JANUARY / FEBRUARY '10

INSIGHTS

OCCURRENCE MANAGEMENT

As a follow-up to a previous Insights article ("Don't Let History Repeat Itself: Manage and prevent occurrences promptly by following these steps" May/June '09), we are offering a more detailed multi-part series. We will present specific examples to show you how to manage and prevent occurrences. This is the second article in the series.

See ***http://www.cola.org/resources.html?PDFCategoryID=4*** *to view previous Insights articles.*

One goal of a laboratory should be to detect, correct and prevent problems.

One means of doing this is through Quality Assessment.

One way of looking at Quality Assessment is through the Quality Systems approach.

The Quality System Essential (QSE) "Occurrence Management" defines the processes a laboratory uses to investigate occurrences, control their impact and implement corrective actions to prevent their recurrence. This QSE is used to identify, report, investigate, track, trend and document occurrences that do not conform to your laboratory's established policies, processes and procedures and/or do not meet your customers' expectations.

Documentation of an occurrence should always include a description of the problem, the date and time it happened, the date and time it was discovered, who was involved, and the remedial action taken. Pertinent information collected during the investigation also needs to be documented. Support documents, such as copies of maintenance and QC records or requisitions and reports, should be included when appropriate. Corrective actions implemented to prevent recurrence and the follow-up review of those actions should also be documented.

Questions to be Asked During the Investigation of an Occurrence

What?	What happened? What part of the path of workflow is involved? What impact did it have on patients and/or personnel?
Who?	Are specific departments or functions involved or impacted? Are particular groups or individuals involved or impacted?
How?	How did the occurrence happen? How was it identified? How long has it been happening? How many are affected?
When?	When did the occurrence happen? When was it discovered? When was it investigated? Were actions timely?
Why?	Why did it happen? Continue to ask why until there are no more answers.

Analytic Scenario: In this article, we will use the QSE: Occurrence Management to investigate an error discovered in the analytic phase of the path of workflow. Even though we will concentrate on one particular test, similar issues could arise in any test system. Thus, a similar investigation could be done in any laboratory.

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Review and Preview

FROM THE CHAIR

At this time of year, to review what happened over the last year and anticipate what is about to happen during the upcoming year comes naturally to most folks. We are no different here at COLA. We'll share a few of our thoughts with you in this issue of *Insights*.

2009 saw the launch of our newest effort to provide you with excellent customer service, COLAcentral. More features and functionality will be added in 2010 beginning with the roll-out of the GOLD level at the beginning of February.

Another 2009 milestone was the appointment of Dr. Regina Benjamin to the post of the U.S. Surgeon General. Dr. Benjamin is a former member of the COLA Board of Directors. We congratulate her on this honor and look forward to see what will happen in 2010.

The lead article on Occurrence Management is the second installment in a continuing series. This, in effect, bridges one year to the next. The first article, from the previous *Insights*, highlighted a scenario from the Pre-analytic phase of the Path of Workflow; the current piece explains an Analytic phase scenario; a future article will focus on the Post-analytic phase.

Finally, we're looking forward to our next Symposium, which will be held in Baltimore during National Medical Laboratory Professionals Week. We're introducing a set of breakout sessions geared specifically toward COLA laboratories which address some issues you may face in your daily operations. You'll find descriptions of these sessions later in this edition of *Insights*.

We're so glad that you shared the past year with us and hope you continue with us throughout 2010.

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

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When performing any test:

Follow the manufacturer's instructions:

Ensure that they are current for the test system in use

Pay attention to the timing and order of the individual steps

Become familiar with:

How the test works

What factors affect testing

The limitations of the test system

Ensure that reagents:

Have not expired

Are being used under the proper conditions (check the temperature and humidity requirements)

The test we are looking at today is a Point-Of-Care (POC) system for PT/INR, which is used to monitor patients on oral anticoagulation (Coumadin® / warfarin) therapy. This system contains reagents and iron particles on a test strip, which is inserted in a meter when performing the test. Timing begins when blood is added to the test strip. The iron particles move in response to a meter generated oscillating magnetic field, until the blood clots. When movement is no longer sensed, the meter notes the elapsed time in seconds. The results may be displayed in seconds (PT) or as INR.[1]

An established patient was seen in the clinic and commented that her INR result was lower than what it usually is. The test was repeated and a similar result was obtained. When questioned about possible lifestyle changes that could affect testing, the patient

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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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assured you that everything was "the same as it has been for years." She had not changed her diet, was not diagnosed with a new illness and was not taking any new prescription or over-the-counter medications. Since this ruled out influences that were particular to this patient, your attention is now drawn to the test system.

The main questions we want answered are *"What happened?"* and *"Why did it happen?"* We know that our patient's INR was lower than usual *(What happened?),* so we have to investigate the causes of a decreased INR *(Why did it happen?).* Before doing this, though, there is something even more basic that has to be checked. *Are we sure that this specimen belongs to this patient?* Since this is a POC test and you applied the patient's drop of blood directly to the test strip when it was in the meter, in this case, patient misidentification is not an issue. However, in similar scenarios, you should confirm patient identity and ensure that the specimen is properly labeled and handled throughout the testing process.

What conditions can affect the test system? Where are these conditions documented?

The product insert and/or the written procedure in the laboratory procedure manual should list test factors that could affect patient results. These sections could be entitled "warnings," "precautions," "limitations," "sources of error" or something similar. Be sure to check the sections on reagent / kit storage and testing requirements, since there may be pertinent information included there also.

According to the product insert, this particular test system has strict temperature, humidity, light and motion requirements. The testing location (and the lighting in that area) has not changed since you initiated PT/INR testing in your clinic. Since you did not move the meter during the test, temperature and humidity remain as conditions to be checked. You perform several tests in your clinic that are affected by temperature and humidity, so you keep a daily log of these environmental conditions. A quick look over the log shows that they have been consistent for the last several weeks.

What now? Has anything else changed? What else could affect patient results?

During your investigation of an occurrence, be sure to check that the entire procedure has been performed according to the manufacturer's instructions. Did the patient have to prepare for the test? Was the correct sample used? Can fingerstick or venous blood be used? For a venous specimen, did you need a clotted or an anticoagulated sample? For fingerstick collection, did you use the first drop of blood or wipe it away? When collecting a swab specimen, was the correct area sampled? Was there enough sample volume to perform an accurate test? Were the procedure steps performed in order? Was the timing for each step correct? Was enough time allowed before reading the final result? Was QC correctly performed according to protocol? Were the QC results valid? Did the QC review show any shifts, trends or changes that were previously overlooked? These are all possible sources of errors during testing.

For the current scenario, you noted only one recent change. Your testing volume has been increasing, so you adjusted the number of test kits that you store on site. You order a larger number of kits, but you ensure that they are all the same lot number. The lot number and expiration date are clearly marked on the kits and testing personnel document that the date has been checked daily prior to use. This has always been part of your routine testing procedure, which has not changed. Another part of your procedure is to remove test strips from storage as they are needed to perform patient testing. This helps ensure that test strips are not hidden in drawers or forgotten on shelves and then mistakenly used after the expiration date. You should be commended since you have implemented steps to prevent errors in testing.

However, an error has happened and we still don't know why. The only change noted, the increased number of stored test kits, couldn't cause a change in patient results. Or could it? To allow for longer storage of the increased number of test kits, the kits are now stored in the refrigerator, rather than in storage cabinets at room temperature. As it turns out, this is what is significant.

According to the manufacturer, the test strips have to be at room temperature prior to testing. This was not an issue when the kits were stored at room temp, but it is now that they are stored in the refrigerator. The manufacturer allows for refrigerated storage, but states that you should remove the test strips from storage at least five minutes before you perform the test, to allow the strips to come to room temp. The product insert states this in the "preparation" section, but not in the "testing procedure" section, so it was overlooked until now.

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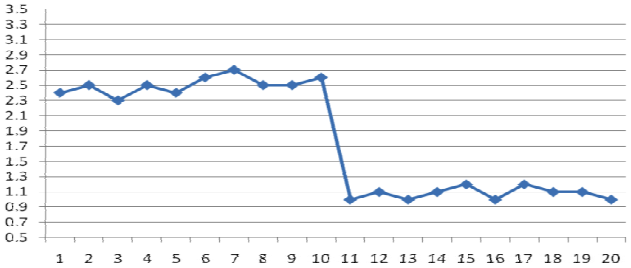
This underlines the importance of being familiar with the entire product insert.

Is the investigation over?

NO. You determined what happened and why it happened, but you don't know how far reaching it is. You know that one patient was affected, but were there others? Every patient tested since the change in storage conditions is potentially affected, unless the test strip had sufficient time to come to room temp prior to testing. In our scenario, for each patient tested, it is not possible to confirm how much time elapsed from when the test strip was removed from the refrigerator to the time the test was actually performed.

Since we know when we began storing kits in the refrigerator, the next step is to review all patient results for testing performed following the change in storage conditions. It is likely that all these results were affected; however, the significance of the effect may be hard to determine. At this time, it would be helpful to consult your lab director and/or clinical consultant. All ordering clinicians should be notified that during this specific timeframe, reported results may be falsely decreased. If necessary, the clinicians should confer with the laboratory director and clinical consultant to determine if patients should be retested and/or if results should be confirmed via alternative methods.

QC records should also be examined. The values may have been within range, but they may have "shifted." For example, QC values may have been running steadily in the center of the acceptable range. Following the change in storage, though, they were running near the low end of the acceptable range. This sort of change is easier to see if QC values are plotted on a chart or graph, rather than just listing the values. This may have helped you catch the change sooner.



You should also confirm that all personnel are aware of the importance of test strips being at room temperature prior to use. Has everyone been properly trained to do the procedure? Was this training documented? Does everyone perform the procedure correctly? Does everyone perform the procedure the same way? Has staff competency been assessed? Was this documented? Do staff members need to be retrained?

The final step in occurrence management is to implement and review corrective action(s). Once the root cause has been determined, steps should be taken to address it and prevent the occurrence from happening again. It is also important to schedule a follow-up review to see if the corrective action you implemented is having the desired effect. If the problem recurs, the root cause may have been misidentified, the corrective actions may not have addressed the root cause or the corrective actions may have been ineffective.

Corrective action for our PT/INR test may be as simple as posting a sign on the refrigerator door reminding staff to remove the test strip from the fridge at least five minutes before it is used. If the investigation warrants a more intense corrective action, all staff may have to be retrained with periodic assessments performed more often than before. When you perform your own investigations, be sure that the corrective action you implement effectively addresses the true cause of the occurrence.

[1]INR (International Normalized Ratio) is a standardized way of reporting PT results regardless of reagents, instrumentation or methodology used. It is the ratio of the patient's result to a control (normal) sample mean, raised to the power of the ISI value of the test system used. INR = $(PT_{test} / PT_{control})^{ISI}$, where ISI is the International Sensitivity Index assigned to the reagent by the reagent's manufacturer.

UNITED STATES SURGEON GENERAL

On January 11, 2010, before a crowd of 600 invited guests, friends and family members, Dr. Regina Benjamin was officially sworn in as the United States Surgeon General. She has been on the job since the US Senate unanimously confirmed her nomination on October 29, 2009.

Since Dr. Benjamin was a member of COLA's Board of Directors in the mid-1990s, she has a unique understanding of laboratory accreditation issues. At the time of her confirmation, the current Chair of the COLA Board, Verlin Janzen, M.D. was quoted as saying, "The United States Senate is to be commended for unanimously confirming this superb physician to this critical post, especially at this challenging time, as our nation confronts the H1N1 virus. COLA congratulates Dr. Benjamin on her new position, and is confident that she will bring awareness and understanding of the important roles of both medical laboratories and CLIA."

The H1N1 virus is part of the reason for the delay of the swearing in ceremonies. Dr. Benjamin has been so busy fulfilling her duties as the nation's "chief health educator" in the midst of the swine flu crisis that Health and Human Services Secretary Kathleen Sebelius said that the department had not been able to spare her for the formal change of command until now.

Although she was surrounded by relatives, Dr. Benjamin has lost several close family members to preventable diseases. As such, she has pledged her official commitment to wellness, disease prevention and public health.

Dr. Benjamin received her M.D. from the University of Alabama at Birmingham in 1984, completed her residency in family practice at the Medical Center of Central Georgia in 1987 and earned an MBA from Tulane University in 1991.

She founded the Bayou La Batre Rural Health Clinic, in Bayou La Batre, Alabama, in 1990 and has served as its CEO ever since. The clinic was heavily damaged by Hurricane Georges in 1998 and by Hurricane Katrina in 2005. It also burned to the ground several years ago. Showing the resolve and patient-focus needed to serve as "America's doctor," Dr. Benjamin continued to see patients during the rebuilding phase following each catastrophe, making house calls when necessary.

In the mid 1990s, Dr. Benjamin was the first African-American woman to serve on the Board of Trustees of the American Medical Association (AMA), where she was also chair of the AMA Council on Ethical and Judicial Affairs.

She is a member of the Institute of Medicine of the National Academy of Sciences and serves on the Board of the Robert Wood Johnson Foundation. She is immediate past chair of the Federation of State Medical Boards and, last fall, was the recipient of the prestigious McArthur Foundation "Genius Award" for her ongoing work in providing health care to underserved populations.

COLA Sessions at the Symposium for Clinical Laboratories

April 21–24, 2010
Hilton Baltimore, Baltimore, MD

At the upcoming Baltimore Symposium, we are celebrating education! We have exciting new breakout sessions that were created with COLA labs in mind. These sessions will be presented by COLA's staff of experts and will cover COLA criteria and processes.

Thursday, April 22, 2010

A04 *Getting the Most Out of Your Proficiency Testing Results*

Richard Gates, MLT(ASCP),
COLA Accreditation Regulatory Team Leader

Leon Headley, MLS, CT(ASCP),
COLA Accreditation Surveyor

This breakout session provides insight into how to review and evaluate your proficiency testing (PT) results so that you may resolve PT failures and identify problems that may occur. We will discuss how to interpret your scores, recognize problems, and implement effective corrective actions to resolve PT problems. The importance of PT as a way to demonstrate quality and help to ensure accurate patient testing will be discussed, and the session will relate the review of PT performance to the COLA criteria and provide helpful suggestions for laboratories to achieve and maintain compliance with COLA and CLIA.

Learning Objectives

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

- Interpret PT scores received from proficiency testing provider
- Recognize and investigate unsatisfactory and unsuccessful PT performance
- Determine and implement steps to take for corrective action
- Document corrective actions taken
- Retain all PT documentation for the required timeframe

Thursday, April 22, 2010

B14 *Personnel Scenarios: Complying With the COLA PER Criteria*

Zerela Henry, BS, MLT(ASCP),
COLA Assistant Accreditation Division Manager

Pam Gottsponer, MT(ASCP),
COLA Accreditation Surveyor

This breakout session is designed to help ensure that your lab is compliant with the COLA personnel criteria (PER 1-6), with a focus on the criteria for personnel competency evaluation and personnel responsibilities. This session will provide real-life scenarios to address issues commonly found in labs of any size. It will also discuss ways to achieve compliance and to prevent or correct specific personnel issues related to the most frequently cited personnel criteria.

Learning Objectives

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

- Summarize frequently non-compliant COLA personnel criteria
- Illustrate non-compliant scenarios
- Formulate and implement appropriate corrective actions to achieve compliance

Thursday, April 22, 2010

C24 *COLA Users Group: Accreditation Update*

Zerela Henry, BS, MLT(ASCP),
COLA Assistant Accreditation Division Manager

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

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

Friday, April 23, 2010

D34 *Incident Management: Meeting COLA Criteria QA20*

Irwin Rothenberg, MBA, MS, MT(ASCP),
COLA Pre-survey Technical Consultant

Leigh Ann Smith, MLS(ASCP),
COLA Accreditation Surveyor

This session will discuss Incident Management (IM) and explain the differences between IM, quality assessment, and occurrence management. Development and implementation of an incident management plan that complies with COLA criteria QA 20.1 and 20.2 will be discussed, and example case studies will demonstrate key points, including root cause analysis. The session will discuss other relevant COLA QA criteria and provide tips to support compliance and prevent repeat citation for QA 20.

Learning Objectives

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

- Distinguish between Quality Assessment (QA) and Incident Management (IM) Programs
- Demonstrate how to implement QA and IM as an integral part of Laboratory Quality Management
- Apply investigative skills to identify potential causes and resolutions of incidents

Friday, April 23, 2010

E44 *Quality Control Basics: COLA QC Criteria*

Louise Jackman, MT(ASCP)
COLA Post-survey Technical Consultant

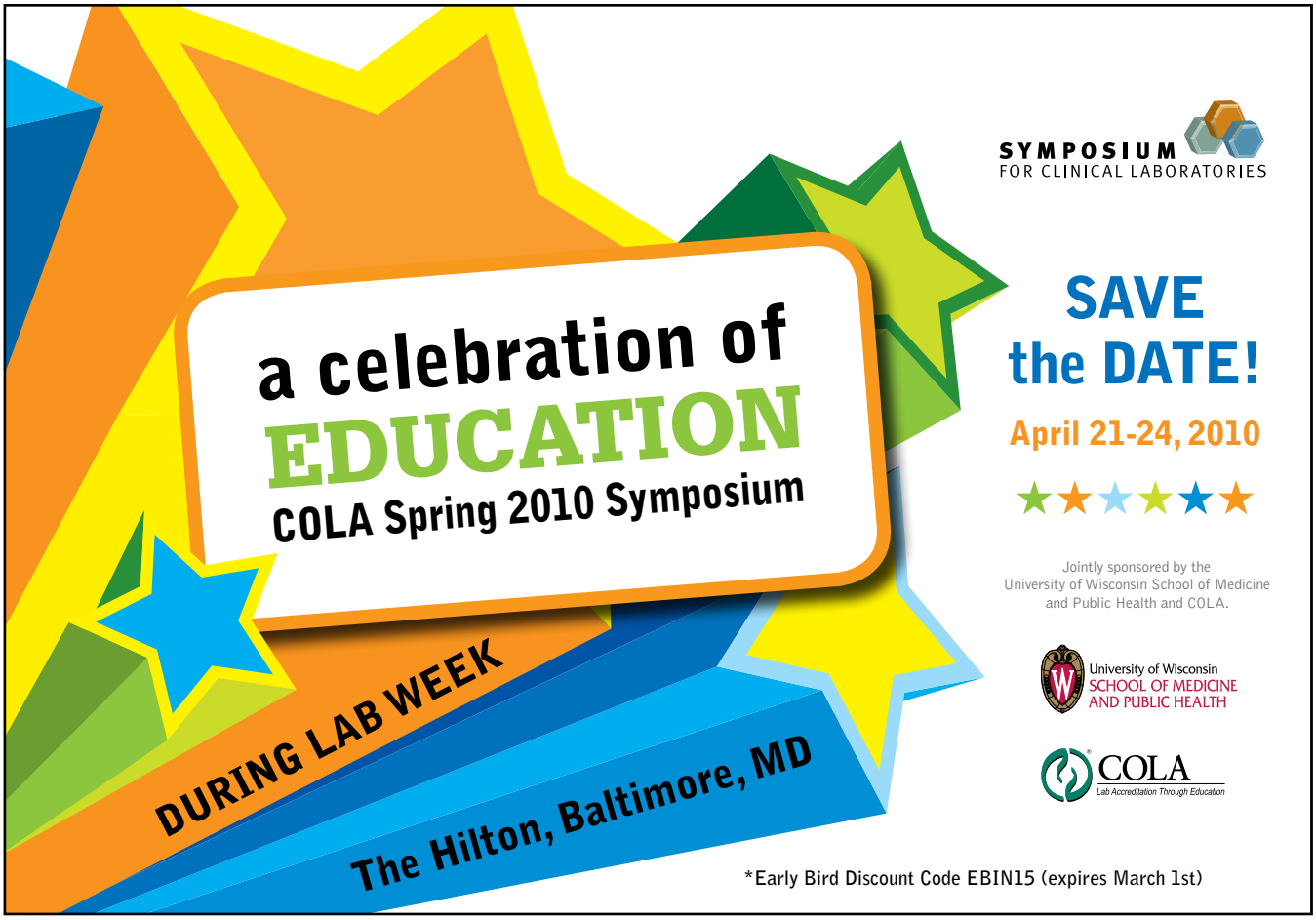
Rebecca Kenner, MT(ASCP) DLM,
COLA Accreditation Surveyor

The purpose of this session is to provide participants with information on the performance, evaluation and interpretation of quality control using the COLA Criteria. We will be concentrating on Quality Control criteria that are the most frequently cited as non-compliant. The presentation today will focus on external quality control for waived testing, non-waived quantitative and general qualitative quality control testing. It will not deal with the specifics of specialty and sub-specialty quality control.

Learning Objectives

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

- Apply COLA requirements for Quality Control
- Interpret quality control and Levey Jennings graphs
- Identify and investigate quality control failures
- Implement corrective actions for quality control failures
- Review case studies of quality control



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