JANUARY / FEBRUARY '11

COLA'S

inSights

INTO Patient Safety

ALSO IN THIS ISSUE:

FROM THE CHAIR

Welcome to the first *Insights* issue of the New Year and the new electronic format of the newsletter!

One of the first things you may notice about the newsletter is that it is nearly twice the size of the printed version. However, navigating the expanded version is easier in the electronic format. Simply click on the title in the Table of Contents and you're taken directly to the appropriate article.

The electronic version not only permits you to browse through the newsletter more easily, the latest cutting edge information is also just a mouse click away. The interactive format allows you direct access to the articles' data sources. That means you'll be the first to discover updated information provided on the source websites.

The online version also enables us to use more graphics, which makes for more enjoyable reading.

All of the articles in this inaugural issue address patient safety. From the main article through the explanations of regulatory updates to the listing of sessions at our upcoming Symposium for Clinical Laboratories, patient safety is the prevalent theme.

As always, we hope that you'll find the information useful and helpful in your laboratory. We welcome your feedback, comments and suggestions.

Verlin K. Janzen, MD, FAAFP
Chair, COLA Board of Directors

COLA
Lab Accreditation Through Education

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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COLA and it's publications do not and will not endorse, directly or indirectly, any advertiser's products or services.

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www.LabUniversity.org
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for newly updated
information

Physician Signature Requirement

DELAY IN IMPLEMENTION

On December 22, 2010, the Centers for Medicare and Medicaid Services (CMS) issued a temporary delay on the implementation of the Physician Signature Requirement. The effective date was changed from January 1, 2011 to March 31, 2011.

"In the November 29, 2010 Medicare Physician Fee Schedule final rule, the Centers for Medicare and Medicaid Services (CMS) finalized its proposed policy to require a physician's or qualified nonphysician practitioner's (NPP) signature on requisitions for clinical diagnostic laboratory tests paid under the clinical laboratory fee schedule effective January 1, 2011. A requisition is the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient.

"Although many physicians, NPPs, and clinical diagnostic laboratories may be aware of, and are able to comply with, this policy, CMS is concerned that some physicians, NPPs, and clinical diagnostic laboratories are not aware of, or do not understand, this policy. As such, CMS will focus in the first calendar quarter of 2011 on developing educational and outreach materials to educate those affected by this policy. As they become available, we will post this information on our website and use the other channels we have to communicate with providers to ensure this information is widely distributed. Once our first quarter of 2011 educational campaign is fully underway, CMS will expect requisitions to be signed."[1]

Although the delay in implementing the signature requirement is welcomed and appreciated, it may *not* be enough to satisfy the physician / laboratory community. The current practice, which does not require physician signatures on requisitions, is a result of the November 23, 2001 final rule, which followed Congressionally-mandated negotiated rulemaking in 2000. At that time, CMS and 18 different organizations representing medical laboratories unanimously agreed that signatures should not be required. That rule has continued in place, without question or confusion, for over ten years. This was stated in a November 22, 2010 letter addressed to CMS from the "Clinical Laboratory Coalition," which consists of 22 healthcare / laboratory organizations.[2] The letter, at the very least, asked for a delay in implementation until January 1, 2012.[3]

In a news release dated November 4, 2010, the American Clinical Laboratory Association (ACLA) stated, "The CMS policy would apply to 'requisitions' but not to other types of orders for laboratory services, such as physician scripts. However, the line between an order and a requisition is not clear. ... Further, the requirement would apply to tests that are paid on the CLFS [Clinical Laboratory Fee Schedule], but not to pathology tests, such as tissue biopsies, that are reimbursed based on the physician fee schedule. However, few physicians know which tests are paid on the CLFS and which are paid on the physician fee schedule—[a] situation that will only add to the likely confusion about when a signature is required."[4] Most likely, these issues will be the focus of the educational and outreach materials mentioned in the CMS announcement.

The ACLA commented on other issues, including some that address patient safety, in a FactSheet released on December 6, 2010.[5] Here are some noteworthy points they raised:

- It is not a viable option for laboratories to refuse to do testing if the requisition is not signed; however, patients may be turned away from blood draw centers. "This will be especially problematic for an elderly Medicare patient for whom travel is difficult, or if the patient has had to fast for some period, as is required for some testing."
- To some, a simple response would be to delay testing and/or reporting test results until a signature is obtained. However, neither of these is an acceptable option. Patients' diagnoses and treatment protocols depend on accurate and timely test results. At times, delays could be life-threatening.
- "Most specimens and requisitions are picked up in the evening, and tested at night, so it is impossible for the laboratory to call the physician for verification, if it receives an unsigned requisition."

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Patient Safety

CREATE A "CULTURE OF SAFETY"

Many facilities place medical laboratories in the basement because there is limited, if any, face-to-face patient contact. This is not always the case when the laboratory is associated with a physician/medical office. Many times the patient care professional is the same person who performs the laboratory testing. This allows for a special approach to patient safety.

For the majority of laboratory professionals, "patient safety" means handling the specimen properly and efficiently which allows accurate testing results to be relayed to the ordering clinician as quickly as possible. For those with patient contact, it means treating the actual person in a protective manner.

In its 1999 landmark publication, *To Err is Human: Building a Safer Health System*,[1] the Institute of Medicine (IOM) concluded that medical "errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them" rather than by individual recklessness. One IOM recommendation to reduce medical errors is to implement "safety systems to ensure safe practices at the delivery level.

"Health care organizations must develop a 'culture of safety' such that their workforce and processes are focused on improving the reliability and safety of care for patients. Safety should be an explicit organizational goal …"

So, how do we develop this "culture of safety"? According to the Agency for Healthcare Research and Quality (AHRQ),[2] "the single most important way [patients] can help to prevent errors is to be an active member of [their] health care team. … Research shows that patients who are more involved with their care tend to get better results."

In a recent Patient Fact Sheet, the AHRQ listed *20 Tips to Help Prevent Medical Errors*.[3] While this was addressed to patients, we, as laboratory professionals, can provide an atmosphere to make it easier for patients to be their own advocates.

- **Speak up if you have questions or concerns**. The atmosphere we create should allow our patients to feel comfortable asking questions or stating concerns. We can ask our patients if they have questions or concerns, allow them time to formulate their thoughts, listen to hear what they are really saying, and answer their questions or address their concerns as completely as possible.
- **Make sure someone is in charge of your care**. Many patients have several health issues and are seen by many different health care providers. We can address this by making sure that the correct individual receives the testing results that we provide.
- **Make sure that all health professionals involved in your care have important health information about you**. We are included in this category of "all health professionals." Ask your patients pertinent questions that could affect the tests they're having done. This information would include any medication or over-the-counter treatments they are taking that could affect testing; if they have been fasting for the appropriate amount of time; and if self-collected samples (e.g. 24 urine samples) were collected as instructed and in the appropriate containers.
- **Ask a family member or friend to be there with you and to be your advocate**. Some patients don't feel comfortable asking questions regardless of the atmosphere. Some may not know what questions to ask. For this reason, we should not dismiss questions from someone other than the patient. That person may be there specifically to ask questions that the patient cannot.
- **Know that "more" is not always better**. Although the patient should question the ordering clinician about whether a test is needed, some may question you as you attempt to collect the specimen. Answer their questions as you can, but don't be afraid to consult with the clinician, if possible.
- **If you have a test, don't assume that no news is good news**. This addresses questions and concerns that arise after testing is completed. Commonly, patients will call their health care provider with questions about results, but occasionally, they may call the laboratory professional directly. If you receive this type of phone call, be aware that when trying to develop a safe, trusting atmosphere for your patients, your phone etiquette is just as important as your face-to-face patient contact.
- **Learn about your condition and treatments**. It may not be appropriate for us to teach our patients about their conditions or treatment, but we can certainly educate them about their laboratory tests. "As professionals who provide clinical laboratory services, it is our responsibility to provide this information to patients. It is not the responsibility of other healthcare practitioners to tell patients what fasting means, what is important with respect to performing a venipuncture for sample collection, or when the clinical laboratory test results will be available, it is ours."

>> CONTINUED ON PAGE 11

Electronic Health Record (EHR) Safety

EHREVENT.ORG: ONLINE SAFETY REPORTING SYSTEM

BACKGROUND: The American Recovery and Reinvestment Act of 2009 (ARRA)[1], which includes the HITECH Act (Health Information Technology for Economic and Clinical Health Act) provided for the creation of an HIT Policy Committee, charged with making recommendations for the development and adoption of a nationwide health information infrastructure.

The HIT Policy Committee is subdivided into several workgroups comprised of stakeholder representatives and subject matter experts. One of these workgroups, the Quality Measures Workgroup, is further divided into teams. With a focus on a different quality measure, each team was charged with identifying a set of sub-domains, prioritizing these sub-domains, and identifying key measures within each sub-domain.

The Patient Safety Team was tasked to identify sub-domains to improve patient safety by integrating quality measures and health information technology. The sub-domains include Medication Safety, Hospital Associated Events, Patient Identification, and Electronic Health Record (EHR) Safety.

COMMITTEE RECOMMENDATIONS: In 2010, the Patient Safety Team's recommendations[2] included:

- Prevention of patient identification errors
  - The team discussed preventative strategies such as using photographs in EHRs. Group members would like to see various EHR functionalities for positively identifying a patient during multiple points of care such as admission, bedside, ambulatory visits, telephone encounters, and e-prescribing.
  - The team recommends measurement of patient identification errors and EHR functionality to prevent patient misidentification.
- Decrease EHR specific patient safety errors
  - The team defined EHR Safety as "measures that establish a mechanism to report EHR-related errors to improve EHRs and maximize patient safety in the context of EHR use."
  - They recommend examination and reporting of common EHR errors as a way of increasing EHR safety. Examples of EHR-related errors include delay in patient care, inappropriate clinical suggestions, and missed reports in an EHR.

HEALTH INDUSTRY RESPONSE: The health industry has responded to the patient safety risks associated with using EHR systems by creating a voluntary, web-based reporting system, located at EHRevent.org[3]. According to an article published by Government Health IT, this "cooperative effort of industry and federal agencies" will allow "physicians and other healthcare providers to describe, on a confidential basis, patient safety risks and concerns involving the deployment of EHRs."[4]

Confidentiality is assured since EHRevent.org is a service of PDR Secure™, a Patient Safety Organization (PSO).[5] PSOs were "created to foster a protected environment conducive to honest disclosure and analysis of patient safety events"[6] by providing privilege and confidentiality to clinicians and health care organizations.

EHRevent.org is a collaboration of the *iHealth Alliance*, the Health and Human Services Department (HHS) and the PDR Network, LLC (publisher of the Physicians' Desk Reference®) subsidiary, PDR Secure™.[7] Its goals are "to improve patient safety and to help reduce EHR vendor and healthcare provider liability by encouraging reporting on EHR issues."[8]

The event reporting form consists of fewer than ten required questions (mostly check-boxes), can be completed in less than five minutes, and has options to provide additional information. This data will be used by medical societies, professional insurance carriers, and government agencies, such as the US Food and Drug Administration (FDA), to better understand EHR events and to develop educational materials to address the potential challenges of adopting EHR systems and to improve patient safety.[9] ■

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COLA's 2011 Patient Safety Goal

REPORTING "PANIC" RESULTS

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. Through this program, COLA will identify an existing COLA criterion or create a new criterion as the patient safety goal for each year, and provide education on good laboratory practices for implementation of that goal. The program has also been integrated into the COLA survey process.

COLA PATIENT SAFETY GOALS

2008 Improving **patient identification**
2009 Improving **specimen identification and labeling**
2010 Improving **tracking of specimens throughout the testing process**

For 2011, our goal addresses the post-analytic phase of the testing process – reporting test results. The COLA Patient Safety Goal for 2011 is:

APM 18: Does the procedure manual include for each test, where applicable: How the laboratory reports results (including panic results)?

What needs to happen after the test result is generated to ensure that the result gets to the right person in a timely manner?

First, every laboratory needs a procedure that describes how the laboratory provides results to the ordering practitioner, including how to report highly abnormal results promptly so that potentially life-saving patient care actions can be initiated.

Include these details in your procedure for reporting test results:

- What information is included in the report
- Descriptions of how reports are:
  - Created
  - Distributed
  - Maintained for future reference
- Procedures for "stat" reporting, or when the patient is waiting for results
- Tests that require urgent action when significantly abnormal (panic) results are obtained
  - For each test, identify the range of abnormal values that require urgent action (for example, glucose values <50 or >400 mg/dl)
  - Describe what additional steps are taken when reporting a panic result to the ordering practitioner

Procedures related to panic result reporting are especially important for patient safety. Panic results are abnormal laboratory test result values with results so far outside the normal range that immediate attention is required. These results, also called "alert" or "action" values, could possibly be life-threatening for the patient and must be relayed to the ordering practitioner as soon as possible. Your written procedure should include:

- A list of panic values for the tests your lab performs (The lab director and clinical consultant can work together to establish panic values, based on your patient population.)
- How the lab ensures that the individual ordering the test is promptly notified of a panic result
- Who to notify, including what to do if that person is not immediately reachable
- The expected timeframe for notifications
- How to document notifications

When calling panic results, begin by asking the recipient to write it down, and always ask the person to read back the patient name and secondary identifier, test, and result, to confirm that everything was heard and written down correctly.

>> CONTINUED ON PAGE 12

Abbott Recall

ABBOTT DIABETES CARE ANNOUNCED RECALL OF 359 MILLION TEST STRIPS

On December 22, 2010, Abbott Diabetes Care announced a recall of 359 lots (approximately 359 million test strips) of Precision Xtra®, Precision Xceed Pro®, MediSense® Optium™, Optium™, OptiumEZ and ReliOn® Ultima Blood Glucose Test Strips in the United States and Puerto Rico.

The affected test strips were manufactured between January and September 2010. They are sold in both retail and online settings directly to consumers, but are also used in health care facilities. The company stressed that the recall involved only the test strips, not the testing monitors. Customers can continue to use the monitors with testing strips that are not affected by the recall.

The testing strips are being recalled because they may give falsely low blood glucose results. Falsely low results may lead customers to try to raise their blood glucose levels when they do not need to do so. A related scenario is that the customer may fail to treat a truly elevated blood glucose level, since the reading shown was lower than the actual value.

The problem appears to be related to longer than expected blood fill times. This may be dependent on the age of the strips and if the strips have been stored in (or exposed to) higher temperatures (above 72˚F and not to exceed 86˚F) for an extended period of time.

Abbott is working with the US Food and Drug Administration (FDA) to recall these test strips. The FDA has provided recommendations that explain how to determine whether a particular lot is affected, how to order free replacement strips, and, if necessary, how to use recalled strips to reduce the likelihood of a false result.

To determine if you have product being recalled:

- Call Abbott Diabetes Care customer service at 1-800-448-5234 (English) and 1-800-709-7010 (Spanish) to speak with a customer service representative.
- Visit www.precisionoptiuminfo.com to look up test strip lot numbers.

The FDA encourages customers to report serious adverse events (side effects) to the MedWatch Adverse Event Reporting program. This can be done online, by USPS mail, by fax, or by phone.

- Online: www.fda.gov/safety/MedWatch/default.htm
- USPS mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 800-FDA-0178
- Phone: 800-332-1088

The following information can also be found on the Abbott Diabetes Care website:

- A list of the affected lot numbers
- Steps to take if the customer must continue to use the recalled test strips while waiting for the replacement strips
- The complete recall announcement

Click here to access the Abbott Diabetes Care website. **Click here** to access the FDA's recall announcement. ■

RESOURCES:

1 Abbott Diabetes Care; Abbott Diabetes Care Announces Recall; December 22, 2010: http://www.abbottdiabetescare.com/abbott-diabetes-care-announces-recall-of-certain-lots-of-precision-xtra-precision-xceed-pro.html - Accessed December 22, 2010.

2 US Food and Drug Administration; FDA Announces Recall of Abbott Glucose Test Strips; December 22, 2010: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm237900.htm?sms_ss=email&at_xt=4d1391bdcd22f3cf%2C0 - Accessed December 30, 2010.

Symposium for Clinical Laboratories

APRIL 27-30, 2011 | HYATT REGENCY, ATLANTA, GA

At the upcoming Atlanta Symposium, we are Celebrating Education during Lab Week!

To educate your staff in matters concerning Laboratory Medicine, we have given you a choice of over 25 breakout sessions, in addition to the General Sessions, including several that address patient safety:

- *Optimizing Laboratory Testing Services for Improved Patient Care*
  Julie Taylor, PhD (from the CDC)
- *CDC's Promotion of Good Laboratory Practices*
  Nancy Anderson, MMSc (from the CDC)
- *Transfusion Services: Where Do We Start?*
  Judy Dixon, BS MT(ASCP), MS
- *Preanalytical Benchmarks & Process Improvement*
  Dennis Ernst, MT(ASCP) & Lisa Balance, MT(ASCP), CLC(AMT)
- *OSHA: Bloodborne Pathogens*
  Elizabeth Staubs, MT(ASCP)
- *Quality Outcomes - Advocating for the Laboratory*
  Diana Mass, MA, MT(ASCP)
- *POCT: Issues & Answers*
  Toni Clinton, PhD (BCLD), MT(ASCP)
- *Venipunctures: Managing the Risk*
  Dennis Ernst, MT(ASCP)
- *Best Practices for Waived Testing*
  Barry Craig, MLT & Elizabeth Staubs, MT(ASCP)

There are also exciting new breakout sessions that were created with COLA labs in mind: these will be presented by COLA's staff of experts and will cover COLA criteria and processes.

THURSDAY, APRIL 28, 2011

COLAcentral Interactive Demo

This hands-on demonstration session is designed for COLA labs and technical consultants who serve COLA labs. Learn how to easily access and get the most out of our helpful COLAcentral features to address your compliance and daily operational needs. See how to upload documents, review proficiency testing results, update demographics, monitor inventory, create and revise training programs, utilize COLA's vast resource bank, and much more!

Note: This session does not provide CME or PACE credit.

Learning Objectives

At the end of the session, participants will be able to:

- Summarize the useful functions of COLAcentral
- Utilize COLAcentral for compliance and daily operational needs

COLAcentral

CENTRAL TO YOUR WORK. CENTRAL TO YOUR LAB.

Transfusion Services: Where Do We Start?
Judy Dixon, BS MT(ASCP), MS

Since we are seeing an increase in transfusion services being provided outside of the hospital setting, COLA classifies Transfusion Services two ways: Full Transfusion and Transfusion Only.

The Full Transfusion Service collects patient samples, performs testing and crossmatching and administers blood and blood components. This is found primarily in the hospital setting. The Transfusion Only service administers blood and blood components received from an approved blood service. This type of service is usually found in small hospitals, Hematology/Oncology practices and Cancer Centers.

Thinking of providing transfusion services? Where do we start? What processes are needed to set up this service? What documentation is required? How do we monitor processes? We will be looking at answers to these questions as they apply to hospitals and physician office laboratories.

Learning Objectives

At the end of the session, participants will be able to:

- Summarize the types of transfusion services
- Determine which service fits your facility
- Develop the pre-analytical, analytical and post-analytical processes
- Design a Quality Assessment program to monitor the processes

FRIDAY, APRIL 29, 2011

COLA Top 20 Citations, Parts 1 & 2
Judy Dixon, BS MT(ASCP), MS & Irwin Rothenberg, MS, MBA, MT(ASCP)

As of December 2010, the most frequently cited citations for COLA surveyed labs are:

- ORG 3, ORG 9, ORG 10, ORG 15
- PER 3, PER 4, PER 5, PER 6
- PRE 17
- PT 5
- CA 1, CA 2
- QC 8, QC 10, QC 16, QC 28
- QA 2, QA 17.1

What is the COLA surveyor looking for when evaluating your lab for compliance with these criteria? These sessions will focus on strategies to help you comply. Actions you can take to correct non-compliances with these criteria and to maintain continuous compliance will be discussed.

In **Part 1**, we will address the most frequently cited **organization**, **personnel**, **pre-analytic**, and **proficiency testing** criteria:

- ORG 3, 9, 10, 15
- PER 3, 4, 5, 6
- PRE 17
- PT 5

In **Part 2**, we will address the most frequently cited **calibration**, **quality control**, and **quality assessment** criteria:

- CA 1, 2
- QC 8, 10, 16, 28
- QA 2, 17.1

Learning Objectives

At the end of each session, participants will be able to:

- Anticipate surveyor expectations regarding these criteria
- Assess your lab's level of compliance with these criteria
- Apply strategies to correct non-compliances and maintain continuous compliance

QA of PT: Proficiency Testing Problem Resolution
Verlin Janzen, MD, FAAFP & Judy Dixon, BS MT(ASCP), MS

In this session, Dr. Janzen and Ms. Dixon will show the importance of evaluating your PT performance and following up on any problems or issues. The concept of quality assessment will be introduced, and ways to monitor your PT performance and identify and resolve problems will be discussed. Case study examples will be used to illustrate how to identify problems, how to determine the problem's root cause, how to formulate a solution, and how to follow up later to see if the solution worked.

This session is designed for physician laboratory directors and for individuals without laboratory training.

Learning Objectives

At the end of the session, participants will be able to:

- Apply quality assessment concepts to evaluate PT performance
- Monitor PT performance to identify problems
- Determine root cause of PT problems
- Formulate solutions to correct PT problems

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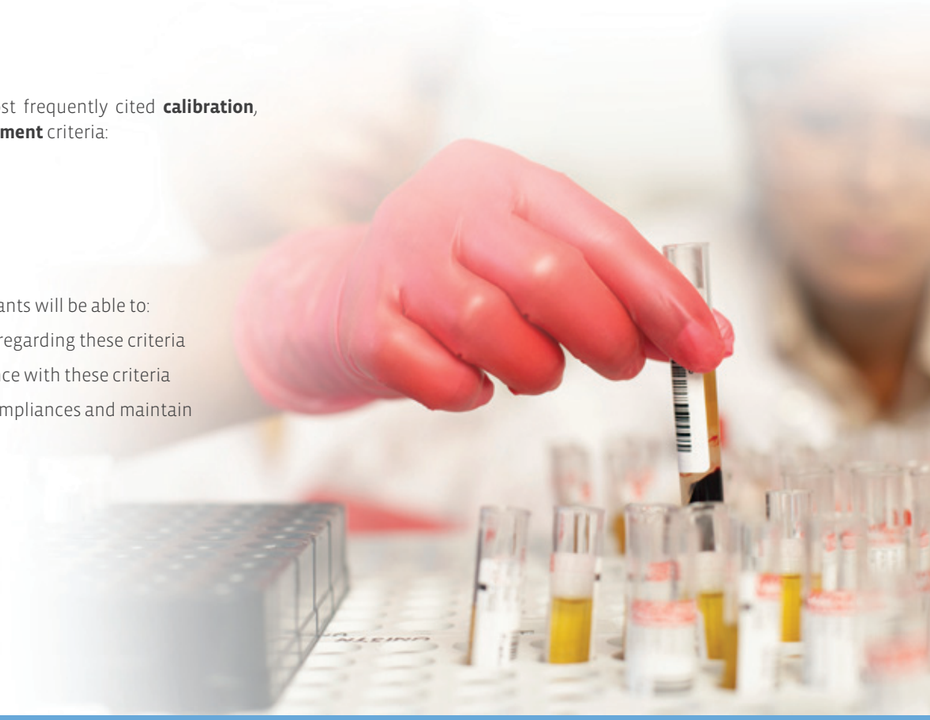

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SYMPOSIUM FOR CLINICAL LABORATORIES

SATURDAY, APRIL 30, 2011

COLA Users Group: Accreditation Update
Irwin Rothenberg, MS, MBA, MT(ASCP)

All accreditation programs for compliance with CLIA begin with the core requirements in the Federal regulations, but COLA's approach has been shown to improve laboratory performance. COLA differentiates their program with a strong emphasis on educating the lab director and staff on practical ways to achieve a high quality laboratory operation. At this Users Group session, participants will have the opportunity to ask questions about implementing COLA criteria that will result in good laboratory practices.

Learning Objectives

At the end of the session, participants will be able to:

- Outline the phases of the COLA survey process
- Perform key responsibilities of the laboratory in the accreditation process
- Implement a plan to assure compliance with COLA criteria
- Predict the impact an educated staff can have on the patient's outcome
- Summarize how COLA uses customer feedback to improve educational products and services

Can It Get Any Worse? Resolving Laboratory Survey Outcomes
Cyril M. Hetsko, MD, FACP & Judy Dixon, BS MT(ASCP), MS

Hear the scoop from COLA's Chief Medical Officer and one of COLA's experienced laboratory surveyors. During this session, Dr. Hetsko and Ms. Dixon share their findings on laboratory non-conformances, and describe how COLA worked with the laboratories to resolve these issues. They bring to light the most common problems encountered by laboratories, and discuss ways to achieve compliance with CLIA and COLA criteria.

Learning Objectives

At the end of the session, participants will be able to:

- Examine five of the common deficiencies found during a laboratory survey
- Develop a plan to implement the activities necessary to comply with the criteria cited in common deficiencies
- Examine the consequences of PT sharing and other violations

Click here to register for the Atlanta Symposium.

SYMPOSIUM
FOR CLINICAL LABORATORIES

REGISTER NOW & SAVE

April 27-30, 2011

Jointly sponsored by the University of Wisconsin School of Medicine and Public Health and COLA.

University of Wisconsin SCHOOL OF MEDICINE AND PUBLIC HEALTH

COLA Lab Accreditation Through Education

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PHYSICIAN SIGNATURE REQUIREMENT

The Clinical Laboratory Management Association (CLMA) does not hold much hope that CMS will rescind the signature requirement. They offer the following advice for laboratories to prepare for the time when the rule will be required and enforced:

"Laboratories should prepare accordingly by educating their clients about the rule and starting to track and collect data on how many [requisitions] they are getting without signatures and who they are coming from. As difficult a process as this will be, the best outcome will be the result of a focused strategic effort, part of which will be working with data that allows the laboratory to identify noncompliant physicians so they can target their education efforts on those physicians, rather than harass the physicians [who] are complying. Labs are also going to have to provide a specific place on the requisition for the physician signatures, if they don't already have a place for the signature on their current requisition form."[6]

CMS will provide updates on this issue throughout the educational period. Also, the Clinical Laboratory Coalition is continuing to meet with CMS, including meetings scheduled in January 2011. COLA will inform you of any changes as they become known. ■

RESOURCES:

1 The Centers for Medicare and Medicaid Services (CMS); http://www.cms.gov/ClinicalLabFeeSched/01_overview.asp
2 The Clinical Laboratory Coalition includes: 1. American Association of Bioanalysts, 2. American Association for Clinical Chemistry, 3. American Clinical Laboratory Association, 4. American Health Care Association, 5. American Medical Technologists, 6. American Society for Clinical Laboratory Science, 7. American Society for Clinical Pathology, 8. American Society for Microbiology, 9. Cheyenne Regional Medical Center, 10. Clinical Laboratory Management Association, 11. College of American Pathologists, 12. Diagnostic Laboratory Medicine, 13. Diagnostic Laboratory Services, Inc., 14. Marshfield Clinic, 15. Mayo Clinic, 16. Medical Group Management Association, 17. National Independent Laboratory Association, 18. Nationwide Laboratory Services, 19. PeaceHealth Laboratories, 20. Roche Diagnostics Corporation, 21. Siemens Healthcare Diagnostics, 22. Sonic Healthcare USA
3 Clinical Laboratory Management Association (CLMA); http://www.clma.org/resource/resmgr/Sign_on_Letter_to_CMS_re__Ph.pdf
4 The American Clinical Laboratory Association (ACLA); http://www.clinical-labs.org/documents/signaturedocumentforWeb.pdf
5 ACLA; http://www.clinical-labs.org/documents/PhysicianSignatureFacts-2doc_000.pdf
6 CLMA; http://www.clma.org/?page=Phy_Sig

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PATIENT SAFETY - A "CULTURE OF SAFETY"

With this in mind, the Patient Safety Committee of the American Society for Clinical Laboratory Science (ASCLS)[4] has developed products that laboratory professionals can distribute to patients. These products include:

- Personal Pocket Laboratory Guide
- Laboratory Patient Safety Tips: What is Fasting?
- Laboratory Patient Safety Tips: Blood Specimen Collection (Venipuncture)
- Laboratory Patient Safety Tips: Glucose Tolerance Test (3 Hour or Gestational)
- Laboratory Patient Safety Tips: Hydrogen Breath Test

All of these products are available at the ASCLS website and each has space to personalize the product with your laboratory's contact information. ASCLS provides these products free of charge, asking only that the ASCLS logo is printed on each product, so others will know who developed the product.

Creating a "culture of safety" for patients encompasses much more than what they experience during laboratory testing. We cannot address all aspects of patient care, but we can certainly create and maintain an atmosphere of safety while they are in our care. This is true whether we handle specimens or have in person contact. ■

RESOURCES:

1 Institute of Medicine; Report brief: To Err is Human: Building a Safer Health System (September 1999): http://iom.edu/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf Accessed January 3, 2011.
2 Agency for Healthcare Research and Quality: http://www.ahrq.gov/
3 Agency for Healthcare Research and Quality; Pub. No. OO-P038; 20 Tips to Help Prevent Medical Errors (September 2000): http://www.ahrq.gov/consumer/20tips.pdf Accessed January 3, 2011.
4 American Society for Clinical Laboratory Science, Patient Safety Committee: www.ascls.org/leadership/psc

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ELECTRONIC HEALTH RECORD (EHR) SAFETY

RESOURCES:

1 The American Recovery and Reinvestment Act of 2009 (The Recovery Act); http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf
2 Health Information Technology (Health IT); Patient Safety Tiger Team Summary 2010_10_26_Final.pdf
3 EHR Safety Event Reporting System, a service of PDR SecureTM; http://ehrevent.org/
4 Government Health IT; Health industry and feds join forces to launch EHR safety reporting system (November 15, 2010); http://govhealthit.com/newsitem.aspx?nid=75108; Accessed January 4, 2011.

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5 In 1999, the Institute of Medicine (IOM) issued a landmark report entitled, "To Err is Human: Building a Safer Health System," which spotlighted a serious need to capture information that would help to improve quality and reduce harm to patients. Addressing this need, Congress passed The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act). (To read the Patient Safety Act, go to http://www.pso.ahrq.gov/statute/pl109-41.htm.) To implement the Patient Safety Act, the Department of Health and Human Services (HHS) issued the Patient Safety and Quality Improvement final rule (Patient Safety Rule). (To read the Patient Safety Rule, go to http://www.pso.ahrq.gov/regulations/fnlrule01.htm.) The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs to improve quality and safety through the collection and analysis of data on patient events.
PSOs are organizations that share the goal of improving the quality and safety of health care delivery. Organizations that are eligible to become PSOs include: public or private entities, profit or not-for-profit entities, provider entities such as hospital chains, and other entities that establish special components to serve as PSOs.
By providing both privilege and confidentiality, PSOs create a secure environment where clinicians and health care organizations can collect, aggregate, and analyze data, thereby improving quality by identifying and reducing the risks and hazards associated with patient care.
The Agency for Healthcare Research and Quality (AHRQ) administers the provisions of the Patient Safety Act and the Patient Safety Rule dealing with PSO operations. http://www.pso.ahrq.gov/

6 EHR Safety Event Reporting System, a service of PDR SecureTM , "YOUR PRIVACY AND SECURITY" page; http://ehrevent.org/PrivacySecurity.html

7 PDR Secure™ receives oversight and governance from the iHealth Alliance, a not-for-profit organization whose mission is to protect the interests of patients and providers, as healthcare increasingly moves online. The iHealth Alliance oversees the security, privacy and data use of the PSO.

8 EHR Safety Event Reporting System, a service of PDR SecureTM , "ABOUT US" page; http://ehrevent.org/Mission.html

9 The FDA has experience with reporting adverse events and educating the public about safety threats associated with the release of new medical devices and pharmaceuticals. For more information on this, and the FDA in general, see their website: http://www.fda.gov/default.htm

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COLA'S 2011 PATIENT SAFETY GOAL

You may wish to create a script for staff to use when reporting panic results by phone. This will ensure that everyone making such a call handles it in the same way and relays the results in a consistent manner.

When reporting panic results, always document the notification, including:

- Who was notified
- The patient's name and secondary identifier
- The test and the results
- Date and time of notification
- Method of notification (by phone, by hand delivered report, etc.)

You may wish to create a log specifically for documenting panic result notifications.

Periodically review your list of panic values to see if it needs adjusting for your patient population or clinicians' needs. If you add a new test to your test menu, determine if it needs to have panic values established.

Train all staff on the panic value reporting procedure and ensure that everyone follows the procedure as written.

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

UPDATE FROM PAGE 3

ASCP says, "Reverse Physician Signature Requirement"

REVERSE PHYSICIAN SIGNATURE REQUIREMENT - TELL CONGRESS TO INSIST THAT CMS TAKE ACTION

On Friday, January 28, 2011, the American Society for Clinical Pathology (ASCP) sent an Action Alert to its membership regarding the physician signature requirement.

Urge Congress to Insist that CMS Reverse Requisition Physician Signature Requirement

Jan. 28, 2011—"Over 1,100 advocates reached out to the Centers for Medicare and Medicaid Services (CMS) to express opposition to a recently adopted rule requiring a physician's signature on requisitions for clinical diagnostic laboratory tests. CMS heard ASCP as well as the other members of the Clinical Laboratory Coalition, and has indicated that it is considering the possibility of eliminating its recent rule or extending further its implementation date. Unfortunately, while the agency has expressed a willingness to reexamine the rule, it is still pursuing implementing this flawed requirement as soon as April 1. ASCP argued the new rule could adversely affect patient care and complicate the provision of laboratory services. CMS must be made to understand. Today, ASCP is launching a new advocacy campaign to encourage you to write your Member of Congress and Senators to encourage them to contact CMS to see the error of their ways and rescind the new rule. ASCP encourages everyone to take a moment to write Congress to urge them to reverse the physician signature requirement on laboratory requisitions."

More information and a sample letter to send to Congress can be found at the following site: http://capwiz.com/ascpath/issues/alert/?alertid=24153506&PROCESS=Take+Action

LabUniversity® News!
New MLE CEexpress Online Course

We now have a new MLE CEexpress online course!

MLE CEexpress 10: Clinical Microscopy is comprised of two articles that describe microscopic procedures common in clinical laboratories and medical offices, as well as microscope use and maintenance.

Article 1 provides a description of some of the most common microscopic test procedures:

- Vaginal Wet Mount Examination
- KOH Preparation
- Sperm Examination
- Fern Test
- Pinworm Examination
- Fecal Leukocyte Examination

Article 2 is about the microscope—the hardware that allows us to visualize those tiny elements in patient specimens. The parts of the microscope and their functions are described, followed by tips and procedures for microscope use, maintenance, and troubleshooting.

Students read the articles, take the quiz, and earn 1 P.A.C.E.® credit.

You can find **MLE CEexpress 10 at www.cola.org** (COLA Store, On-line Courses, Subcategory: CEexpress, MLE CEexpress), and like all the CEexpress courses, **it's only $15.**