methods are in place to ensure that the correct numbers of legible and accurate labels are available during the collection. All extra labels are discarded to prevent future mislabels.
- Conditions are defined for the rejection of specimens that have incomplete or internally inconsistent labels.

Opportunities for Measurement:

- Monitor the error rates of patient identification.
- Monitor the clinical and financial consequences of patient identification errors.

Domain: Sample Acceptability

The Problem

Specimen collection is an important component of care. Studies conducted by CAP on rates of specimen rejection have revealed that some of the primary reasons for a rejected sample are poor collection techniques—for example, specimen clotting has occurred, the specimen has hemolyzed, or insufficient quantity was collected.[52,53,54] The CAP study evaluating specimen rejection rates concluded that 10 percent of the institutions in the study had rejection rates three times the mean.[55]

If a specimen is not collected properly, another specimen may need to be drawn. This is not only inconvenient for the patient, but it also increases the patient's risk of anemia in the case of blood draws, (particularly for hospitalized patients).[56] Repeating specimen collection means that a patient's sample has a greater risk of being misidentified or mislabeled; it also contributes to inefficiency in the healthcare system.

Certain standards must be followed to ensure that the clinical specimens that are collected for analysis are appropriate for the tests that are being ordered.[57] All specimens should be collected and handled in proper containers and at appropriate times so that there is no interference with analysis.[58] The responsibility for appropriate specimen collection is shared by clinicians and laboratory staff. CLIA stipulates that the laboratory must make collection instructions available for each assay offered and must provide a clinical consultant to answer questions about the collection.[59]

Improvement in specimen collection can be achieved. One separate Q-Tracks study of 356 institutions demonstrated that blood culture contamination was significantly higher in institutions that used nonlaboratory personnel to collect blood.[60] Additionally, monitoring specimen collection quality on a consistent basis through a Q-Tracks program or through other techniques is associated with improved performance over time.[61] One review article that summarized the results of studies examining laboratory errors found that a high percentage of such errors occurred in the preanalytic phase and concluded that it is important for organizations to monitor errors and process workflow changes to reduce errors.[62] Utilizing appropriate specimen collection and handling techniques would contribute to improvements in the numbers of acceptable specimens that are collected, the timing of collection, and the volume of collection and would help lower rates of specimen contamination, thereby enhancing patient safety.

Preferred Practice 3: Collection and processing facilities should ensure that acceptable specimens are collected using appropriate techniques.

Specifications:

- A standard operating procedure should be generated outlining all steps for proper collection and processing.[63]
  - Protocols should be in place for the maximum number of attempts per patient permitted during a single visit for blood or other specimen collection.[64]
  - Protocols should address collections in specific populations, such as neonates (i.e., heelsticks).
- The organization will assure that the individuals collecting specimens are adequately trained to do so.
  - Appropriate skin disinfectant procedures should be used prior to blood culture collection.[65]
  - Protocols outlining proper collection technique should be available to all personnel trained to collect specimens.
  - If nonlaboratory personnel are utilized for the collection of specimens (blood and nonblood), the laboratory should assume responsibility for the development and dissemination of adequate training materials to ensure that standard procedures are employed during the process.
- To the extent possible, the quality and appropriateness of a specimen should be verified before a patient leaves the outpatient collection area.[66]
- Specimens that are known to not meet standards for acceptability should not be tested.[67]
  - Clinicians should be notified when a patient's specimens cannot be tested.[68]

  - The criteria for specimen acceptability should be readily available.
- Specimens should be processed, transported, and stored within a timeframe and under conditions that do not interfere with specimen quality.[69]
- Patients should receive instructions for test preparations and timing, as appropriate.
- Laboratory or collection facilities should implement a system to track collection and processing errors (i.e., rates of specimen rejection, specimen contamination, and timing of specimen collection and volume of collection sample).[70,71,72]

Example Implementation Approaches:

Specimen Collection

- Operating procedures specify that tubes are checked against orders before a patient leaves the outpatient collection area.
- Policies and procedures are available that indicate the timeframes and conditions under which specimens must be transported to the laboratory in order to maintain specimen integrity; assay manufacturer's instructions usually provide guidance. If manufacturer's instructions are not met, the laboratory must reestablish test method specifications.
- Laboratory personnel are utilized to as great a degree as possible to collect specimens in order to reduce the specimen rejection rate.
- Information involving collection parameters and technique protocols is made available electronically and/or on paper in collection locations and on patient floors.
- A dedicated staff member is available for drawing blood cultures to ensure aseptic technique.
- An electronic solution is used that can provide collection parameters for each type of test.
- To prevent specimen hemolysis and dilution effects, specimens are collected without the use of a newly placed intravenous line.

Training and Competency

- A member of the department is assigned or dedicated to train employees and ensure competency.
- New staff members are trained on collection procedures using a standardized and documented process.
- Competency is monitored for specimen collection techniques. An employee at a higher level than the trainee is responsible for evaluating the trainee's competency. A competency checklist may be used.

Specimen Processing/Acceptability

- The specimen collection time, in addition to the time of receipt in the laboratory, is documented in the laboratory information system so that specimen acceptability can be assessed more accurately.
- In situations where various specimen types are acceptable, factors are considered such as the convenience of collection and the accuracy of testing to determine the appropriate specimen type.
- Laboratories follow specimen acceptability criteria defined by the manufacturer or validate criteria internally, as applicable.

Opportunity for Measurement:

- Monitor the rates of specimen rejection and specimen contamination, the timing of specimen collection, and the volume of collection samples. Monitor adherence rates of policies and procedures.

Domain: Test Order Accuracy

The Problem

The laboratory testing process begins with test ordering.[73] Errors in ordering can delay diagnosis, consume resources, and cause patient inconvenience and adverse events.[74] Inaccuracy in ordering may cause a laboratory to perform a test that a clinician did not order or to not perform a test that was requested.[75] Ensuring the accuracy and timeliness of a test must begin with a thoughtful process of considering why it is needed in the first place.[76]

Test orders should accurately transmit a clinician's request for specific laboratory services, along with any special information necessary to carry out the request.[77] CAP examined the incidence of errors occurring during test orders through two Q-Probes studies.[78] These studies evaluated more than 1,100 institutions in inpatient and outpatient settings and their use of computer order entry of send-out tests and concluded that errors occurred more frequently in hospitals without policies requiring staff to verify the accuracy of the order and without preprinted "check-off" order forms.[79] In addition, another inpatient study involved participants from 577 institutions examining the accuracy of physicians' inpatient test orders when transmitted to the laboratory.[80] The results from this study found a 2.5 percent error rate of 224,431 tests for which written orders could not be found on laboratory requisitions, and a 2.8 percent error rate of 225,457 tests for which results could not be found in patient records.[81]

In the outpatient setting, errors occur more frequently with the use of verbal order requests than with the use of written orders.[82] One outpatient study involving 660 laboratories documented 5,514 tests (4.8 percent) for which at least one order entry error occurred; the most common error was incorrectly entering the ordering physician's name.[83] Ten percent of the participating institutions also reported errors for at least 18 percent of their requisitions.[84] Errors from computer order entry for send-out tests occurred twice as frequently as order entry errors for other types of tests.[85] Of note, order accuracy errors for send-out tests present additional challenges beyond those encountered with routine test order entry.[86] Send-out tests usually are more expensive, and therefore an incorrect order can easily become a large, wasteful expense; laboratories using more than one reference testing facility risk the chance of experiencing delays or routing errors with an incorrect test order, and with a larger variety of tests, the potential for mix-ups increases.[87]

A key component of test order entry is communication between staff at the healthcare organization and staff at the laboratory.[88] The process of decisionmaking for laboratory services usually is divided between the caregiver and the clinical laboratory. Often, when the caregiver has made a final decision to order a specific test or blood product, the reasons for ordering that test or blood product are not communicated accurately to the laboratory. However, the laboratory can occasionally become involved in decisionmaking as well, particularly when expensive or infrequent tests are ordered, and at this time, clinical consultants should be made available to offer decision support. CLIA requires that certain

standards be followed to ensure accurate order communication.[ii,89] As noted previously, to effectively reduce the incidence of order entry errors, standardized order code sets must be established and systems must be instituted to audit redundancy and accuracy. This is a process that involves multiple players, and it goes beyond the walls of the laboratory.[90]

Preferred Practice 4: Organizations should implement systems to ensure that all test orders are accurately communicated to laboratory staff in a timely manner.

Specifications:

- Explicit organizational policies and procedures should be implemented for electronic, verbal, and telephone communication of test orders.[91]
- Verbal, written, and telephone communication of test orders should be limited to urgent situations for which immediate electronic communication is not feasible and should be followed up with a written request.[92]
  - Communication of test orders/results after practice hours should also include the patient's contact information (i.e., phone numbers or other methods of direct contact).
- Nomenclature should be standardized within the organization and should comply with regulatory standards.
- The laboratory should have a written or electronic request for patient testing from a legally authorized person.[93]
- If the verbal or telephone order requests that a test be added to an existing specimen in the laboratory (i.e., an add-on test), a procedure should be in place to determine whether the existing specimen is available and acceptable to perform the requested test.[94]

Example Implementation Approaches:

- Laboratory requisitions or requisitions specifically designated for the confirmation of verbal orders are available in all patient locations. These requisitions can be filled out and faxed to the laboratory. Incomplete test orders (those without an authorized person's name) are not accepted. If appropriate, the patient returns to his or her physician to complete the requisition prior to specimen collection, or the laboratory contacts the physician.
- Test requisitions and electronic entry screens are organized logically, with the most common tests available for the clinician to check off.
  - Components of test panels should be listed individually.
  - Provide requisitions that include the location of specific test menus.
- Laboratory personnel are assigned to audit the receipt of the written or electronic orders following a verbal request.
- Laboratory personnel are available to answer questions regarding test orders, particularly those for send-out testing.
- The name of the authorized person who requested the test order in writing, electronically, or verbally is recorded in the laboratory information system.
- A standard operating procedure is generated and available to laboratory staff to assist with specimen acceptability for add-on testing.

[ii] The standards required by CLIA to ensure accurate order communication are included in the specifications of this practice.

- Electronically scan test requisitions for future referral.
- Minimize manual entry of test orders and related information to avoid errors.
  - Implement computerized physician order entry (CPOE) with order communication to the laboratory.[iii]
- Organizations consider managing test utilization to reduce unnecessary testing.

Opportunity for Measurement:

- Manually compare ordered tests identified in clinical records or test requisitions against the orders actually entered into laboratory information systems.

POSTANALYTIC LABORATORY PHASE

Domain: Verbal Communication

The Problem

A large contributing factor to postanalytic errors is the disconnect between the laboratory and the rest of the healthcare delivery system in some settings.[95] Communication failures are also a common cause of unintentional patient harm.[96] As the clinical care environment becomes more complex, and combined with the limitations of human performance, effective communication and teamwork become even more important in providing safe healthcare.[97] Additionally, transitions in care, or hand-offs, are a critical area in which communication is vital.[98] Communication is particularly relevant when dealing with clinical laboratories, because many patient specimens are sent to these laboratories for analysis and accurate diagnosis. Accurate and timely communication of results to the team directly caring for the patient is needed.

Clinical laboratories have adopted approaches from other industries and areas of the hospital to avoid miscommunications, reduce the risk of medical errors, and improve patient safety.[99] These approaches include having the licensed caregiver record critical results, ensuring that verbal read-back of critical results occurs, and ensuring that the individual reporting the results confirms them.

One study that monitored the accuracy of read-back in hospitals[100] examined 3 health-care organizations and found that of 822 calls made from the laboratory, 29 errors were detected (for an error rate of 3.5 percent).[101] The average time required to read-back was 12.8 seconds.[102] In the CAP Q-Tracks study, laboratory critical values also were monitored by 180 institutions. The Q-Tracks study found an improvement in critical value reporting over a three-year period resulting from participation in monitoring programs and the implementation of different quality improvement measures, such as the criteria used to identify the personnel qualified to receive results.[103]

The lack of timely communication of care information and incomplete closure of information loops are frequent causes of preventable harm to patients, including incorrect diagnosis, delayed treatment, and the use of less optimal tests and treatments.[104] An analysis of more than 2,000 sentinel events reported to The Joint Commission revealed that communication failure was the primary root cause for approximately 70 percent of those reported

[iii] See NQF's report *Safe Practices for Better Healthcare–2009 Update: A Consensus Report.* Safe Practice 16 provides the detailed specifications and implementation approaches for CPOE.

events.[105] Accordingly, The Joint Commission requires clinical laboratories to establish a policy regarding communication hand-off of test results both to clinicians and within the laboratory.

Systematically addressing issues involving communication in the patient safety context has clear benefits. For example, Kaiser Permanente implemented a patient safety approach within its healthcare system.[106] Following Crew Resource Management (CRM), a standardized communication training resource used in aviation, Kaiser Permanente undertook the adoption of behaviors and skills focused on effective communication and teamwork;[107] 12 clinical teams participated in a 3-day training about the application of standard tools and behaviors to improve patient safety and ensure effective communication.[108] Another study looked at communication errors in the laboratory by auditing corrections made to clinical chemistry tests and found a high rate of postanalytic errors.[109] The study, conducted in a pediatric hospital, suggested that a direct interface between the instruments and the laboratory information systems may reduce communication errors.[110]

Information loops among and within healthcare organizations must be addressed. Enhancing communication among multiple medical team members, and creating an environment in which patients can speak up and express concerns are effective strategies for improving communication and reducing risk.[111,112]

Preferred Practice 5: For verbal or telephonic reporting of critical test results, verify the test results by having the person who is receiving the information record and read back the complete test result.

Specifications:

- Critical test results and critical tests should be defined by the laboratory, reviewed regularly by caregivers as applicable, and documented in laboratory policy.[113]
- After result verification and patient identification, the individual receiving the critical test results or critical test should report it to the licensed care provider in a timely manner.
- Following read-back, a confirmation of accuracy should be received from the individual who gave the test result and should be accompanied by the reporting of results electronically, when available.[114]
- The notification of critical results should be documented by the laboratory. Documentation should include a record of who was notified and when and whether the result was read back.
- The laboratory should investigate and summarize patterns of failure related to critical result communication, including appropriate corrective action.

Example Implementation Approaches:

- Critical test results should be those that meet the criterion of "imminent danger" to the patient so that critical callbacks are handled efficiently. This also prevents unnecessary interruptions for clinicians. Laboratories could define location- or patient-specific critical values, as well.
- The laboratory information system flags critical test results and critical tests to alert the technologist, and these results are verified in the laboratory before they are reported.

- A critical test result and critical test "work list" is printed frequently by the laboratory staff to ensure that timely communication of the critical results and tests occurred.
- Appropriate communication of critical test results and critical tests is audited by the laboratory routinely, even if this must be done manually.
- Corrective action is documented for results or tests that were not communicated in a timely manner.
- An electronic system, such as a two-way pager, is used to notify the ordering clinician and allow confirmation of the critical test result or critical test.
- The laboratory requires ordering provider information on the test requisition, particularly for outpatients, so that the laboratory can more easily identify the appropriate clinician to call with a critical test result.
- Form a hospital committee for the review and audit of critical test results and critical test processes that includes representation by the laboratory and information technology staff, administrative and nursing personnel, and physicians. The audit should include an assessment of the effect that errors have on patient outcomes. (See also the Laboratory Leadership preferred practice.)
- The organization defines "escalation" to ensure that the laboratory can contact a licensed care provider at all time.
- Laboratory staff have access to approved communication scripts described in policies or procedures. These scripts may be printed on paper or appear on computer screens.
- Regardless of how they are displayed, the script specifically prompts the caller to request a read-back. This read-back is documented in the laboratory information system and/or in the medical record.

Opportunity for Measurement:

- Monitor the error rate and/or compliance rate when using read-back.

Domain: Critical Value/Result Reporting[iv]

The Problem

The delivery of safe and effective healthcare relies on timely and accurate communication among caregivers, and this includes the communication of critical test results and critical tests. Each step within the process of communicating results requires efficiency, and any lapse could cause serious harm.[115] One study that evaluated how critical laboratory results were handled revealed that in 27 percent of cases, more than five hours passed before appropriate treatment was administered.[116] Studies have shown that, particularly within the ambulatory care setting, a large number of adverse events result from missing critical laboratory results. Not having these critical laboratory results often can lead to delayed diagnosis or the presentation of wrong treatment options.[117,118] Accrediting and regulatory organizations, such as CAP and CLIA, have mandated laboratories and hospitals to have a procedure in place for the immediate notification of physicians of critical test results.[119] In addition, regulatory bodies have required that other elements of

[iv] The Joint Commission *National Patient Safety Goals.* 02.03.01 states that the laboratory should define critical tests, critical results, and critical values and the timeframes around these values.

the healthcare system, such as those involving anatomic pathology, cardiology, and radiology, communicate critical test results in a timely manner. Despite these regulations, problems involving the communication of critical test values and results continue to have a significant impact on errors.

Critical care information often is not communicated between care settings, and, as a result, caregivers and patients may lack the necessary information to make informed decisions regarding care.[120] Although the definition of "critical information" can vary by institution, it usually includes laboratory values, diagnostic interpretations, and high-priority laboratory tests.[121] And for critical values/results, the focus for assessment should be the time that elapses between the initial verification of the critical value/results and the receipt of that information by the ordering physician.[122] Telephone calls from the laboratory to the caregiver to report critical test results are the most common mechanism used, but this process requires improvement because of the possibilities of human error.[123] Studies have found that turnaround time for results in various settings is suboptimal and affects patient care.[124,125]

The communication of finalized test results to clinicians and patients, as necessary, could be improved. The breakdown of the communication of critical test values/results often is attributed to a lack of "ownership" among the laboratories, physicians, and nursing units.[126] A recognized strategy in this area involves improving the system within which physicians practice. Information technology also can provide reliable systems for notification of critical values/results.

Stringent guidelines for critical value/results reporting have not been recognized or adopted internationally, but dissemination of information about the importance of reporting is under way.[127] Because critical values/results are defined in different ways depending on the hospital system or laboratory, the development and use of common evidence-based standards and practices for the reporting of critical values/results is key for patient safety and improved healthcare quality.

Preferred Practice 6: Communicate critical laboratory values/results to the individuals who require them and appropriately document them in a secure, confidential, accurate, and timely manner.

Specifications:

- The laboratory should establish and follow policies and procedures to verify the accurate, timely, and confidential transmission of laboratory information to the authorized individual who will use that information. Policies and procedures should be in compliance with all applicable local, state, and federal regulations.
- Policies defining timeframes (i.e., turnaround time) for time-sensitive results should be developed, implemented, and monitored by the laboratory.

Example Implementation Approaches:

- Laboratories consider the advisability of establishing turnaround time expectations for certain types of tests and care settings. If set expectations are established, laboratories meet those expectations.
- Electronic solutions are used to improve communication. For example:
  - a test order entry system may reduce turnaround time;

  - a test management system that tracks test order completion and prioritizes workflow may reduce delay in test result review;
  - the use of alphanumeric pagers may allow the clinician to be notified about important results in real time; and
  - the use of models, such as those demonstrated by the EHR-Lab Interoperability and Connectivity Specification (ELINCS) project, provides the delivery of real-time laboratory results from a laboratory's information system to an electronic health record.
- A direct interface of the testing instruments with the laboratory information system is used to reduce errors in communicating test results to clinicians.
- The most effective means of communicating test results is used, which may be by telephone, fax, or electronically, depending on the circumstances.
- A regular evaluation is conducted of the use of technologies to enable the closure of information loops only after the workflow and care process systems are clearly understood. This could include providing patients access to electronic personal health records or to suppliers of secure services so that they may be enabled to manage certain health information.
- Opportunities are identified for performance improvement.
- A member(s) of the laboratory staff is responsible for quality assurance and quality improvement in the laboratory and solicits recommendations from within and outside the laboratory.
- Staff (both those employed by the organization and those working independently) are trained regarding the importance of communication hand-offs both within and outside the laboratory.[128]
- A hand-off communication policy is employed that considers communication between shifts, between supervisors and staff, between technologists, between medical technologists and pathologists, and during break coverage. The policy provides for the opportunity to ask and respond to questions. A communication log may be useful for tracking and documenting important communications, but verbal communication is critical.
- Laboratories initially upon implementation and then periodically verify their process (electronic or manual) for transmitting results accurately, confidentially, and in a timely manner to authorized persons. Regular monitoring of report samples for certain data elements is helpful.

Opportunity for Measurement:

- Monitor the error rate of reporting critical events and how it relates to communication among medical staff.

Research Recommendations

During the course of this project, promising practices that lacked sufficient evidence for advancement were identified. The development of measures to fill gaps should be a high priority. Two specific areas were identified as being especially important for future research:

- **Utilize standardized criteria for specimen rejection for common assays.** Standardizing specimen rejection criteria across the industry or within an organization is important. Currently, however, laboratories are required to use unmodified Food and Drug Administration-approved tests unless a validation study is being performed. In addition, the concept of cost-benefit analysis was reviewed, as was whether cost-benefit information would be helpful when making decisions for specimen rejection criteria. It was determined that at this time, there is insufficient evidence to support fully the development of a practice to address standardization for specimen rejection criteria, but additional research is called for.
- **Deploy industry-wide standards for minimum reporting elements/fields.** Within the context of this recommendation, two areas were recognized—the content of reports and the formatting of reports. Some regulation by industries in the field of the content of the reports, including standards for electronic reporting, is in place, but other elements of reporting, such as who is authorized to receive it, and elements related to formatting, such as minimum elements to be included and amendments or corrections, are vital to laboratory medicine. It was determined, however, that insufficient evidence exists to support the development of improvements for report standardization and that further research is warranted.

References

1 The Lewin Group, *Laboratory Medicine: A National Status Report,* Falls Church, VA: The Lewin Group; 2008.

2 Centers for Medicare & Medicaid Services (CMS), *Medicare and Medicaid Statistical Supplement,* 2003. Available at www.cms.hhs.gov/MedicareMedicaidStatSupp/LT/List.asp. Last accessed July 2008.

3 Ibid.

4 Trusko BE, Pexton C, Harrington J, et al., *Improving Healthcare Quality and Cost with Six Sigma,* 2007, 1st ed., Upper Saddle River, NJ: FT Press; 2007.

5 College of American Pathologists (CAP), *Q-Probes/Q-Tracks Studies,* Northfield, IL: CAP. Available at www.cap.org. Last accessed February 2009.

6 The Lewin Group, *Laboratory Medicine: A National Status Report,* Falls Church, VA: The Lewin Group; 2008.

7 Centers for Disease Control and Prevention (CDC), *Laboratory Medicine: Best Practices: Developing an Evidence Based Review and Evaluation Process, Final Technical Report 2007: Phase 1,* Atlanta, GA: CDC; 2008. Available at www.cdc.gov/dls/bestpractices/LabBestPractice.pdf. Last accessed March 2009.

8 Ibid.

9 Stankovic AK, The laboratory is a key partner in assuring patient safety, *Clin Lab Med,* 2004;24:1023-1035.

10 Wang S, Ho V, Corrections of clinical chemistry test results in a laboratory information system, *Arch Pathol Lab Med,* 2004; 128(8):890-892, p. 891.

11 Stankovic AK, The laboratory is a key partner in assuring patient safety, *Clin Lab Med,* 2004;24:1023-1035.

12 Institute of Medicine, *Performance Measurement: Accelerating Improvement,* Washington, DC: National Academies Press; 2005.

13 Valenstein P, *Quality Management in Clinical Laboratories: Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

14 Schifman RB, Strategies for quality management in clinical microbiology, *Clin Lab Med,* 1995;15(2):437-446.

15 Valenstein P, *Quality Management in Clinical Laboratories: Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

16 Ibid., p. 53.

17 Valenstein P, *Quality Management in Clinical Laboratories: Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

18 Weiss RL, Training in laboratory management and the MBA/MD in laboratory medicine, *Clin Lab Med,* 2007;27(2):381-395.

19 Bamberg R, Akroyd D, Moore TM, Factors that impact clinical laboratory scientists' commitment to their work organizations, *Clin Lab Sci,* 2008;21(3):167-177.

20 Galloway M, Nadin L, Benchmarking and the laboratory, *J Clin Pathol,* 2001;54(8):590-597.

21 Plebani M, Ceriotti F, Merreri G, et al., Laboratory network of excellence: enhancing patient safety and service effectiveness, *Clin Chem Lab Med,* 2006;44(2):150-160.

22 Jones BA, Walsh MK, Ruby S, Hospital nursing satisfaction with clinical laboratory services: a College of American Pathologists Q-Probes study of 162 institutions, *Arch Pathol Lab Med,* 2006;130(12):1756-1761.

23 Dighe AS, Rao A, Coakley AB, et al., Analysis of laboratory critical value reporting at a large academic medical center, *Am J Clin Pathol,* 2006;125(5):758-764.

24 CMS, *Clinical Laboratory Improvement Amendments,* Baltimore, MD: CMS; 2008. Available at www.cms.hhs.gov/CLIA. Last accessed December 2008.

25 Howanitz PJ, Errors in laboratory medicine: practical lessons to improve patient safety, *Arch Pathol Lab Med,* 2005;129(10):1252-1261.

26 National Quality Forum (NQF), *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington, DC: NQF; 2007, pp. 95-118.

27 Dzik WH, Murphy MH, Andreu G, et al., An international study of the performance of sample collection from patients, *Vox Sang,* 2003;85(1):40-47.

28 The World Health Organization (WHO), *Patient Safety Solutions: Patient Identification,* Geneva: WHO; 2007. Available at www.ccforpatientsafety.org/common/pdfs/fpdf/presskit/PS-Solution2.pdf. Last accessed March 2009.

29 NQF, *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington, DC: NQF; 2007, pp. 95-118.

30 Hayden RT, Patterson DJ, Jay DW, et al., Computer-assisted bar-coding system significantly reduces clinical laboratory specimen identification errors in a pediatric oncology hospital, *J Pediatr,* 2008;152(2):219-224, p. 220.

31 Quillen K, Murphy K, Quality improvement to decrease specimen mislabeling in transfusion medicine, *Arch Pathol Lab Med,* 2006;130:1196-1198, p. 1196.

32 WGI, *Patient Safety Solutions: Patient Identification,* Geneva: WHO; 2007. Available at www.ccforpatientsafety.org/common/pdfs/fpdf/presskit/PS-Solution2.pdf. Last accessed March 2009.

33 Valenstein PN, Sirota RL, Identification errors in pathology and laboratory medicine, *Clin Lab Med,* 2004;24(4):979-996.

34 Ibid.

35 Howanitz PJ, Renner SW, Walsh MK, Continuous wristband monitoring over 2 years decreases identification errors. a College of American Pathologists Q-Tracks Study, *Arch Pathol Lab Med,* 2002;126:809-815.

36 Howanitz PJ, Errors in laboratory medicine: practical lessons to improve patient safety, *Arch Pathol Lab Med,* 2005;129(10):1252-1261.

37 Howanitz PJ, Renner SW, Walsh MK, Continuous wristband monitoring over 2 years decreases identification errors. a College of American Pathologists Q-Tracks Study, *Arch Pathol Lab Med,* 2002;126:809-815.

38 Ibid.

39 Novis DA, Detecting and preventing the occurrence of errors in the practices of laboratory medicine and anatomic pathology: 15 years' experience with the College of American Pathologists' Q-PROBES and Q-TRACKS programs, *Clin Lab Med,* 2004;24(4):965-978.

40 Howanitz PJ, Renner SW, Walsh MK, Continuous wristband monitoring over 2 years decreases identification errors. a College of American Pathologists Q-Tracks Study, *Arch Pathol Lab Med,* 2002;126:809-815, p. 811.

41 Bologna LJ, Lind C, Riggs RC, Reducing major identification errors within a deployed phlebotomy process, *Clin Leadersh Manag Rev,* 2002;16(1):22-26.

42 Hayden RT, Patterson DJ, Jay DW. Computer-assisted bar-coding system significantly reduces clinical laboratory specimen identification errors in a pediatric oncology hospital, *J Pediatr,* 2008;152(2):219-224.

43 Bologna LJ, Lind C, Riggs RC, Reducing major identification errors within a deployed phlebotomy process, *Clin Leadersh Manag Rev,* 2002;16(1):22-26.

44 Hayden RT, Patterson DJ, Jay DW, Computer-assisted bar-coding system significantly reduces clinical laboratory specimen identification errors in pediatric oncology hospital, *J Pediatr,* 2008;152(2):219-224.

45 Ibid., p. 223.

46 Bologna LJ, Lind C, Riggs RC, Reducing major identification errors within a deployed phlebotomy process, *Clin Leadersh Manag Rev,* 2002;16(1):22-26.

47 Makary MA, Epstein J, Pronovost PJ, et al., Surgical specimen identification errors: a new measure of quality in surgical care, *Surgery,* 2007;141(4):450-455.

48 Valenstein P, *Quality Management in Clinical Laboratories. Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

49 NQF, *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington, DC: NQF; 2007, pp. 95-118.

50 Valenstein PN, Sirota RL, Identification errors in pathology and laboratory medicine, *Clin Lab Med,* 2004;24(4):979-996.

51 Valenstein P, *Quality Management in Clinical Laboratories. Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

52 Alsina MJ, Alvarez V, Barba N, et al., Preanalytical quality control program—an overview of results (2001 – 2005 summary), *Clin Chem Lab Med,* 2008;46(6):849-854.

53 Lippi G, Banfi G, Buttarello M, et al., Recommendations for detection and management of unsuitable samples in clinical laboratories, *Clin Chem Lab Med,* 2007;45(6):728-736.

54 Valenstein P, *Quality Management in Clinical Laboratories. Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

55 Ibid., p. 74.

56 Howanitz PJ, Errors in laboratory medicine: practical lessons to improve patient safety, *Arch Pathol Lab Med,* 2005;129 (10):1252-1261.

57 Valenstein P, *Quality Management in Clinical Laboratories. Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

58 Ibid.

59 Ibid.

60 Tepus D, Fleming E, Cox S, et al., Effectiveness of Chloraprep in reduction of blood culture contamination rates in emergency department, *J Nurs Care Qual,* 2008;23(3):272-276.

61 Valenstein P, *Quality Management in Clinical Laboratories. Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

62 Bonini P, Plebani M, Ceriotti F, et al., Errors in laboratory medicine, *Clin Chem,* 2002;48(5):691-698.

63 Alsina MJ, Alvarez V, Barba N, et al., Preanalytical quality control program—an overview of results (2001–2005 summary), *Clin Chem Lab Med,* 2008;46(6):849-854.

64 Dale JC, Novis DA, Outpatient phlebotomy success and reasons for specimen rejection, *Arch Pathol Lab Med,* 2002; 126(4):416-419.

65 Tepus D, Fleming E, Cox S, et al., Effectiveness of Chloraprep in reduction of blood culture contamination rates in emergency department, *J Nurs Care Qual,* 2008;23(3):272-276.

66 Dale JC, Novis DA, Outpatient phlebotomy success and reasons for specimen rejection, *Arch Pathol Lab Med,* 2002;126(4):416-419.

67 Stark A, Jones BA, Chapman D, et al., Clinical laboratory specimen rejection-association with the site of patient care and patients' characteristics, *Arch Pathol Lab Med,* 2007;131(4):588-592.

68 Lippi G, Blanckaert N, Bonini P, et al., Haemolysis: an overview of the leading cause of unsuitable specimens in clinical laboratories, *Clin Chem Lab Med,* 2008;46(6):764-772.

69 Stark A, Jones BA, Chapman D, et al., Clinical laboratory specimen rejection-association with the site of patient care and patients' characteristics, *Arch Pathol Lab Med,* 2007;131(4):588-592.

70 Wagar EA, Stankovic AK, Raab S, et al., Specimen labeling errors: a Q-probes analysis of 147 clinical laboratories, *Arch Pathol Lab Med,* 2008;132(10):1617-1622.

71 Dzik WS, Beckman N, Selleng K, et al., Errors in patient specimen collection: application of statistical process control, *Transfusion,* 2008;48(10):2143-2151.

72 Murphy MF, Stearn BE, Dzik WH, Current performance of patient sample collection in the UK, *Transfus Med,* 2004;14(2):113-121.

73 Novis DA, Detecting and preventing the occurrence of errors in the practices of laboratory medicine and anatomic pathology: 15 years' experience with the College of American Pathologists' Q-Probes and Q-Tracks programs, *Clin Lab Med,* 2004;24(4):965-978.

74 Valenstein P, Meier F, Outpatient order accuracy: a College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions, *Arch Pathol Lab Med,* 1999;123(12):1145-1150.

75 Siddiqui S, Laboratory errors as judged by test request slips and test reports, *J Coll Physicians Surg Pak,* 2006; 16(2):136-138.

76 Valenstein P, *Quality Management in Clinical Laboratories: Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

77 Ibid.

78 Novis DA, Detecting and preventing the occurrence of errors in the practices of laboratory medicine and anatomic pathology: 15 years' experience with the College of American Pathologists' Q-Probes and Q-Tracks programs, *Clin Lab Med,* 2004;24(4):965-978.

79 Ibid., 968.

80 Ibid.

81 Ibid., 967.

82 Ibid.

83 Valenstein P, *Quality Management in Clinical Laboratories: Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61-87.

84 Valenstein P, Meier F, Outpatient order accuracy: a College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions, *Arch Pathol Lab Med,* 1999;123:1145-1150.

85 Valenstein PN, Walsh MK, Stankovik AK, Accuracy of send-out test ordering: a College of American Pathologists Q-Probes study of ordering accuracy in 97 clinical laboratories, *Arch Pathol Lab Med,* 2008;132:206-210.

86 Ibid.

87 Ibid.

88 Valenstein P, *Quality Management in Clinical Laboratories: Promoting Safety through Risk Reduction and Continuous Improvement,* Northfield, IL: CAP; 2005, pp. 61–87.

89 Ibid.

90 Novis DA, Detecting and preventing the occurrence of errors in the practices of laboratory medicine and anatomic pathology: 15 years' experience with the College of American Pathologists' Q-Probes and Q-Tracks programs, *Clin Lab Med,* 2004;24(4):965-978.

91 NQF, *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington, DC: NQF; 2007, pp. 95-118.

92 Pennsylvania Patient Safety Reporting System, *Patient Safety Advisory. Improving the Safety of Telephone or Verbal Orders,* Harrisburg, PA: Patient Safety Authority; 2006. Available at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2006/Jun3(2)/Pages/01b.aspx. Last accessed March 2009.

93 Wagar EA, Tamashiro L, Yasin B, et al., Patient safety in the clinical laboratory. a longitudinal analysis of specimen identification errors, *Arch Pathol Lab Med,* 2006;130(11):1662-1668.

94 Melanson, SF, Hsieh, Flood JG, et al., Evaluation of add-on testing in the clinical chemistry laboratory of a large academic medical center: operational considerations, *Arch Pathol Lab,* 2004;128(8):885-889.

95 Stankovic AK, The laboratory is a key partner in assuring patient safety, *Clin Lab Med,* 2004;24(4):1023-1035.

96 Leonard M, Graham S, Bonacum D, The human factor: the critical importance of effective teamwork and communication in providing safe care, *Qual Saf Health Care,* 2004;13 (Suppl 1):I85-I90.

97 Ibid.

98 Barenfanger J, Sautter RL, Lang DL, et al., Improving patient safety by reporting (read-back) telephone reports of clinical information, *Am J Clin Pathol,* 2004;121(6):801-803.

99 Ibid.

100 Ibid.

101 Ibid.

102 Ibid.

103 Wagar EA, Stankovic AK, Wilkinson DS, et al., Assessment monitoring of laboratory clinical values: a College of American Pathologists Q-Tracks study of 180 institutions, *Arch Pathol Lab Med,* 2007;131(1):44-49.

104 NQF, *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington, DC: NQF; 2007, pp. 95-118.

105 Leonard M, Graham S, Bonacum D, The human factor: the critical importance of effective teamwork and communication in providing safe care, *Qual Saf Health Care,* 2004;13 (Suppl 1):I85-I90.

106 Ibid.

107 Ibid.

108 Ibid.

109 Wang S, Ho V, Corrections of clinical chemistry test results in a laboratory information system, *Arch Pathol Lab Med,* 2004;128(8):890-892.

110 Ibid.

111 NQF, *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington, DC: NQF; 2007, pp. 95-118.

112 Leonard M, Graham S, Bonacum D, The human factor: the critical importance of effective teamwork and communication in providing safe care, *Qual Saf Health Care,* 2004;13 (Suppl 1):I85-I90.

113 Hanna D, Griswold P, Leape LL, et al., Communicating critical test results: safe practice recommendations, *Jt Comm J Qual Patient Saf,* 2005;31(2):68-80.

114 NQF, *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington DC: NQF; 2007, pp. 95-118.

115 Ibid.

116 Kuperman GJ, Boyle D, Jha A, et al., How promptly are inpatients treated for critical laboratory results? *J Am Med Inform Assoc,* 1998;5(1):112-119.

117 Woods DM, Thomas EJ, Holl JL, et al., Ambulatory care adverse events and preventable adverse events leading to a hospital admission, *Qual Saf Health Care,* 2007;16(2):127-131.

118 Fernald DH, Pace WD, Harris DM, et al., Event reporting to a primary care patient safety reporting system: a report from the ASIPS Collaborative, *Ann Fam Med,* 2004;2:327-332.

119 Haverstick DM, Critical value called, read-back obtained, *Am J Clin Pathol,* 2004;121:790-791.

120 NQF, *Safe Practices for Better Healthcare—2006 Update: A Consensus Report,* Washington, DC: NQF; 2007, pp. 95-118.

121 Hanna D, Griswold P, Leape LL, et al., Communicating critical test results: safe practice recommendations, *Jt Comm J Qual Patient Saf,* 2005;31(2):68-80.

122 Ibid.

123 Barenfanger J, Sautter RL, Lang DL, et al., Improving patient safety by reporting (read-back) telephone reports of clinical information, *Am J Clin Pathol,* 2004;121(6):801-803.

124 Hawkins RC, Laboratory turnaround time, *Clin Biochem Rev,* 2007;28(4):179-194.

125 Steindel SJ, Howanitz PJ, Physician satisfaction and emergency department laboratory test turnaround time, *Arch Pathol Lab Med,* 2001;125(7):863-871.

126 Schiff GD, Kim S, Krosnjar N, et al., Missed hypothyroidism diagnosis uncovered by linking laboratory and pharmacy data, *Arch Intern Med,* 2005;165(5):574-577.

127 Lippi G, Giavarina D, Montagnana M, et al., National survey on critical values reporting in a cohort of Italian laboratories, *Clin Chem Lab Med,* 2007;45(10):1411-1413.

128 CMS, *Medicare and Medicaid Statistical Supplement,* 2003, Baltimore, MD: CMS. Available at www.cms.hhs.gov/MedicareMedicaidStatSupp/LT/List.asp. Last accessed March 2009.

THE NATIONAL QUALITY FORUM (NQF) is a private, nonprofit, open membership, public benefit corporation whose mission is to improve the American healthcare system so that it can be counted on to provide safe, timely, compassionate, and accountable care using the best current knowledge. Established in 1999, NQF is a unique public-private partnership having broad participation from all parts of the healthcare industry. As a voluntary consensus standard-setting organization, NQF seeks to develop a common vision for healthcare quality improvement, create a foundation for standardized healthcare performance data collection and reporting, and identify a national strategy for healthcare quality improvement. NQF provides an equitable mechanism for addressing the disparate priorities of healthcare's many stakeholders.

NATIONAL QUALITY FORUM
601 13th Street NW
Suite 500 North
Washington, DC 20005
202-783-1300
www.qualityforum.org

ISBN: 978-1-933875-31-6