

Evaluating the Connections Between Primary Care Practice and Clinical Laboratory Testing

A Review of the Literature and Call for Laboratory Involvement in the Solutions

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• **Context.**—Growing evidence has demonstrated a high frequency of quality gaps in laboratory medicine, with recent studies estimating that 15% to 54% of primary care medical errors reported by primary care physicians and staff are related to the testing process. However, there is lack of evidence-based performance metrics in the preanalytic and postanalytic phases of the testing pathway for primary care practices.

Objective.—To use results of the literature review to assist in the development of quality indicators that could improve preanalytic and postanalytic processes in primary care-based laboratory medicine.

Data Sources.—Literature in Ovid/MEDLINE from 2001 through 2011 was searched as a primary source of information. Ninety-five peer-reviewed and non-peer-reviewed publications were retrieved following title and abstract review and 10 articles were reviewed in their entirety by the authors. A systematic review of the literature was

conducted regarding the connections between clinical laboratories and primary care offices and the resulting errors. Root causes of errors were categorized into 7 major themes: process failures, delays, communication gaps, errors in judgment and cognition, influence of minorities/language, practice culture, and lack of patient centeredness. Selected articles were evaluated for evidence quality using the Systematic Evidence Review and Evaluation Methods for Quality Improvement grading scale developed by the Centers for Disease Control and Prevention.

Conclusions.—The focused literature review documented 7 key error themes in the laboratory medicine/primary care testing process. Performance metrics related to these themes are proposed that deserve future study for evidence-based improvement.

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Primary care physicians order many laboratory tests for their patients. Recent estimates are that the average family physician and general internist order laboratory testing in 29% and 38% of patient encounters, respectively.¹ In addition to high laboratory test volume, there is growing evidence of the high frequency of quality gaps in primary care laboratory medicine, with recent studies estimating that 15% to 54% of primary care medical errors reported by primary care physicians and their staff are related to the testing process.¹ Because of the volume of laboratory testing and high frequency of medical errors due to laboratory testing, there is a need for improved quality in the area. The Institute of Medicine (IOM) provides a

framework for understanding the quality of health care by defining it as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.² The IOM further classifies quality into 6 domains: safety, timeliness, effectiveness, efficiency, equity, and patient centeredness^{3,4} (Figure 1). In laboratory medicine, multiple studies have shown that the majority of errors or gaps in quality take place in the preanalytic and postanalytic phases of the total testing pathway (TTP).^{5–12} The TTP is a systems-based framework for the evaluation of the interactions, connections, and activities involved in the testing process (Figure 2). As the figure describes, the process is circular and includes the preanalytic, analytic, and postanalytic phases of the testing cycle. Cognitive tasks are required at multiple steps, by both the primary care provider and the laboratory.

When errors are categorized into general process categories, frequent preanalytic errors involve inadequate sample collection, inappropriate sample transportation, and incorrect test requests for patients.^{13,14} Frequent categories of postanalytic errors include delivery of duplicate reports and delays in receiving reports.^{13,14} Additionally, the connection between health care quality and communication is an issue of critical importance, especially in laboratory medicine.^{15–22} Poor communication among health care providers is the root cause of most medical

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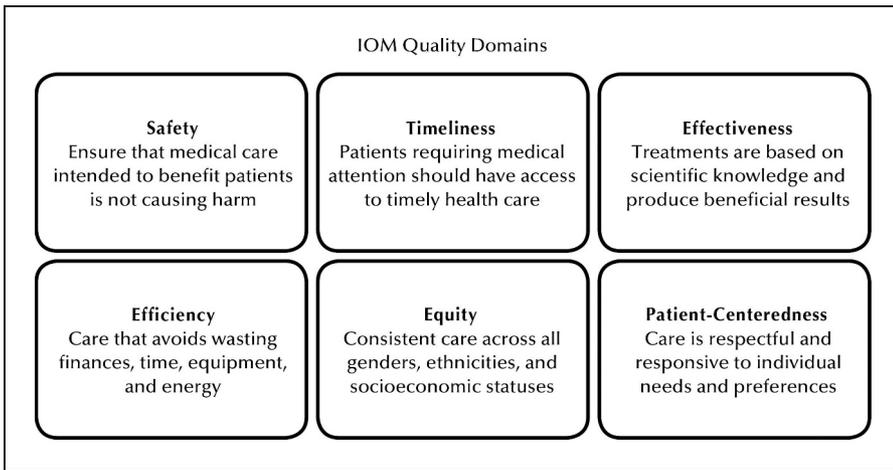


Figure 1. Six health care quality domains as defined by the Institute of Medicine (IOM). Data derived from Richardson WC, Corrigan J. The IOM Quality Initiative: A Progress Report at Year Six. IOM Newsl. 2002;1(1):1-7. ²

errors, including sentinel events.^{15,16} Handoffs are especially critical processes in which communication failures place patients at risk.^{17,18} Much attention has been directed at quality initiatives within the analytic phases of testing in the laboratory with quality control programs such as the College of American Pathologists quality improvement programs and laboratory accreditation. Given the high frequency of these quality gaps in laboratory testing and the relative lack of laboratory quality initiatives aimed at improving the quality of testing in one of these phases, there is a critical need for the development of

evidence-based performance metrics in the preanalytic and postanalytic phases of the TTP.

OBJECTIVE

Our primary goal is to identify potential laboratory testing performance and quality indicators in the pre-analytic and postanalytic phases of testing. As an initial step, through funding from the Centers for Disease Control and Prevention, we performed a literature search to assist in the development of performance and quality indicators that might serve to improve primary care

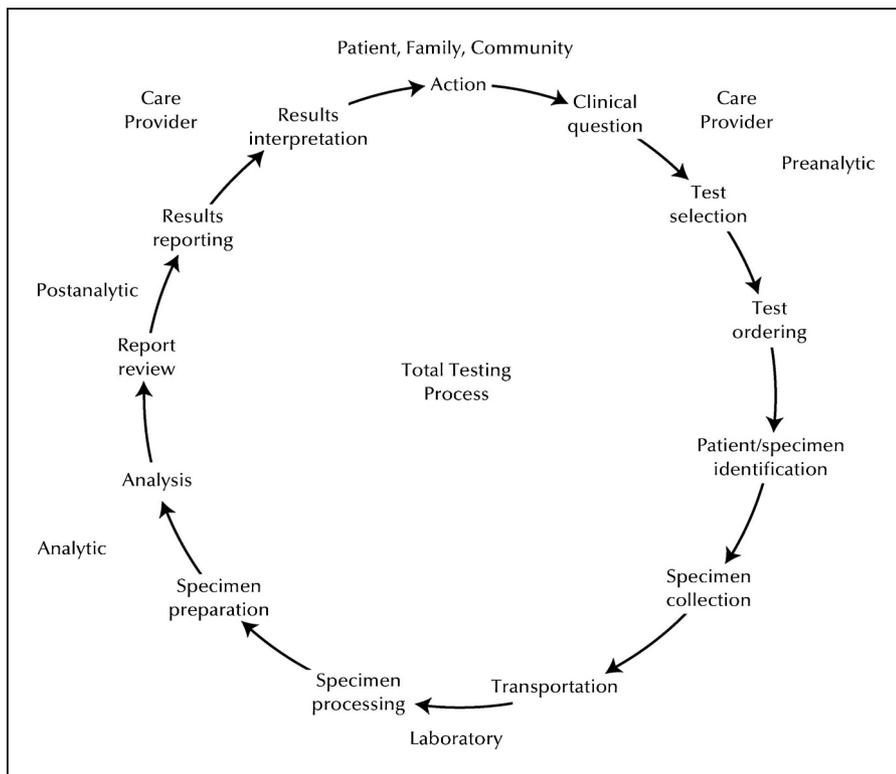


Figure 2. The total testing process begins with a clinical question and the care provider and patient. Each larger step in the process comprises many smaller steps, and laboratory medicine is the sum total of all testing steps. Adapted with permission from Boone J. Presentation at the Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health, September 23-26, 2007; Atlanta, GA: Centers for Disease Control and Prevention; and Barr JT, Silver S. The total testing process and its implications for laboratory administration and education. Clin Lab Manage Rev. 1994;8:526-542^{36,37}.

Table 1. Main Themes Identified With Associated IOM Quality Domains and Affected Total Testing Pathway (TTP) Phases

Source, y	IOM Quality of Health Care Domains					
	Safety	Effectiveness	Efficiency	Timeliness	Equity	Patient Centeredness
Pace et al, ²⁵ 2005	Delays Communication Judgment/cognition	Process	Process Communication	Process Communication	Minority	
Graham et al, ³⁰ 2008 Kaprielian et al, ³² 2008 Gandhi et al, ¹² 2006	Culture Delays Communication Judgment/cognition	Process Judgment/cognition	Process Culture	Process Delays		Centeredness Culture Communication
Staes et al, ³¹ 2008 Lin et al, ²⁶ 2006 Elder et al, ²⁴ 2009	Delays Communication Culture		Delays Process Culture	Delays Communication Process		Delays Culture
Casalino et al, ²⁸ 2009 Hickner et al, ²⁷ 2008 Smith et al, ²⁹ 2005	Delays	Process Process Process	Process Process Process	Process Process Process	Minority	Centeredness

Abbreviations: Centeredness: issues regarding care that considers the patient's desire for information and for sharing decision making, and responding appropriately; Communication: failures in the exchange or transmission of information among parties relevant to the appropriate clinical care or management of a patient, including verbal, written, or electronic documentation, messages, or data; Culture: issues regarding the behaviors and expressed beliefs by leadership, clinicians, and staff that demonstrate a commitment to quality and patient safety; Delays: postanalytic delays in reporting laboratory results to practices, physicians, or patients; Judgment/cognition: errors in an individual's skills, knowledge, training, experience, and reasoning used to make appropriate decisions about a patient's clinical care and management; Minority: issues regarding unequal care among racial and ethnic minorities or due to language barriers; Process: breakdown in test ordering, test implementation, test reporting to provider, clinician response, or patient notification.

laboratory testing processes important for quality and safety.

DESIGN

A focused search of peer-reviewed literature, without meta-analysis, was developed in order to establish the current state of knowledge regarding laboratory-related processes involving clinical laboratories and primary care offices and the resulting errors. The literature scan was developed through consultation with a librarian at the University of Colorado in Aurora specializing in database and Internet information science, and used Ovid/MEDLINE as a primary source of information. Supplemental information was gathered from several conference proceedings and multiple electronic bibliographic databases, such as PubMed. The search strategy used for the bibliographic databases was a combination of title and topic that included the following primary domains and alternative terms: patient harm (medical error, adverse events, and patient safety), laboratory tests (results, diagnostic tests, and screening tests), communication (transition, handoff, handover), and primary health care (ambulatory care, family practice, internal medicine, general practice, and patient-centered medical home). The Agency for Healthcare Research and Quality Advances in Patient Safety publications from prior Agency for Healthcare Research and Quality-funded studies were manually searched for related articles, as they are not included in the above databases. The search included the following inclusion/exclusion criteria: (1) limited to literature published from the last 10 years, (2) available in English, and (3) no global restrictions applied.

Articles selected for review underwent further analysis for the level of evidence quality by 2 reviewers, using a grading scale developed by the Centers for Disease Control and Prevention called Developing Systematic Evidence Review and Evaluation Methods for Quality Improvement.²³ Briefly, the scale required the reviewers to rate the quality of each article based on a 10-point

scale, while evaluating the following 6 dimensions: observed effect size, relevance, study, practice, outcome measures, and findings/results. Articles that received greater than 7 points on average were reviewed by the 8 reviewers as a group. Major themes from each article were identified and associated with the affected IOM quality domains.

RESULTS

All articles were first reviewed by title and abstract, yielding a total of 95 potentially relevant articles. Ten articles scored greater than 7 points on the grading scale and were reviewed in their entirety by the group of reviewers. Each article was discussed by the group and key points were extracted. A summary of the key points from all the articles revealed the following 7 key concepts in laboratory medicine—primary care: (1) process failures, (2) delays, (3) communication gaps, (4) errors in judgment and cognition, (5) influence of minorities/language, (6) practice culture, and (7) lack of patient centeredness. Table 1 identifies and defines the main themes from the articles along with the associated IOM quality domains and affected TTP phases. Table 2 displays the proposed potential metrics based on the themes found in the literature review.

Breakdowns or Failures in Process

Highlighting an important overall theme, several articles addressed breakdowns or failures in the overall TTP. First, some practices demonstrated a complete lack of a process for ordering, implementing, and reporting laboratory results. Elder et al²⁴ observed 2 primary care practices that had no written protocols or procedures for any results management steps. Similarly, Pace et al²⁵ also determined that a total lack of a process system was associated with laboratory errors and a frequent contributor to patient harm. Lin et al²⁶ reported that difficulty accessing laboratory results and the lack of a defined

TTP Phase Affected		
Preanalytic	Analytic	Postanalytic
X		X
X	X	X
X	X	X
X	X	X
		X
		X
		X
X		X
X		X
X	X	X

follow-up system contributed significantly to lost laboratory results. Hickner et al²⁷ reported that practices that used more than one laboratory, and thus were forced to have more than one process, were much more likely to experience preanalytic and postanalytic errors in testing (17% versus 5%). In addition, Hickner et al²⁷ found failures in all phases of the TTP. Casalino et al²⁸ reported that partial medical records were highlighted as potential causes of error because having information in multiple areas added complexity to the process. The end result of process failure is clinical decision without necessary laboratory information. Smith et al²⁹ identified 6.1% of primary care visits were performed with missing laboratory results. Graham et al³⁰ studied mitigation of near-miss events and found a high number of physician-mitigated events in the preanalytic phase of the TTP after failures in the laboratory process. Lack of or failures in a process may affect all IOM quality domains, but are most significant in the domains of effectiveness, timeliness, and efficiency.

Delays in Diagnosis

Four articles specifically addressed how delays in reporting were a contributing factor to laboratory errors. Staes et al³¹ found that delays in reporting and processing significantly increase risk to patients due to delays in decision making by a patient's clinical team. In addition, when laboratory tests are delayed or missed, patients

incur additional costs, inconvenience, and discomfort for repeat testing without additional benefit. Twenty-four percent of errors resulted in delays in diagnosis. Hickner et al,²⁷ Pace et al,²⁵ and Gandhi et al¹² all reported that postanalytic delays in reporting to physicians and to patients can contribute significantly to laboratory related errors. Delayed diagnoses primarily affect the IOM quality domain of safety and timeliness.

Communication Gaps

Preanalytic and postanalytic communication gaps were addressed in 3 articles and were identified as a major theme in the literature. Gandhi et al¹² reported that communication handoffs contributed to 20% of laboratory errors and represented a primary factor that lead to errors. Similarly, Pace et al²⁵ identified that communication within the practice and between the practice and another location can be subject to communication gaps and errors that lead to patient harm. Lin et al²⁶ described how communication gaps may result in communication failures among staff and found that 16% of staff stated in a survey that they were not clear on who was responsible for following up on laboratory results. Communication failures focus on the IOM quality domains of safety, communication, and patient centeredness.

Errors in Judgment and Cognition

Two articles addressed the impact of preanalytic and postanalytic errors in judgment or cognition. Gandhi et al¹² reported that frequent breakdown points occurred when providers failed to order appropriate diagnostic tests (55%) and when physicians misinterpreted a diagnostic test (37%). The most common explanation for these failures was that the physician seemed to lack knowledge of the appropriate test. Other factors, including failures in judgment (79%) and vigilance or memory (59%), also contributed to errors. Likewise, Pace et al²⁵ reported that judgment was a significant factor that contributed to laboratory errors that lead to patient harm. The IOM quality domains of safety and effectiveness are highlighted by judgment and cognitive failures.

Influence of Minorities and Language Barriers

Two articles commented specifically on how race/ethnicity influences laboratory errors. Hickner et al²⁷ reported that errors in laboratory test implementation were nearly double for minority groups compared with

Laboratory–Primary Care Error Theme	Proposed Potential Metrics
Breakdowns in process ^{24–30}	Practice protocols should include an outlined procedure for laboratory test ordering, reporting of results, and patient notification.
Delays in diagnosis ^{12,25,27,31}	Laboratory results should be communicated to patients within 1 business day of receipt by the practice.
Communication gaps ^{12,25,26}	Practices should have a clearly defined role/responsibility for tracking and responding to laboratory data.
Errors in judgment and cognition ^{12,25}	Primary care providers should have convenient access to laboratory physicians to assist in laboratory test ordering and interpretation.
Influence of minorities and speech barriers ^{24,32}	Additional study and root-cause analysis is required.
Practice culture ^{24,32}	Indirect measures include the presence of a quality improvement program, monthly quality conference, procedures on how to handle errors, and the presence of an error tracking system.
Patient centeredness ^{27,30}	Practices should have a protocol for informing patients of laboratory results and involving them in the decision making process.

non-Hispanic whites (32% versus 18%). Additionally, minority patients were more than twice as likely to experience adverse consequences or harm as a result of the errors. Similarly, Pace et al²⁵ associated language barriers with harm to patients with respect to laboratory medicine. These studies highlight the IOM quality domain of equity.

Practice Culture

The culture of a practice regarding laboratory testing and laboratory errors was a major theme identified by the reviewers and was evaluated in 2 articles. Kaprielian et al³² described how a common barrier to reporting and thus addressing laboratory errors is fear of betraying colleagues. Elder et al²⁴ stated that safety awareness was an important factor in assessing test results management quality and that leadership focus and communication that occurs around quality and safety was necessary. A safe culture impacts all phases of testing and is important for IOM quality domains of safety, efficiency, and patient centeredness.

Patient Centeredness

Hickner et al²⁷ commented on establishing explicit rules for the postanalytic notification of results and eliminating the use of the phrase “no news is good news”—an assumption that the Agency for Healthcare Research and Quality counsels patients not to make.³³ Graham et al³⁰ echoed this focus on patient centeredness, commenting that offices should empower patients to contact them if things do not appear to be handled correctly. They continued to add that patients have the potential to be effective mitigators, as they have a different lens on events and can see things that are often missed by office staff.

CONCLUSIONS

The comprehensive literature review documented the following themes as sources of laboratory–primary care errors: breakdowns in process, delays in diagnosis, communication gaps, errors in judgment and cognition, influence of minorities and speech barriers, practice culture, and patient centeredness. Many articles suggested each event was the result of not one but a series of errors. These themes are fertile fields for the development of practice metrics aimed at evaluating primary care–laboratory medicine risk and decreasing risk of error and adverse events. A summary of findings, IOM domains involved, and potential metrics is given in Table 1.

Breakdowns in Process

In an ideal state, laboratories and primary care practices have a duty to their patients to develop comprehensive processes designed to allow accurate and complete follow-up beginning in the preanalytic phase and ending in the postanalytic phase. Two articles (Staes et al³¹ and Lin et al²⁶) recommended the use of computerized reporting systems in order to improve process tracking. However, others suggest complex technology-driven systems may result in overreliance (Hickner et al²⁷) and simple paper tracking systems may be superior (Kaprielian et al³²). As a start, a potential metric may be an outlined procedure for laboratory medicine process in practice protocols.

Delays in Diagnosis

The lean principle of just-in-time work flow suggests customers receive what they want and need, exactly when

they need it.³⁴ As customers of our services, patients deserve timely and accurate results. Laboratories should work with practices to develop more efficient ways to communicate results in an effort to ease and improve the communication of results to patients. As a proposed benchmark, laboratory results should be communicated to patients within one business day of receipt by the practice.

Communication Gaps

Two areas of communication failure were identified: failures within primary care practices and failures between practices and laboratories. One important lean manufacturing principle is to standardize work, which includes identifying who is responsible for each step of a task.³⁴ Practices might assign one support staff member to track all laboratory orders and results or spread the responsibility, as long as it is clear who is responsible for what. Again, laboratories have an opportunity to improve their service by working closely with practices to improve communication.

Errors in Judgment and Cognition

This might seem like one of the more difficult themes to address and will require more study. However, root cause analysis³⁵ of the fundamental errors in laboratory utilization may reveal additional factors contributing to errors. Perceived errors in judgment and cognition often result in individual blame, finger pointing, and retraining when in reality these errors may be due to underlying process design failures. Attempts should be made to separate true failures in judgment and cognition from system-related failures. One of these systematic failures is the limited exposure to laboratory medicine in medical school and residency. With the ever-burgeoning volume of medical science to keep up with, perhaps primary care providers need more access to skilled laboratorians to help advise them on appropriate testing algorithms and result interpretation. Electronic physician order entry systems have the capability of including reminders and remarks to assist with judgment and cognition when placing laboratory orders. It is unlikely that simply asking primary care physicians to work harder on laboratory result tracking, as has been suggested,²⁸ will improve outcomes, particularly without associated incentives. As a metric for study, we postulate that primary care providers should have convenient access to laboratory physicians to assist in laboratory test ordering and interpretation. It should be noted that appropriate reimbursement for these efforts is a limiting factor in realizing this additional support.

Influence of Minorities and Speech Barriers

Our literature highlighted an important concept with regard to minority and language barrier populations and their increased risk in the laboratory–primary care testing process. This important area requires additional study as to the root cause of this finding and possible solutions. One may speculate cultural and language barriers lead to isolation and difficulties communicating regarding tests ordered, results, and significance.

Practice Culture

The importance of practice culture with regard to safety cannot be overemphasized. Without a global mission for patient safety and quality and support from leaders in the practice and laboratory, significant improvements are

not likely. Metrics to measure practice culture are very difficult to develop. Indirect measures include the presence of a quality improvement program, monthly quality conferences, procedures on how to handle errors, and whether error tracking is performed.

Patient Centeredness

As our ultimate customers, patients play an important role in the process. Studies reviewed showed that patients are effective mitigators of near-miss events and should be more actively involved in the process. Practices should have a protocol for informing patients of laboratory results and involving them in the decision-making process.

Primary care providers are customers of the clinical laboratories, because they generate samples for testing. Therefore, directors of clinical laboratories play a role in addressing their customer needs and providing timely and accurate service. The literature review highlights several areas wherein the clinical laboratory could strive to improve its service, not just in the analytic phases of testing but extending service to the preanalytic and postanalytic phases. Based on the findings from the literature review, several possible metrics have been proposed to begin the evaluation of the primary care laboratory process (Table 2). Our next steps involve practice survey studies and finalization of possible performance metrics.

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