



**INTEGRATING LABORATORIES INTO THE PCMH MODEL
OF HEALTH CARE DELIVERY:**

A COLA White Paper

OVERVIEW

The concept of the “Patient Centered Medical Home” (PCMH) has the potential to transform the healthcare delivery experience for both patients and providers alike. Originating in the 1960s, it is now experiencing increasing application.

Given the important role played by laboratories in the continuum of quality patient care, there are opportunities to integrate laboratories into the PCMH model, such as through COLA's Patient Centered Laboratory Excellence (PCLE) program, established to support development of – and ultimately recognize – large and small practice laboratories that meet National Committee for Quality Assurance (NCQA) standards for a patient home. This white paper reviews challenges facing physician office laboratories seeking PCMH integration, and offers approaches toward excellence of controls in three key areas: test utilization, Pre and Post-analytical laboratory errors, and electronic health records.

THE PATIENT CENTERED MEDICAL HOME: BACKGROUND, PURPOSE, AND APPLICATION

PCMH is a health care model intended to establish a foundation for primary care that achieves the Institute for Healthcare Improvement's three-fold aim of better health, better care, and lower costs.^[1] PCMH foundational principles were jointly developed by the American College of Physicians, American Academy of Pediatrics, American Academy of Family Physicians, and the American Osteopathic Association.^[2]

The PCMH model of healthcare delivery is representative of the healthcare reform programs championed by the Center for Medicare and Medicaid Innovation, and has become one of the central models for efforts of primary caregivers to improve delivery of healthcare, patient satisfaction, and cost controls. It assumes that better coordination among caregivers will result in cost savings as well as improved patient care.

The Patient Centered Primary Care Collaborative (PCPCC) monitors implementation of PCMH across the U.S., and reports key outcomes that demonstrate progress towards the goals of PCMH. According to the PCPCC implementation report of January 2014, 90 commercial and not for profit health care providers are engaged in PCMH.^{[3][4]}

In order to obtain recognition in Medical Home programs and potentially qualify for additional reimbursement from insurance providers, physician practices must undergo

an assessment process, and provide first contact, continuous, comprehensive, whole person care for patients across the practice, and team-based care for at least 75% of its patients. The National Committee for Quality Assurance (NCQA) has the most common medical home recognition program. The NCQA measures practices on 27 elements across 6 standards.^[2] There are minimum level requirements to be considered a PCMH; higher-level scores may be associated with increased reimbursement.^[5]

Many small and specialty practices will need assistance in reforming to NCQA medical home requirements. Several publications evaluated implementation of the medical home among primary care groups and found a strong association with large physician groups (i.e., practices with greater than 11 physicians) and multi-specialty practices. As a result, there is significantly less adoption of medical home processes among smaller and medium-size practices, where the majority of Americans receive their health care.^{[6][7]} Hollingsworth compared resources reported from physician practices with various infrastructures to the NCQA standards. In this review, nearly 40% of primary care practices lacked the systems and infrastructure to meet the minimum NCQA requirements for a PCMH, especially the standards for electronic medical health information systems and establishing performance measurements for monitoring quality improvement. For the NCQA elements of ordering tests, retrieving test results electronically, and being able to identify redundant testing, there was also a significant difference between percent compliance to the requirements by larger practices than medium to smaller practices.^[7]

INTEGRATING LABORATORIES INTO THE PCMH MODEL

Laboratory testing is the single highest-volume medical activity, with an estimated 13 billion tests performed in the United States each year.^[8] About two-thirds of clinical decisions are based on laboratory test information.^{[9][10]} As the laboratory is part of the PCMH “neighborhood”^[11] and lab testing is often directive of more costly downstream care, opportunities exist for lab personnel to take the lead in establishing practices aligned with PCMH standards^[12] in three key areas:

- Controlling test utilization;
- Identifying risks and controls for all phases of laboratory testing including pre-analytic, analytic and post analytic;
- Coordinating lab results among primary care providers, other providers in the PCMH “neighborhood,” and the patient.

Controlling Test Utilization

Inappropriate testing takes several forms:

- Overutilization (ordered but not indicated)
 - o At initial patient evaluation
 - o In response to new symptoms
 - o Inappropriate repeat testing
- Underutilization (indicated but not ordered)

There are abundant publications on inappropriate testing, assessing a wide variety of patient populations, care environments, lab tests evaluated, statistical analysis tools, and criteria for determining what makes a test request inappropriate (i.e., objective vs. subjective criteria, restrictive vs. permissive criteria).

The authors reviewed abstracts from 493 peer-reviewed journal articles on redundant lab testing and filtered them to 42 publications that met the criteria they required to be able to conduct a statistical analysis of the lab test utilization data provided. They found that there was no significant difference between U.S. and ex-U.S. estimates of over-utilization of lab tests, and no difference in over-utilization rates over the 15 years reviewed. From those 42 publications, which covered 46 common lab tests, the overall rate of redundant testing was 20.6%.^[13]

Ramifications of overutilization go far beyond laboratory costs, unnecessary sample collection, and the burden placed on health care resources. Downstream effects include increased likelihood of false results leading to incorrect diagnoses, unnecessary prescription drugs, longer hospital stays, and additional medical or surgical interventions.^[13] Solutions for lab utilization controls that could be implemented by both small and large physician office laboratories include physician education on laboratory test costs and evidence-based medicine, restriction-on and auditing-of test ordering, and decision support laboratory ordering systems—with or without “hard stop” features for orders deemed to meet trigger criteria for redundant testing.

Identifying Risks and Controls for All Phases of Laboratory Testing

With the shift toward patient-centered medical practice, there is also a need to evaluate the laboratory from a patient-centered viewpoint. Ehrmeyer defines patient safety in a point of care environment as “the freedom from being placed at increased risk of injury due to either failure of the testing process, or to delayed or inappropriate

responses to test results by the clinician.”^[14] Undeniably, the total test process (TTP) is a complex chain of sub-processes that culminate in a result for the patient—and the laboratory test itself is only one cog in the chain. To help comprehend the true scope of the TTP, Lundberg defined the concept of the “brain-to-brain loop” for laboratory testing in 1975.^[14]

The loop begins with the question that the clinician is addressing, followed by diagnostic test selection, sample collection, transport to the lab, analysis of the sample, reporting and interpretation of test result. The loop closes with decisions by the clinician regarding patient management. Taking appropriate action based on the result is the most critical step in the loop; otherwise it is as if the cycle never started.^{[14][15][16]}

The concept has evolved over the last 40 years to go beyond consideration of the action undertaken on the patient based on laboratory results. Clinicians and laboratory professionals should be “concerned about the effects of that laboratory test and whether the performance of it was useful for the patient or for the public’s health.”^[15] The TTP we consider today is comprised of five phases, summarized in Table 1.^{[16][17][18][19][20]}

The focus over the past several decades by laboratory medicine and in-vitro diagnostic manufacturers of improving analytical error and quality control has resulted in analytical error rates of 4-5 sigma—which surpasses most other areas of healthcare.^[16] Plebani compared error rates between 1996 and 2006 from an Italian stat laboratory. The total error rate was reduced by 34% over the ten-year period; however, the distribution of pre- and post-analytical error rates remained essentially the same. Pre-pre-analytical errors account for 46-68% of mistakes in the TTP, mostly in specimen collection or identification.^[16] Most pre-pre-analytical errors are detected before testing, however, 20-25% may lead to inappropriate investigation and increased cost.^[16] Errors in the post-post analytical phase of the TTP are the second highest in frequency, comprising 25-46% of TTP errors. Data from a 2011 CDC survey of primary care and general practice physicians across the U.S. revealed that although one third of patient visits included laboratory test requests, 14.7% of respondents were uncertain about which test to order, and 8.4% of respondents were uncertain about interpretation of the test results.^[21] Breakdown in result communication among caregivers is the most common root cause of delayed treatment or failure to followup. An estimated 3-12 % of TTP errors could cause patient harm due to inappropriate care or therapy.^{[9][16][18][20][22]}

Although the laboratory detects the majority of pre-analytical errors, the average cost

related to correcting the specimen error approaches \$1.2 million dollars a year for a 650-bed hospital.^[9] From a risk management point of view, a Point of Care (POC) testing environment should have fewer pre-analytical error opportunities due to fewer steps. Nevertheless, there are greater risks for analytical errors in the POC environment associated with incomplete procedures, protocol non-compliance, and insufficient tester understanding of the entire testing process, limited laboratory oversight, and a lack of continuing process assessment to identify problems and make improvements.^{[15][17]}

As previously mentioned, improved analytical quality assurance for reagents and instrumentation and advances in IT capabilities contribute to a relatively low analytic error rate. The introduction of specimen processing workstations helps decrease pre-analytical specimen preparation errors. Laboratory information systems with interface to analyzers significantly reduce data transcription errors in the post-analytic phase. While these manufacturer and laboratory-controlled improvements help reduce TTP errors, accreditation agencies also expect laboratories to monitor and improve key quality indicators for processes associated with pre-pre and post-post analytical phases. Joint Commission International Standards require accredited organizations to implement JCI International Patient Safety Goals (IPSGs). The first Standard, IPSG 1, applies to the most critical pre-pre-analytical step of assuring patient identification. ISPG-1 requires an organization to develop and document an approach to identify patients at least two ways before sample collection. ISPG-2 requires an organization to develop and document approaches to assure effectiveness of pre- and post-analytical phase communication. This includes the processes for test requests and for critical value reporting for potentially life-threatening conditions that could result in serious adverse outcome for the patient.^[16]

One challenge to establishing quality assessment programs for extra-analytical errors is the lack of a common reporting system based on standardized specifications and data collection. Ideally, standardization will enable all labs to benchmark their practices to other similar labs, and continuously improve their performance. The International Federation of Clinical Chemistry and Lab Medicine (IFCC) Working Group is currently finalizing a common set of TTP quality specifications and collecting data to benchmark performance error rates throughout the TTP.^{[14][16][17][20][22]} The IFCC working group developed a harmonized list of Quality Indicators (QI) that comprehend QIs across all steps of the TTP applicable to laboratories of all complexities, technology level, and size. Table 2 lists the highest priority, critical QIs, which the IFCC working group members agreed to monitor and report in a standardized format in representative laboratories their countries.^[23]

Based on data collected from pilot labs around the globe focusing on errors related to IPST1 and IPST2, the IFCC set preliminary goals of <0.4% for incorrect sample identification, <50 minutes for average time to communicate critical results, and >96% of critical results reported. The IFCC expects laboratories already exceeding these goals to set more appropriate standards for themselves based on their own data monitoring results.^[16]

From the discussion thus far, it is evident that a laboratory operating in a patient-centered practice must monitor and investigate the TTP for any actual or potential adverse impact on the patient. The concept of Total Quality Management, routinely used by Manufacturers, is also appropriate for application to laboratories responsible for the quality of the total testing process. Moreover, accreditation agencies require the clinical laboratory operation to have a Quality Management System and evidence that they are competently applying their Quality System to the TTP.^[22] Quality System essentials include: policies, process documentation, organizational structure, personnel requirements and training, equipment validation and maintenance, supplier management, process controls, inspections, record control, incidents reporting and investigation, process improvement, as well as facility and safety procedures.^[18]

The TTP should be treated as a system. There is a wide range of errors in the TTP; each lab has to evaluate its own processes to discover its “weak links” and identify appropriate remedies.^[10] Lean tools such as 5S (sort, straighten, shine, standardize, sustain), process and value stream mapping, and Kaizen Blitzes can be employed to improve workflow and environment. CLSI’s EP23A document provides a Risk Assessment tool for predicting accidental events, probability of harm to patients, and focusing improvement efforts to reduce risk for human errors.^{[20][22]}

Coordinating lab results among primary care providers, other providers in the PCMH “neighborhood,” and the patient

The increasing use of health information technology (HIT) is key to the success of PCMH, as HIT is anticipated to reduce health care costs, while improving health care quality, care coordination, and patient outcomes.^{[24][25]} Many test devices used in physician office laboratories are connected to the laboratory or hospital information system, such that all relevant data are captured as part of the process. HIT enables the practice to capture and document the entire point of care testing process in the patient records, including: test and quality control results, billing, and the clinician’s response to test results.^[26] Incentives (and dis-incentives) from The Health Information Technology for Economic and Clinical Health (HITECH) Act are expected to drive adoption of Electronic Health Records (EHR) to 90% of physician practices and 70% of hospitals by 2019.^[25]

With JCI's ISPG2 requirement, accredited laboratories must document approaches to assure effectiveness of pre- and post-analytical phase communication, regardless of the technology used. Ironically, the ECRI Institute's 2014 report of "Top 10 Patient Safety Concerns for Healthcare Organizations" rates Test Result Reporting as #3 in the top 10 list of all events reviewed for their 2014 report—following Electronic Record Data Integrity errors (#1) and Poor Coordination of Patient's Next Level of Care (#2). Delay or failure to report laboratory test results to ordering physicians was the root cause for 10% of the 2,420 error events reviewed.^[27] Typically, the failures were due to one or a combination of: 1) inadequate interface between an EHR system and a laboratory system, 2) provider-to-clinician communication gaps, or 3) staffing or training failures within a practice regarding process for communication of results.^[27]

Best practice Quality System policies and procedures for reporting test results should, at minimum, address issues including:

- Receipt of results
- Review of results and how long a reviewer has to review results
- Back-up reviewing when a primary reviewer is not available
- Reporting and confirming receipt of results by the patient—including patients that are not directly available
- Handling of abnormal results
- Reporting timeframe for critical as well as normal results
- Qualification and Training requirements for results reporting
- Quality plan for reporting process audits

Clinicians seeking opportunities to improve ordering and reporting lab tests are looking to integration of new HIT--such as handheld devices--with the capability to receive results remotely, provide electronic clinical decision support, and notify physicians of alarm-level results.^[21] Physician practices should also consider setting up Lab Medicine or pathology consultants for fast and easy access to their laboratory expertise.

Finally, to facilitate the exchange of healthcare information with patients and improve patient satisfaction, patient-accessible medical record portals are proliferating in practice and acceptance by patients. A patient portal is an Internet application that enables patients to access their electronic health records, communicate with their health care providers, review lab results, and manage medications. In general, patients found the benefits of patient portals outweighed concerns over patient privacy.^{[24][28][29][30]}

COLA'S PATIENT CENTERED LABORATORY EXCELLENCE PROGRAM

COLA is the largest independent, non-profit laboratory accreditation organization, providing clinical laboratory education, consultation, and accreditation services. COLA accredits over 7,400 clinical diagnostic laboratories, whose practical and educational standards have a positive and immediate impact on quality laboratory medicine. COLA's services enable clinical laboratories and staff to meet CLIA and other regulatory requirements, act in accordance with Quality Systems, and, through quality diagnostic results, provide quality patient care.

With the passing of the Patient Protection and Affordable Care Act (PPACA), and subsequent development and application of the Patient Centered Medical Home (PCMH), COLA recognizes the key role diagnostic laboratories play in providing accurate and timely results in order to ensure quality patient care. To that end, COLA developed the Patient Centered Laboratory Excellence (PCLE) program to help laboratories integrate into the PCMH model.

In addition to PCMH integration, the PCLE Program has three basic objectives:

- 1) Achieve a continuous quality culture in labs;
- 2) Assist laboratories in making better informed, needs appropriate resource decisions;
- 3) Recognition from payer incentive programs;

COLA's PCLE program is scalable to fit the needs of all laboratories, no matter the annual test volume, number of specialties. The online PCLExcelerator online evaluation module provides practices with physician-operated laboratories with a scoring mechanism designed to help them understand their readiness to participate in a medical home. It allows independent physicians, group practices, hospitals, health care systems, payers and health plans to meet the goals of increasing patient satisfaction and providing high quality focused care in combination with increased incentives and lower care costs – all primary objectives of the PCMH.

CONCLUSION

The Patient Centered Medical Home (PCMH) is a team-based model of care led by a personal physician who provides continuous and coordinated care throughout a patient's lifetime to maximize health outcomes. At the heart of the PCMH model is the concept that primary care is a comprehensive process, one which engages primary care providers, the patient, the patient's family, and other providers. The PCMH model has been applied with increasing frequency in recent years, especially at larger primary care practices.

Given that laboratories perform work that impacts about three quarters of diagnostic decisions affecting patients, and an estimated 13 billion tests are performed in the United States each year, the ultimate success of the PCMH depends upon successfully integrating laboratories into the model. A review of existing literature indicates that this can be accomplished in three ways:

- Controlling test utilization;
- Identifying risks and controls for all phases of laboratory testing;
- Coordinating lab results among primary care providers, other providers in the PCMH “neighborhood”, and the patient.

COLA's Patient Centered Laboratory Excellence (PCLE) program was created specifically to help laboratories achieve these and other objectives necessary to achieve PCMH integration.

Table 1. Total Testing Process

Phases of the TTP	Definition	Examples of Activities in Phase	Estimated contribution to TTP errors
Pre-Pre Analytical	Activities associated with initial selection of the test	Inappropriate test request, order entry, patient/specimen misidentification, inappropriate sample collection, inappropriate container, handling, storage or transportation.	46–68%
Pre-Analytical	Pre-test laboratory activities	Errors in sorting, pipetting, labeling, centrifugation	3–5%
Analytical	Testing-associated activities	Equipment malfunction, sample mix-ups, assay interference, undetected failure in quality control	7–13%
Post-Analytical	Post-test laboratory activities	Erroneous validation of analytical data, excessive turn-around-time, improper data entry or manual transcription error, failure/delay in reporting critical values	13–20%
Post-Post Analytical	Activities associated with interpretation of test results by the clinician	Delayed/missed reaction to laboratory reporting, incorrect interpretation, inappropriate/inadequate follow-up plan, failure to order appropriate consultation	25–46%

Table 2. IFCC Working Group List of Highest Priority TTP Errors

Process Phase	Quality Indicator
Pre-pre analytical	Patient misidentification errors
	Test Transcription errors
	Incorrect sample type
	Incorrect fill level
	Unsuitable samples for transportation and storage
	Contaminated samples
	Hemolyzed samples
	Clotted samples
Analytical	Test with inappropriate internal QC
	Test performance error discovered with unacceptable External Quality Assessment or Proficiency Control
	Unacceptable performance in an External Quality Assessment or Proficiency Testing
Post Analytical	Manual transcription data errors
Post-Post Analytical	Inappropriate TAT for STAT tests
	Incorrect laboratory reports
	Failure to notify of critical values

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