

COLA'S

inSights

INTO

COLA

Initiatives

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FROM THE CHAIR

“COLA is a physician-directed organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.”

At COLA, we take our mission statement seriously. We strive to “promote excellence in laboratory medicine and patient care” in everything that we do – including our plans for the future.

This issue of *Insights* discusses some of the programs COLA will offer over the next year. Since these initiatives may change your outlook on laboratory medicine, we wanted to give you a glimpse of what is coming, even though we are still working on the details. The programs are designed to help modify how you think about the lab testing you perform; help you take pride in your work; and help you realize the importance of what you do.

Within this edition, you will find articles about COLA’s newly launched “Continuous Quality Program,” the upcoming “Physician Centered Laboratory Excellence” program, and COLA’s thoughts on the “Individualized Quality Control Plan” (IQCP) being implemented by CMS.

As one calendar year ends and a new one begins, we look forward to sharing a bright, new phase of laboratory excellence with you.

W. James Stackhouse, MD, MACP
Chair, COLA Board of Directors



COLA INSIGHTS

COLA is sponsored by the American Academy of Family Physicians (AAFP), the American Medical Association (AMA), the American Osteopathic Association (AOA), and the American College of Physicians (ACP); and is endorsed by 29 national and state medical organizations. Letters to the editor are welcome.

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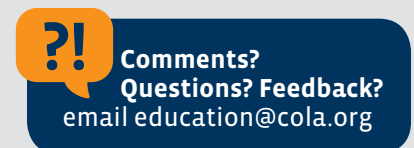
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Continuous Quality Program

Through COLA's recently introduced Continuous Quality Program, we help laboratory professionals implement, achieve, and improve quality standards throughout the testing process – every day of testing

Every laboratory strives to provide high quality services that result in accurate and reliable test results leading to higher quality patient care.

Data has shown that 60-80% of patient treatment and diagnoses are based on laboratory test results, which highlights the importance of providing quality test results.¹ However, the question remains, would you allow your family members (parents, grandparents, children) to be treated on the basis of the test results you provide? If there is any doubt, there is room for quality improvement in your laboratory.

According to a recent article in the journal *The Clinical Biochemist Reviews*, “Quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process (TTP) is correctly performed, thus assuring valuable medical decision making and effective patient care.”² Unfortunately, some feel that quality should be a concern only when preparing for an onsite survey.

COLA believes quality is an **everyday** process, and as a result, has launched a new initiative — the Continuous Quality Program (CQP). The CQP is designed to help laboratories achieve and maintain quality standards every day of testing throughout the entire testing process: pre-analytic, analytic, and post-analytic phases. The program employs COLA Quality Advisors (CQAs) to assist in achieving these standards. The CQAs are your valuable resource in the area of quality laboratory medicine. Their focus includes, but is not limited to:

- Technical and operational matters;
- Specific regulatory requirements;
- Personnel issues;
- Performance of quality assessment and quality control; and
- New uses for information technology.

If additional assistance is required, the CQAs will reference relevant educational products for more in depth learning.



RATIONALE FOR CONTINUOUS QUALITY

Poor laboratory performance and inefficient operations can lead to substandard patient care and an increase in operational expenses. Continuous quality monitoring has the opposite effect and can help prevent the problems that lead to substandard care and increased expenses.

The re-testing of patient specimens is a major source of inefficient operations, increased expenses, and compromised quality of patient care. Specimens may have to be rerun if there are quality issues in any part of the testing process, such as questions about quality control; instrument maintenance or calibration; and/or laboratory staff competency and training (which are all part of the analytic phase). While errors can also occur in the post-analytic phase (e.g., errors while communicating with clinicians, or discrepancies in the test report), you should be aware that pre-analytic errors, (such as patient misidentification, or incorrect specimen handling and processing) account for up to 70% of all laboratory errors.³

If errors such as these are not properly addressed, issues with patient identification, specimen handling, instrument operation, and communications may occur, which all negatively impact laboratory test results and patient care. Issues such as these may also compromise cost effectiveness within the practice. Monitoring and improving the quality of your services in all phases of testing will not only improve the quality of patient care but will also help decrease laboratory expenses.

>> CONTINUED ON PAGE 4

QUALITY AND COMPLIANCE

From a compliance standpoint, laboratories may be fined or forced to cease testing if regulatory guidelines are not followed, or if operational procedures constitute a risk of harm to patients. To prevent such scenarios from occurring, you must be familiar with the current regulations (including federal, state, and local laws) as well as accrediting agency requirements.

Laboratory Directors are ultimately responsible for all laboratory processes, procedures, and services, but some of the duties can be delegated to other laboratory professionals. Specific positions and allowable assigned duties are defined in the federal CLIA regulations.

You may also need assistance with testing personnel requirements including:

- Ensuring qualified staff for your laboratory's testing complexity (verified through education and experience);
- Performing and documenting personnel training and continuing education; and
- Meeting certification, licensing, and regulatory guidelines.

A thorough knowledge and implementation of CLIA, and if applicable, State personnel requirements will help ensure your laboratory provides high quality testing.

Laboratory quality is also demonstrated by the test results produced. One way to verify the accuracy of your laboratory's results is by performing Proficiency Testing (PT). Failures in PT may identify system deficiencies that affect the quality of test results, and subsequently, patient care. Therefore, these deficiencies must be investigated immediately. During the investigation, it is essential to identify the root cause of the failure so appropriate corrective action can be taken.

Looking at just this partial list of quality indicators, wouldn't having a partner to help address these, and many other quality issues, be a welcome addition in your laboratory?

CONTINUOUS QUALITY

COLA, through the Continuous Quality Program, enters into a partnership with laboratories and helps ensure all pertinent information is available for them to:

- Meet regulatory requirements;
- Have qualified, competent staff in all positions;
- Perform quality testing that provides accurate and reliable results; and
- Create and maintain a quality laboratory resulting in excellent patient care.

Quality laboratories are not accidental — they require effort: effort to honestly assess your laboratory's strengths and weaknesses; to efficiently organize processes and records; and to stay committed to established quality goals.

In addition, laboratory resources should be aligned with laboratory needs. Areas such as adequate staffing, appropriate supplies, and proper instrumentation and infrastructure should be reviewed periodically to ensure reliable test results are provided in a timely fashion.

Competency, training, communication, and continuing education are all important components of continuous quality. It is important to ensure that all staff are properly trained and competent in the performance of their duties. Staff should stay abreast of changes in procedures — whether they are changes in manufacturer's instructions, or organizational or regulatory changes. Staff continuing education — focused on new techniques, methodologies, updates, and trends in laboratory medicine — is another way to improve your laboratory services.⁴

COLA Quality Advisors are available to assist you with all of these steps, and any others needed to help create, drive, or improve a culture of continuous quality in your laboratory.

The CQP was established to help laboratory professionals improve laboratory services. For more information, please visit any of the following COLA websites: www.COLA.org; www.COLACentral.com; or www.COLAinsider.com. Information on educational products and online courses can be found at www.LabUniversity.org.

RESOURCES:

¹ Trevor Peter, Philip Rotz, Ducan Blair, et al., "Impact of Laboratory Accreditation on Patient Care and the Health System," *American Journal of Clinical Pathology*, 2010 134:550-555; doi:10.1309/AJCPH1SKQ1HNWGHF; <http://ajcp.ascpjournals.org/content/134/4/550.full>; last accessed January 2013.

² Mario Plebani, "Quality Indicators to Detect Pre-Analytical Errors in Laboratory Testing," *The Clinical Biochemist Reviews*, 2012 August, 33(3): 85-88; <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3428256>; last accessed January 2013.

³ G Lippi, JJ Chance, S Church, et. al., "Preanalytical Quality Improvement: From Dream to Reality," *Clinical Chemistry and Laboratory Medicine*, 2011 Jul, 49(7): 1113-26. doi: 10.1515/CCLM.2011.600. Epub 2011 Apr 25; <http://www.ncbi.nlm.nih.gov/pubmed/21517699>; last accessed January 2013.

⁴ See the May/June 2012 issue of *Insights* for detailed information on Competency Assessment and other personnel requirements.

Patient Centered Laboratory Excellence

COLA defines the Patient Centered Medical Home (PCMH) for medical laboratories. The Patient Centered Medical Home is also referred to as the Primary Care Medical Home, advanced primary care, and the healthcare home.



According to the American College of Physicians (ACP):

“The Patient Centered Medical Home (PCMH) is a care delivery model whereby patient treatment is coordinated through their primary care physician to ensure they receive the necessary care when and where they need it, in a manner they can understand.

“The objective is to have a centralized setting that facilitates partnerships between individual patients and their personal physicians, and when appropriate, the patient’s family. Care is facilitated by registries, information technology, health information exchange and other means to assure that patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.”¹

ADOPTION AND RECOGNITION

Several recognition / certification programs have been introduced to promote the adoption of PCMH. Each of the four national organizations representing primary care physicians [American Association of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Osteopathic Association (AOA)] has created their own PCMH program.

These same organizations also collaborated with the National Committee on Quality Assurance (NCQA), the Healthcare Information and Management Systems Society (HIMSS), and other stakeholders to develop a set of standards known as the Physician Practice Connections® — Patient Centered Medical Home™ (PPC®-PCMH™).

Through this program, NCQA identifies and recognizes medical practices that demonstrate the PCMH standards. By using this set of standards that describe clear and specific criteria, the program gives healthcare practices information about organizing care around patients, working in teams, and coordinating and tracking care over time. NCQA offers three levels of PPC-PCMH recognition, based on a point system where points are earned through meeting these standards.²

Becoming a recognized PCMH practice will lead to improved patient care and afford the opportunity for the practice to take advantage of private or public incentive payments that reward patient-centered medical homes. Other benefits of recognized PCMH practices include team building among providers and clinicians, and precise patient care documentation.

The Joint Commission (TJC) also offers recognition for TJC accredited ambulatory care organizations through its Primary Care Medical Home (PCMH) Certification. This certification focuses on care coordination, access to care, and how effectively a primary care clinician and interdisciplinary team work in partnership with the patient (and where applicable, the patient’s family).³

PCMH RESOURCES

The Agency for Healthcare Research and Quality (AHRQ) is one of 12 agencies within the Department of Health and Human Services. With a mission to improve the quality, safety, efficiency, and effectiveness of health care for all Americans, AHRQ supports research that assists individuals in making more informed decisions, and that improves the quality of health care services.

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PATIENT CENTERED LABORATORY EXCELLENCE

AHRQ provides access to evidence-based resources regarding PCMH and its potential to transform primary care, and improve the quality, safety, efficiency, and effectiveness of U.S. healthcare. These resources (which can be found at http://www.pcmh.ahrq.gov/portal/server.pt/community/pcmh_home/1483) offer a comparative overview of the various PCMH programs, ultimately assisting practices in making well informed decisions on selecting appropriate PCMH programs.

COLA'S INITIATIVE

Currently, all PCMH programs focus on primary care practices; however, COLA is in the process of creating a voluntary accreditation program specifically for clinical laboratories, regardless of whether they perform waived or non-waived testing. The program, **Patient Centered Laboratory Excellence** (PCLE), will help laboratorians make better informed, needs-appropriate resource decisions, allowing for integration into the PCMH model while achieving a culture of continuous quality in the laboratory.

Laboratories enrolled in the PCLE program, will demonstrate a commitment to quality laboratory services (and ultimately continuous quality patient care) through compliance with PCLE criteria that go above and beyond existing COLA accreditation / waived criteria. The PCLE criteria include new criteria addressing continuous quality, effective communication, and continuing education.

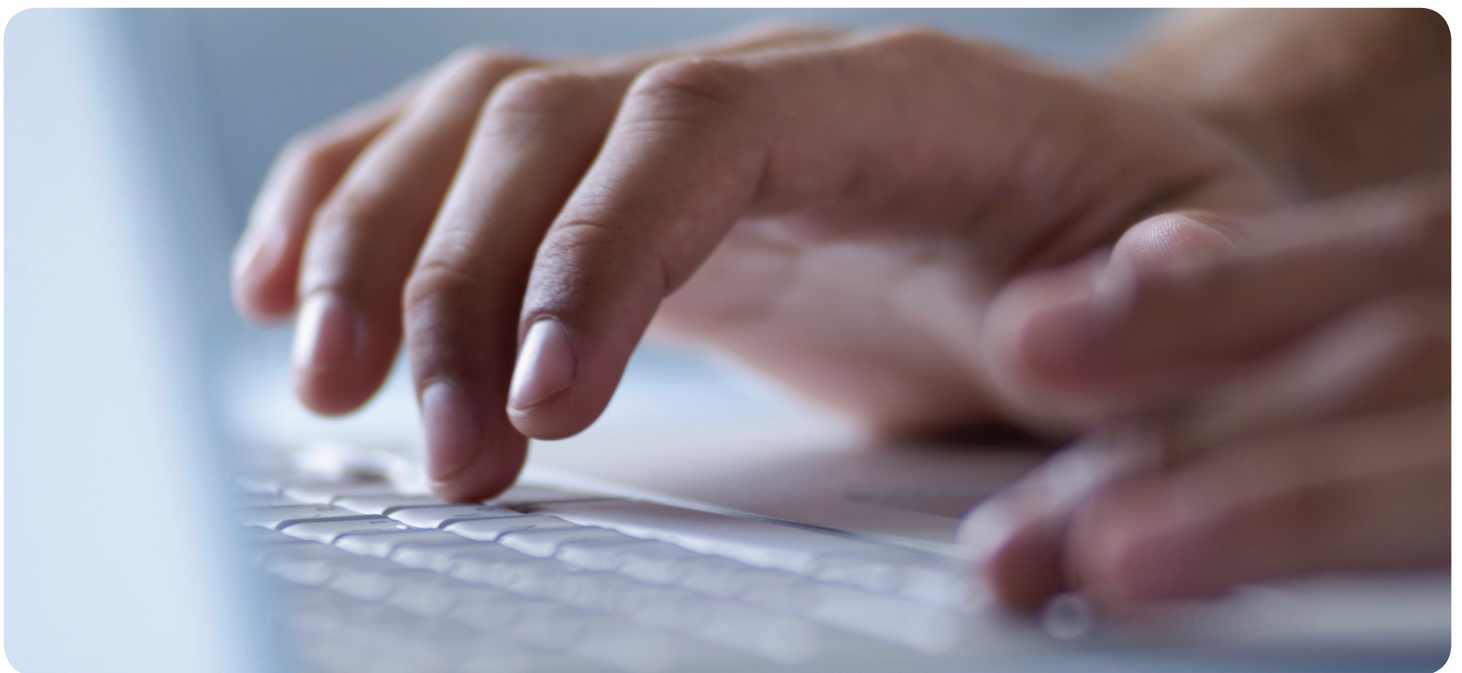
COLA will continue to offer you assistance and education to meet our current criteria as well as the expanded criteria for the PCLE program. Whether it is through existing technology (e.g., COLAcentral), new partnerships (e.g., Continuous Quality Program), or future initiatives, COLA strives to positively impact the quality of patient care.

RESOURCES:

¹ American College of Physicians, Running a Practice, Delivery & Payment Models, Patient Centered Medical Home http://www.acponline.org/running_practice/delivery_and_payment_models/pcmh/understanding/what.htm; last accessed January 2013

² Healthcare Information and Management Systems Society (HIMSS) / National Committee on Quality Assurance (NCQA) PCMH Factsheet, *Leveraging Health IT to Achieve Ambulatory Quality: The Patient-Centered Medical Home (PCMH)*. http://www.ncqa.org/Portals/0/Public%20Policy/HIMSS_NCQA_PCMH_Factsheet.pdf; last accessed January 2013 HIMSS focuses on the optimal use of information technology and management systems for the betterment of healthcare. Health information technology (HIT) that supports high-quality patient care (including electronic recordkeeping, electronic disease registries, internet communication with patients and electronic prescribing) is crucial to a fully functioning medical home.

³ The Joint Commission, Primary Care Medical Home Certification, fact sheet, <http://www.jointcommission.org/accreditation/pchi.aspx>; last accessed January 2013



EQC, EP23, IQCP – Past, Present, and Future

Changing interpretation of Quality Control regulations

PAST

Through the Interpretive Guidelines for Laboratories (appendix C), the Clinical Laboratory Improvement Amendments (CLIA) allow for an alternative to daily external quality control (QC) for eligible test systems — Equivalent Quality Control (EQC).

Laboratories were required to follow several steps prior to the implementation of EQC:

- Verify test system eligibility;
- Select the appropriate EQC procedure;
- Successfully complete an appropriate qualifying study; and
- Monitor test system performance (which includes taking corrective action and resuming daily external QC, if indicated).

If any of the following situations occurred, laboratories had to discontinue EQC procedures and take corrective action.

- Internal or external QC failures that were not resolved by repeating the control just once;
- PT failure;
- Any test system problems identified through quality assessment (QA) activities.

During the problem investigation and corrective action period, laboratories had to return to performing the default requirement of two levels of external QC each day of patient testing. All patients tested since the last acceptable external QC had to be evaluated to determine if test results were affected by the test system problem. Additionally, another EQC qualifying study had to be performed before EQC procedures could be resumed.

Even though many labs successfully implemented EQC without any quality problems; industry personnel, clinical laboratory professionals, and medical experts expressed concerns that labs did not have enough information to determine and mitigate all relevant sources of testing error, and thus do the “right” QC for each test.

Therefore, the Centers for Medicare and Medicaid Services (CMS) challenged the Clinical Laboratory and Standards

Institute (CLSI) to develop a new consensus QC guideline. In 2005, CLSI convened a meeting, sponsored by accrediting organizations (including COLA), industry, professional organizations, and government agencies, to address “QC for the Future.” The resulting guideline, EP23, was developed based on the ideas exchanged.

PRESENT

The Clinical Laboratory and Standards Institute (CLSI) is a not-for-profit membership organization that guides the development and implementation of clinical laboratory testing standards and guidelines to help clinical laboratories produce quality test results and enhance patient care.

EP23: CLSI document; EP stands for Evaluation Protocol. The complete title of EP23 is Laboratory Quality Control Based on Risk Management; Approved Guideline.

IQCP: Individualized Quality Control Plan; how CMS plans to implement EP23.

EQC: Equivalent Quality Control; a current option that will become obsolete as IQCP is implemented.

The standards and guidelines are classified into various categories, including, *Quality Systems and Laboratory Practices (GP)*, *Point-of-Care Testing (POCT)*, *Molecular Methods (MM)*, and *Automation and Informatics (AUTO or LIS)*. The *Evaluation Protocols (EP)* category includes standards and guidelines for method comparisons; precision, linearity, and bias; interference; and quality control. EP23, the approved guideline for QC entitled *Laboratory Quality Control Based on Risk Management*, was published in October 2011.

EP23 was created to help laboratory professionals evaluate the risk and severity of potential sources of error of the test systems they utilize, and establish the “right” QC plan for their specific circumstances. It guides professionals in developing a custom alternative QC plan while using many of their existing

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EQC, EP23, IQCP – PAST, PRESENT, AND FUTURE

quality practices. Patient population, test volume, frequency of test performance, education level of testing personnel, and testing method utilized are some of the factors to be considered when determining the correct QC procedures to be implemented.

FUTURE

CMS has embraced EP-23 and will implement it through the Individualized Quality Control Plan (IQCP). Details of the program have not been finalized yet, but the Interpretive Guidelines are currently being revised to incorporate key EP23 concepts.

ACCORDING TO THE CMS WEBSITE¹

“The guidance and concepts for IQCP are a formal representation and compilation of many things laboratories already do to ensure quality test results. IQCP permits the laboratory to customize its QC plan according to test method and use, environment, and personnel competency while providing for equivalent quality testing. It is the ‘Right QC.’”

IQCP is Quality Control based on Risk Management and consists of the following key components:

- Perform and document the risk assessment;
- Establish the “right” QC plan for your testing to control potential sources of error (at a minimum, the manufacturer’s QC protocol must be followed);
- Monitor the QC plan for effectiveness.

CMS has stated that there will be an educational, transition period of at least two years before IQCP goes into effect. During this period (which could begin as early as Spring 2013), they will provide information and guidance to clinical laboratories and accrediting organizations to help them implement IQCP. After the educational period, once IQCP is effective, EQC will no longer be an option for quality control.

The main differences between EQC and IQCP are:

- All specialties (except Pathology) will be eligible for IQCP. Only specific test methodologies were eligible for EQC.
- While EQC was based on standard qualifying studies, IQCP will be based on a risk assessment performed within your laboratory based on your unique circumstances.
- IQCP focuses on the “right” QC, which is not necessarily less frequent QC, which was the goal of EQC.

Even though there are differences in the programs, when EQC is no longer an option, COLA expects that labs that formerly used EQC will implement IQCP for those same tests, and possibly, for additional test methods.

Instead of implementing IQCP, laboratories can continue to run the “default” QC – two levels of controls each day of patient testing. The manufacturer’s recommendations will remain the minimum acceptable QC protocol. An IQCP is not required if the manufacturer’s stated number, type, and frequency of control procedures meet or exceed the CLIA requirement of two levels each day.²

FOLLOW THESE STEPS TO DEVELOP AN IQCP:

- Gather and compile information for each test under consideration;
- Perform the risk assessment for each test;
- Determine the “right” QC for each test;
- Write the IQCP;
- Ensure all involved are trained to the IQCP;
- Monitor the effectiveness of the IQCP and make changes, if necessary.

While IQCP may seem quite confusing now, it will become less so over the next several months as additional information and resources become available. It will be evident that IQCP is a valuable way of utilizing your current quality assessment data to focus current QC procedures on what is appropriate for your unique laboratory environment. COLA will also incorporate IQCP protocols into the COLA accreditation criteria, and provide more specific guidance and information in the coming months.

RESOURCES:

¹ The “Individualized Quality Control Plan” (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) policy currently under development as an alternate QC option allowed by 42CFR493.1250 http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html; last accessed Jan 2013

² Clinical Laboratory Improvement Amendments (CLIA), subpart K, 42CFR §493.1256(d)(3)(i) and §493.1256(d)(3)(ii): For quantitative procedures, the minimum requirement is two levels each day of testing. For qualitative procedures, the minimum requirement is to test a negative and a positive each day of testing. See *Subpart K, Sec. 493.1256, Standard: Control procedures* for more information. CLIA, subpart K, §493.1256, http://wwwn.cdc.gov/clia/regs/subpart_k.aspx#493.1256; last accessed January 2013

COLA *FAST FACTS* 35-2013

COLA Patient Safety Program – Patient Identification

COLA began the COLA Patient Safety Program in 2008 with the intent of focusing on areas in laboratory medicine that are found to have high error rates and significant impact on patient safety. COLA is also focused on reducing the frequency of citations for criteria that impact, or can potentially impact, patient safety. Through this program, COLA will identify an existing COLA criterion or patient safety issue as the patient safety goal for each year, and provide education on good laboratory practices for implementation of that safety goal. The program has also been integrated into the COLA survey process.

The COLA Patient Safety Goal for 2013 is:

PRE 16: Prior to the collection of a patient’s specimen, is the patient’s identity verified using two separate identifiers?

Proper patient Identification is an essential part of the testing process. Laboratories need to be aware of the emphasis in the medical community to reduce medical errors due to misidentification of the patient. A successful mechanism is to utilize at least two patient identifiers to verify that the specimen is being collected from the correct patient. Appropriate identifiers include:

- Name
- Birth date
- Medical record number
- Last 4 digits of social security number

Patients may be asked to state and spell their name, and give their birth date as a means of identification. Some medical offices and outpatient facilities ask for a picture ID to verify the patient’s identity. In hospital settings, identity may be verified verbally, and by checking the armband to confirm the identity of the patient.

Bar-coding technology is becoming quite sophisticated, and in some settings may be part of the patient identification system as well as the specimen labeling system. While barcodes can create unique identification, there is still an opportunity for error if the barcode is not matched to the proper individual. In this circumstance, using a second identifier beyond the barcode could help to prevent identification errors and subsequent specimen labeling errors.

Consider this example:

You automatically assume that when you call out a name to a waiting room full of people that you will be properly heard and the correct person will respond. Do not make this assumption! Confirm the patient identity by asking the patient to state and spell their full name, and state their date of birth. Verify that the same identifiers are present on all of the following that are applicable:

- Requisition (order)
- Patient wristband
- Patient chart
- Barcodes
- Sample labels

Correct patient identification is critical. Test results performed on specimens collected from a misidentified patient will be linked to the wrong patient, and may put the health of two patients at risk.

Think about this important patient safety goal, and take steps to ensure compliance in your laboratory.



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Speaker: Kathy Nucifora, COLA

Accreditation Division Manager

Date: Wednesday, April 3, 2013

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Title: COLA Compliance: What's New for 2013? Part II

Speaker: Kathy Nucifora, COLA

Accreditation Division Manager

Date: Wednesday, April 24, 2013

Time: 2:00PM EST

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See www.LabUniversity.org for details and more information on the listed programs, and for additional courses and products.