

MAY/JUNE '10

# INSIGHTS

## OCURRENCE 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 fourth and final 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. Documentation should be retained for the appropriate amount of time, which varies depending on the testing specialty involved.

### Post-Analytic Phase

In the previous articles of this series, we presented an investigation of specific scenarios to demonstrate how to manage occurrences in the pre-analytic and analytic phases of testing. We'll do things slightly differently for the post-analytic phase: instead of one specific scenario, we'll identify several possible occurrences. Some may be uncommon but, hopefully, they will help you see a broader picture and recognize possible occurrences.

The post-analytic phase includes anything that happens after testing is completed. Processes for reporting, distributing, maintaining, and archiving test reports and processes for managing specimens after testing is complete are all part of the post-analytic phase.

Your laboratory should have policies and procedures for the preparation, release and retention of all test reports, including original, preliminary, corrected and final reports. How your laboratory handles reference laboratory results, corrected results, and alert (panic) values should also be addressed.

### Specimen Management

Your laboratory should have a policy in place stating if and how specimens are stored once testing has been completed. Some specimens may have to be refrigerated while others should be frozen. You may perform tests that require repeat, reflex or confirmatory testing on the same sample, so specimens will have

*continued on page 2*



9881 Broken Land Parkway, Suite 200 | Columbia, MD | 21046-1195  
[www.cola.org](http://www.cola.org) | [www.LabUniversity.org](http://www.LabUniversity.org) | [www.COLAcentral.com](http://www.COLAcentral.com)



Patient Safety

## FROM THE CHAIR

*Patient Safety* has become a "buzz word" of modern day healthcare, yet it is far more than that. The safety of our patients is the underlying foundation of all we do. It permeates our thinking, affects our policies, and guides our procedures. It has also influenced this issue of *Insights*.

"Specimen Identification throughout the Path of Workflow," the COLA Patient Safety Program for 2010, is debuted in this issue. The main article, which is the final article in our Occurrence Management series, mentions possible events that could occur when specimen identification is *not* confirmed throughout the Path of Workflow.

Another article sheds light on a worrisome development in today's laboratory that could definitely have a detrimental effect on patient safety. The ASCP Board of Certification has issued a warning about "Fraudulent Certification."

A new online MLE CEExpress course addressing a patient safety concern and occupational hazard, "Bloodborne Pathogen Safety in the Lab" is profiled in this issue.

Finally, as a means to help you stay abreast of all things that can affect patient safety, we are offering you an online "Patient Safety Resource" maintained by the Department of Health and Human Services.

At COLA, we truly care about you and the daily issues you face in your laboratory. We encourage you to contact us with any questions or comments and we look forward to helping you.

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

OCCURRENCE MANAGEMENT continued from page 1

to be stored relatively close-at-hand until the duplicate or subsequent testing is completed. You may have limited storage capacity which will affect how many samples can be saved. You may decide that some samples do not have to be retained at all since they are easily obtainable and the time of specimen draw is not a critical issue. Your Laboratory Director and Technical Consultant / Technical Supervisor are responsible for developing these policies.

### Test Reports

The following elements are required in the final test report:

- Unique identification of the patient
- Name of test performed
- Specimen source, when appropriate
- Patient result, including interpretation and/or applicable units of measurement
- Date of testing and date & time specimen was collected, when applicable
- Reference (normal) range for test results
- Name and address of laboratory where test was performed

Although, problems leading to an occurrence can happen with any of these elements, we will highlight just a few possibilities.

### Unique Identification of the Patient

Federal regulations, Good Laboratory Practices (GLP) and the COLA Patient Safety Program stress the importance of using two unique patient identifiers *throughout* the testing process, including the post-analytic phase.

- Your laboratory does PT/INR testing for both Joe Montani and his son Joe Montani, Jr. The son came in for testing, but the results were reported on the father because the unique patient identification was not confirmed throughout the post-analytic phase. The father's medication was adjusted based on the test results improperly posted to his chart. The mistake was discovered when the son called to ask about his test results. The father had to be contacted and arrangements had to be made for him to be tested to ensure his levels were still within the therapeutic range.

continued on page 3

## 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.

**ADVERTISING POLICY**  
COLA accepts advertising requests for inclusion in its publications. All advertisements are subject to review and approval by COLA. COLA reserves the right to reject or cancel any advertisement that is not in keeping with COLA's standards as a national accreditation organization and its publication standards. COLA and its publications do not and will not endorse, directly or indirectly, any advertiser's products or services. If you would like to discuss advertising opportunities, please contact COLA at 410.381.6581, ext. 368.

© COLA 2010. COLA INSIGHTS is published periodically by COLA, 9881 Broken Land Parkway, Suite 200, Columbia, MD 21046-1195. COLA INFORMATION RESOURCE CENTER: 800.981.9883. This publication may be obtained through enrollment in a COLA accreditation program, or by subscription for \$48 per year. ALL RIGHTS RESERVED. Reproduction in whole or in part without written permission is prohibited.

OCCURRENCE MANAGEMENT continued from page 2

- Susan Woods (dob 10.10.2005) had a throat culture performed by your laboratory. However, the results were posted to the chart of Susan Woods (dob 04.17.2003). The mistake was discovered when the mother was called with the results of the culture. She stated that her daughter had not visited the office and did not have a throat culture done. If the mother had not questioned the phone call, her daughter may have been treated needlessly and the patient who needed treatment may not have received it.

### Specimen Source

Even though a blood sample is the most common specimen source, it may be necessary to note whether the specimen was whole blood, plasma or serum. Additionally, since some analytes can be found and measured in other body fluids as well as blood, it is important to note the source on the test report.

- Your laboratory protocol is to perform a qualitative urine pregnancy screen for all first time hCG requests. Subsequent tests are performed on blood samples. A doctor, who is new to the area and to your laboratory, is questioning the test result he received. Instead of "positive," he is requesting the actual quantitative level of hCG. Since "urine" was not indicated as the source of the specimen, the doctor thought that the test was performed on a serum sample and you would just have to look at the instrument print-out to tell him the number that was reported. He was confused because the lab that he used previously would routinely run hCG tests on serum samples unless the clinician specifically ordered a urine pregnancy screening test.

### Patient Result

You would not intentionally report an incorrect patient result, but incorrect results can be reported inadvertently.

- Let's take another look at the PT/INR testing you perform. According to procedure, you confirm that the results from the analyzer are the same results reported in the LIS. Recently, you've had to modify most of the INR results because they have not matched. Your investigation showed that this started after the LIS software was upgraded to a newer version. Further scrutiny showed that prior to the upgrade, the analyzer calculated the INR and transferred the result to the LIS. With the upgrade, the LIS was programmed to accept the PT result, calculate the INR and report the INR result determined by the LIS. Once this was discovered, the LIS settings were reset to what they were prior to the upgrade.

Several important points can be drawn from the investigation and the implemented corrective action:

- You should know if calculated results are determined by your instrument or by your LIS. Components used in the calculations may be specific to the lot of reagent in use. Since these values have to be changed when the lot number changes, you have to know whether the instrument or the LIS has to be modified.
- It is very important to include a verification step in your normal routine. If your procedure did not include the confirmation of results, incorrect INR values could have been reported on several different patients over the course of several days. This could have had disastrous repercussions.
- There may be another electronic interface that cannot be verified with each patient, such as the transfer of data from the LIS to an Electronic Medical Record (EMR). The EMR should be monitored to ensure that all pertinent information from the LIS is reported accurately and in a timely manner.
- You should assess the changes involved with computer system upgrades to instruments, Laboratory Information Systems and EMR systems just as you would if you were installing a new analyzer. Verification of performance specifications for the computer system, including software, is required prior to reporting patient results. Someone who understands laboratory functions should work alongside the computer technicians to ensure that any new system settings do not affect the accuracy of laboratory reports. At the very least, the laboratorian should be available to answer questions during the upgrade. Once the upgrade is complete, routine functions must be evaluated prior to reporting patient results to confirm accuracy and determine if modifications may be necessary to any laboratory procedures.

### Date of test and time of specimen collection

Some tests, such as PT/INR and glucose, are repeated frequently for the same patient. Some tests have to be performed at a specific time. Therapeutic Drug Monitoring (TDM) specimens can be peak, trough or random samples, depending on the medication and when the specimens are drawn. Patients can also have specimens drawn prior to transfusion and/or treatment and have additional specimens drawn after treatment.

continued on page 4

OCCURRENCE MANAGEMENT continued from page 3

- Your laboratory is a reference lab with an LIS that is programmed to set the collection time to 00:00 (midnight) when no collection time is specified. The "test time" is added to the report as the time test results are received. As she was reviewing patient test results, Dr. Wilson discovered several test reports with the midnight time stamp. She was hoping to see if Mr. Matthew's new treatment was effective, but she could not determine what result correlated with which collection time. All testing was time stamped with midnight as the collection time and was resulted within a 30 minute time frame. Dr. Wilson fully realizes her staff should have documented the collection time, but she wants to work with you on a corrective action plan to develop a more effective method of handling specimens when the collection time is not included.

*Name and address of laboratory where testing was performed*

Healthcare providers and patients must be able to reach the laboratory where testing was actually performed. Under federal regulations, they can ask for specific testing information (test method, performance specifications, test interferences, etc.) which the laboratory must supply.

- Your laboratory recently purchased a refurbished chemistry analyzer from another laboratory. Patient testing was begun only after the proper protocols to bring the instrument on board were completed. However, you neglected to change the laboratory name and address in the analyzer. So, test reports listed the original laboratory's name and address as the testing site. Three weeks worth of test reports, include Proficiency Testing, had to be reprinted and redistributed once the oversight was discovered. The report with the other laboratory information gives the appearance of sending PT specimens to that laboratory for testing. Therefore, documentation of this occurrence, investigation and corrective action is critical to allay any concerns a surveyor might have about this seeming referral of PT samples to another lab. Referral of PT samples to another laboratory could result in your laboratory losing its CLIA certificate and your Laboratory Director being prohibited from directing a laboratory for a minimum of one year.

**Test Results**

*Alert Values*

Laboratory personnel must immediately notify the ordering clinician when any test result indicates a life-threatening

condition or a panic (alert) value. Your procedure should include *who* has authority to be contacted (ordering clinician, assistant, office manager, etc.), *how* they are contacted (in person, phone call, pager, etc.), steps to follow if the authorized person cannot be contacted in a timely manner, and how the notification is documented (written and/or electronic, log book, on test report, in patient chart, etc.)

- Maria spoke to Janice in Dr. Green's office to report a panic level potassium result. Janice had to take care of a minor emergency and was not able to immediately follow up with the potassium patient. The result was not addressed after the emergency, either. Dr. Green received the test report the next day and was furious that he was not notified when the patient was still in the office. Since Maria did not document that she had spoken with Janice, who is now denying any knowledge of the result, Dr. Green is threatening to send his patients to another laboratory.

The nature of some testing may require you to notify the ordering clinician even if the result is not an alert value. Cytology and/or surgical pathology results as well as some other test results may have to be relayed to the clinician immediately. The notification step and its documentation should be clearly stated in your laboratory procedures.

*Corrected Results*

When a test result has to be corrected, the laboratory is responsible to promptly notify the ordering clinician and promptly issue a corrected test report. Again, the notification step and its documentation should be clearly stated in your laboratory procedures. Copies of both the original and corrected reports and the notification documentation must be maintained for the required amount of time.

*Reference Laboratory Results*

If your laboratory refers patient specimens for outside testing, your laboratory cannot revise results obtained by the reference laboratory. You may allow the reference lab to send the results directly to the ordering clinician but you must be able to produce an exact duplicate of this report for your lab's records.

You should give clinicians who refer patients to your laboratory a list of tests you perform and keep them informed as to which reference laboratory you use for other tests. As stated earlier, the test reports should clearly indicate where the testing was actually performed.

continued on page 5

OCCURRENCE MANAGEMENT continued from page 4

Your laboratory policies should address monitoring completion of tests sent to outside laboratories. Work with the reference laboratory to determine the expected turn-around-time (TAT) for individual tests. If this TAT is exceeded, you should have a procedure in place stating how often to look for the pending results and when the reference lab and/or ordering clinicians should be contacted. If there are no procedures addressing this, the potential exists for results to be pending for inordinate periods of time, which could lead to strained relationships between your laboratory and your clinicians.

**Conclusion**

The post-analytic occurrence is no different than any other occurrence; it must be investigated. During the investigation, the most important question to ask is, "Why did this happen?" Continue to ask this question until you discover the root cause. Corrective action to address the root cause must be implemented to prevent recurrence. Conduct follow-up reviews immediately after implementation of corrective actions and periodically thereafter to ensure that the corrective action is effective.

Remember that the purpose of Occurrence Management is to detect and correct problems so your laboratory's ultimate goal of providing quality patient care is achieved.

**FRAUDULENT CERTIFICATION**

Reproduced with permission from the ASCP Board of Certification, <http://www.ascp.org/FunctionalNavigation/certification/AlreadyCertified.aspx>

**Beware of Fraudulent Certification**

The number of people misrepresenting their certification status has significantly increased over the years. Misrepresentation has occurred in a variety of ways. Individuals have improperly obtained ASCP Member ID cards or certificates of qualification from ASCP certified individuals, made copies and changed the name to their own. This copy is then used to obtain employment in a higher level job. In some cases, individuals have modified their own Member ID card to indicate a higher level of certification.

When hiring laboratory professionals, **do not accept copies** of certificates or Member ID cards. Ask to see the original. If in doubt, certification should be verified through online verification of certification. The individual's certification category, certification number, and date of certification will be provided by e-mail.

Protect the integrity of your credentials and your own certification record by not loaning your certificate or Member ID card to another individual. Individuals who misrepresent or misuse their certification status will be barred from future certification in any category and any current certification may be revoked.

**Enjoy the fruits of lab results in your EMR.**

Much of the data retained in a patient's medical record comes from the clinical laboratory, and without an LIS in your lab, there is no easy way to populate your EMR with lab results. With an Orchard LIS, system integration is routine, and interfaces between your EMR, billing system, and reference laboratories provide a seamless flow of demographic and clinical data between systems. So if you are in search of an EMR system, consider shopping for a laboratory information system, too, and enjoy the fruits of lab results in your EMR.

**Harvest the power of EMR integration with an Orchard LIS.**

**OrchardSoftware**  
Harvest the Power

(800) 856-1948 [www.orchardsoft.com](http://www.orchardsoft.com)  
© 2010 Orchard Software Corporation

## COLA PATIENT SAFETY PROGRAM 2010: SPECIMEN IDENTIFICATION THROUGHOUT THE PATH OF WORKFLOW

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 COLA criterion as the patient safety goal for each year, and provide education on good laboratory practices for implementation of that criterion. The program has also been integrated into the COLA survey process.

### The COLA Patient Safety Goal for 2010 addresses:

*PRE 19: Are all specimens uniquely identified through all phases of testing?*

Proper patient identification (the Patient Safety Goal for 2008) followed by proper specimen identification and labeling (the Patient Safety Goal for 2009) that continues throughout the path of workflow (the Patient Safety Goal for 2010) are essential parts of a safe testing process. Laboratory personnel need to be aware of the emphasis in the medical community to reduce medical errors due to mislabeled specimens.

According to CLIA (Sec. 493.1232), "The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results."

## LabUniversity NEWS! NEW MLE CEExpress ONLINE COURSE

### MLE CEExpress 9: Bloodborne Pathogen Safety in the Lab

As a follow-up and companion to MLE CEExpress 8: Introduction to Bloodborne Pathogens, we have now have MLE CEExpress 9: Bloodborne Pathogen Safety in the Lab.

Exposure to bloodborne pathogens is a serious occupational hazard for healthcare workers, but most exposure incidents are preventable. This MLE CEExpress contains two articles about exposure prevention strategies and recommended precautions for workers who collect, process, and perform laboratory testing on biological specimens.

Article 1 provides a review of bloodborne pathogens, and describes some organizational and personal methods of minimizing the risks of working with blood and other potentially infectious materials. Article 2 describes proper cleaning and disinfection practices, hazardous waste disposal, and exposure incident procedures.

CEExpress is fast and easy – read the articles, take the quiz, and earn 1 P.A.C.E.® credit.

You can find MLE CEExpress 9 on the COLA web site at [www.colas.org](http://www.colas.org) by going to the COLA Store and selecting On-line Courses, Subcategory CEExpress.

This means going further than just labeling the specimen immediately after collection using at least two identifiers. You must ensure that the specimen is uniquely identified through all phases of testing.

Verify that the same identifiers are present on all of the following that are applicable:

- Requisition (order)
- Patient wristband
- Patient chart
- Barcodes
- Sample labels
- Sample aliquots
- Test devices or cartridges
- Test results / reports

At times, it is difficult to use two identifiers throughout the entire testing process, especially on smaller aliquot cups. A single identifier can be used on these smaller sample cups but it should be referenced to a chart, map, or list that contains other patient and/or sample identification. This paperwork (the chart, map, or list) should be kept as part of the testing records and retained according to CLIA guidelines.

Correct specimen identification across the path of workflow is critical. Test results performed on mislabeled specimens will be linked to the wrong patients and may put the health of these patients at risk.

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

## PATIENT SAFETY RESOURCE

The subject of a Patient Safety "database" was proposed while our staff was brainstorming ideas to be included in this issue of *Insights*. The thought was to provide you with a list of websites that address Patient Safety issues. Research on the subject showed that not only does such a resource already exist, but that it is maintained by the federal government. The information that follows was drawn from the public information listed on their website: <http://psnet.ahrq.gov/index.aspx>

The AHRQ Patient Safety Network (PSNet) is a national web-based resource featuring the latest news and essential resources on patient safety. AHRQ is the Agency for Healthcare Research and Quality, the health services research arm of the US Department of Health and Human Services (HHS). AHRQ, complementing the National Institutes of Health (NIH) – the biomedical research arm of HHS, is the nation's lead federal agency for research on health care quality, costs, outcomes, and patient safety. They are a science partner, working with the public and private sectors to build the knowledge base for what works – and does not work – in health and health care and to translate this knowledge into everyday practice and policymaking.

The PSNet site offers weekly updates of patient safety literature, news, tools and a vast set of carefully annotated links to important research and other information on patient safety. PSNet users can customize the site's powerful search capability around their own interests. The site is also tightly coupled with *AHRQ WebM&M*, the popular monthly journal that features user-submitted cases of medical errors, expert commentaries, and perspectives on patient safety.

One feature of the site is the *AHRQ PSNet Collection*. This is an extensive selection of resources relevant to the patient safety community. These resources come in a variety of formats, including literature, research, tools, and websites. Resources are identified using the National Library of Medicine's Medline database, various news vendors and content aggregators, and the expertise of the AHRQ PSNet editorial and technical teams.

Echoing the information stated in the disclaimer on the PSNet website, COLA does not endorse or recommend the resources, information, products, or services offered on the site. We are simply supplying you with a starting point to help you meet your patient safety needs.



**Calibration verification/linearity testing has a new address.**

**Yes, it's that easy.  
1: Open. 2: Dispense.  
3: Run.**

Calibration verification/linearity testing doesn't get much easier than VALIDATE®. Our liquid, ready-to-use testing kits minimize the need for manual dilutions, saving you time and making your job easier. Plus, you get our promise of 100% satisfaction, backed by experts who are ready to help you with any questions or concerns.

To learn more about VALIDATE®, call us at 1-800-377-9684 or visit [www.mainestandards.com/POL.htm](http://www.mainestandards.com/POL.htm).



**maine standards**  
COMPANY LLC

Find out **WHAT'S HOT** in the laboratory landscape!

**SAVE-THE-DATE**  
The Symposium for Clinical Laboratories  
**SEPTEMBER 29-OCTOBER 2, 2010**

Talking Stick Resort  
Scottsdale, AZ

# Help Your Lab Deliver The **Gold Standard** of Care

COLAcentral is the revolutionary web portal that empowers laboratorians to take control of their labs and deliver high quality, consistent patient care.



COLAcentral gives your lab the tools and the education to prevent repeat citations, keep staff CLIA/ COLA compliant and dramatically improve practice management.

**Document Repository** Laboratories get 2 GB of space to upload and safely store compliance materials, CLIA certificates, personnel certifications, diplomas and other important documents.

**Single Sign On Feature** Allows Consultants/Managers to view all of their labs under one COLAcentral user log in.

**Laboratory Operations** A customized inventory control module created specifically for your lab to put you in control of maintenance, quality and profitability.

**Visit [COLAcentral.com](http://COLAcentral.com) to get started  
or call 1-800-981-9883.**



9881 Broken Land Parkway, Suite 200  
Columbia, MD 21046-1195  
[www.cola.org](http://www.cola.org) | [www.COLAcentral.com](http://www.COLAcentral.com)

**PAID SUBSCRIPTION**

NON PROFIT ORG.  
U.S. POSTAGE  
**PAID**  
PERMIT #273  
ANNAPOLIS, MD