

# INSIGHTS

## **DON'T LET HISTORY REPEAT ITSELF** **Manage and prevent occurrences promptly by following these steps**

*By Karen Appold*

Occurrence management involves detecting, reporting, investigating, tracking, and trending events that do not conform with your laboratory's established policies, processes, and procedures. Learn how well your laboratory functions by analyzing where problems occur and why.

An occurrence can broadly be defined as anything that happens that should not happen. When applying this term to a laboratory, the type of laboratory must be considered. For instance, the aforementioned might be a good working definition for a reference laboratory, but it may not be appropriate for a hospital laboratory because occurrences may be reported that the laboratory has no authority to resolve, said Kathryn Connolly, COA(ASQ), MT(ASCP), quality systems manager, COLA.

Ultimately, the broader your definition, the more occurrences your facility will report. If the laboratory is the only department within an institution that is seeking to identify, track, and correct occurrences, Connolly advised a more specific definition. If all departments within a facility are involved, then include all of them in a discussion leading to a definition.

A more detailed definition for a laboratory might be: Anything that occurs during the pre-analytic, analytic, or post-analytic phase of testing that should not occur. Some laboratories may want to

specify what is included in each phase, such as ordering, collection, and transport of laboratory samples.

The filter for determining whether a specific occurrence is something that should not happen is best determined by the individual experiencing the occurrence, Connolly continued. What a tech may not deem an occurrence, a phlebotomist or patient may view quite differently.

"I recommend reporting and then deciding," Connolly said. "If someone believes a particular process should happen differently, this can be used as a tool to teach why the process needs to happen the way it is currently designed. Or, it might reveal an unintended outcome or it could be an opportunity for improvement that had not been previously recognized."

Ultimately, Christine Flaherty, MHA, MT(ASCP), CLS, CPHQ, regional laboratory director, Sutter Health Sacramento Sierra Region, said that there should be multiple avenues in place to identify an occurrence. These include:

- Recognition by laboratory employees during the course of performing their daily work.
- Periodic review of laboratory records by supervisors and managers.
- Formal internal audits.
- Complaints or feedback from other employees (internal customers within the organization, but outside of the laboratory).
- Complaints or feedback from external customers.

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**FROM THE CHAIR** This is my last column, as I hand off the responsibilities of the Chair to Verlin K. Janzen, MD, FAAFP. Dr. Janzen is a long-time board member whose commitment to COLA's standards of excellence and to the healthcare community is exemplary. His early experience as a medical technologist has been an asset to COLA, and he serves as an instructor for the Laboratory Director Curriculum at the COLA Symposium for Clinical Laboratories.

In this issue we tackle the all-too-common problem of things that don't happen as they should. It is important to learn from these occurrences so that they don't happen again. The *Insight Into QMS* article further explores occurrence management from a quality management systems perspective. COLA is committed to quality in laboratory medicine and always strives to provide the information and tools you need to continually improve your laboratory processes and procedures.

Along those lines, we are pleased to report that we had a great educational event at the COLA Symposium for Clinical Laboratories in Dallas, Texas. I am pleased to announce that I will be speaking again on the laboratory's importance in HIV/AIDS Care at the next symposium which will take place in Buena Vista, Florida, September 16-19, 2009.

It has been an eventful and rewarding two years as the Chair, and although my term as Chair is ending, I look forward to continuing as a member of the COLA Board of Directors.

**Donna E. Sweet, MD, MACP**  
Chair, COLA Board of Directors

#### *DON'T LET HISTORY REPEAT ITSELF*

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- External assessments (e.g., accreditation surveys, inspections, and audits).

#### **Who's Responsible for Reporting?**

Simply put, an occurrence should be reportable by anyone involved in either the department creating the issue or anyone aware of the issue, said Patrick J. Maul, MT(ASCP), MBA, Lean Six Sigma Black Belt, principal consultant, BD Diagnostics.

This would include anyone who works in the facility, not just laboratory employees. "Because staff outside of the laboratory are often involved in pre-analytic and post-analytic processes, they have an important perspective regarding the input (i.e., order or sample) and output (i.e., result) of the laboratory testing process," Connolly said.

Occurrences reported by patients should enter the complaint process. "One might argue that items reported by nurses, physicians, or staff outside of the laboratory should go into the complaint process as well, because these individuals are also customers of the laboratory," Connolly said.

Flaherty concluded that although room for variation exists, the reporting process should be designed so that the right people have knowledge (i.e., the right information) of the occurrence at the right time.

#### **Reporting an Occurrence**

An occurrence should be quickly reported to a stakeholder who is accountable for the process, area, or department in which the occurrence was detected, Maul said.

Flaherty prefers electronic reporting because data has to be entered only once and some occurrence management software can provide reminders and overdue alerts for recommended actions.

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Connolly advised completing a standardized form, either paper or electronic, that will gather sufficient information to conduct an investigation and elicit the information needed to take remedial action once the cause is known. Choose a form that can be routed to the appropriate parties to append information during the investigation and resolution.

Another option might be to set up a specific extension in your phone system for callers to report occurrences. This works best when the extension is manned by specially-trained personnel, so that key pieces of information are consistently obtained for each occurrence reported, Connolly said. This might work best in a reference laboratory that has dedicated client service representatives.

Regardless of the reporting mode, the reporting process should be simple, accessible, and easy to use. It should not create a barrier to reporting.

Consider allowing anonymous reporting to get the process started and to help overcome a culture that doesn't trust the concept of "no blame," Connolly said. "This can be tricky, as it can be difficult to get enough information to act on and thus identify what went wrong and why, so an action plan can be developed to prevent it. Buy-in is particularly critical. If you use anonymous reporting and don't get enough information to resolve the reported issue, the occurrence reporting may be viewed as a failure and abandoned without giving consideration to the way in which it was implemented."

### **Benefits of No-Fault Reporting**

No-fault reporting encourages the reporting of problems. "In most cases, there should be an understanding that the occurrence was created by a breach in either policy or process and was most likely not created by someone intentionally trying to create the failure," Maul said.

If the department is run in conjunction with good practices and particularly with Lean and Six Sigma in mind, there should always be a mechanism built into the department's structure to allow for the reporting of issues without fear of retaliation.

Connolly said that without no-fault reporting, individuals won't learn how to improve their processes. Staff should be encouraged to report their mistakes so that management can improve the tools and support systems to help staff do the right thing and make the right decisions easily.

### **Classifying Occurrences**

Joan M. Carlson, MLT(CSMLS), BSc(MLS), MT(ASCP), regional manager, Quality and Education, Alberta Health Services, said her facility initially classifies occurrences according to the laboratory testing phase, i.e., pre-analytic, analytic, post-analytic, and other (which includes equipment, laboratory information system/information system, patient concern, complaint, purchasing, housekeeping, and transportation/courier).

Maul recommends also classifying an occurrence according to the severity of harm to the patient. Consider using Failure Modes Effects Analysis (FMEA), a Six Sigma tool, to determine the likelihood of detecting it, the risk to both the organization and the patient, and the cost to correct and possibly litigate the occurrence. Contact Joint Commission Resources for more information on FMEA.

Flaherty prefers a classification scheme that considers the severity of the occurrence and the probability that it will occur. The Safety Assessment Code (SAC) matrix from the National Center for Patient Safety (NCPS) is one such scheme.

### **The Process of Remedial Action**

The next step in the process of occurrence management is to implement remedial action. Alberta Health Services asks the staff member discovering the occurrence to perform the remedial action if it is within his or her scope and abilities. "That person usually understands the event better than anyone else and has had initial contact with an involved caregiver or other laboratory staff," Carlson said.

If that individual cannot remediate, he or she will take the occurrence to an immediate supervisor or manager. That person will review the occurrence form and examine the root cause. Remedial action is

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reviewed to see if additional follow up is required. "We try to focus the supervisory review on system failures," Carlson said. "The supervisor will also make any further notifications of the event that may be required. If the event involved a nursing unit, for example, and the nursing supervisor should be notified, a hospital occurrence will be generated. The supervisory review will be documented. Any other staff involved in the event are also notified."

At this stage, consider whether the process implicated needs to be stopped until a fix can be put into place, Connolly said. Also answer these questions: What back-up methods are available? How quickly can they be implemented? Is there a need to notify laboratory customers? If so, how quickly? Is there a way to detect other patients or samples that may be affected?

### **The Benefits of Occurrence Analysis**

Analysis helps to get to the root cause of an occurrence to ensure that effective actions are developed. Track reported occurrences over time to detect patterns and quantification of occurrences, which can lead to realizations such as:

- Repeated occurrences indicate that a corrective action plan was ineffective or was not implemented.
- Reduced occurrences could indicate successful system improvements, a lack of reporting, or a loss of trust in the no-fault process.
- Trends and patterns that suggest where to focus resources for corrective action to address the underlying cause.

Corrective action is any change in process which is implemented as a result of an occurrence. The change is made in an attempt to error-proof the process or procedure so the problem does not recur, Carlson explained.

A corrective action might involve education, monitoring via measurements, control plans, automation, mechanization, or removal of automation or mechanization, Maul said.

Ultimately, analysis will increase the knowledge of laboratory testing phases and specific activities that

are risky or error-prone, Carlson said. This knowledge can be used to make changes in processes and procedures that result in fewer errors. Cumulative data can lead to in-depth root cause analysis and ways to improve and eliminate problems. Oftentimes, the improvement is a joint activity with patient-care areas which leads to a sense of collaboration and an interdisciplinary approach to patient safety.

### **Sharing Occurrence Information**

Occurrence information should be shared with all employees involved and with those who could potentially be involved. All employees should learn from a mistake and clearly understand the root cause. Management and customers should be informed of improvements.

Setting a target number for occurrence data allows for the monitoring of laboratory performance and can signal when a process is becoming problematic, Carlson said. Target number analysis may indicate the need for additional staff training, the need to update a procedural document, or the need to monitor a change in process more closely.

Ultimately, reporting an occurrence should be encouraged and celebrated, Connolly concluded. After all, this should prevent a mistake from happening repeatedly, and contribute to your laboratory's overall success.

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### **Resources**

#### **Joint Commission Resources**

www.jcrinc.com

#### **National Center for Patient Safety**

www.patientsafety.gov

*Hear more from Kathryn Connolly, Joan Carlson, and Luci Berte in Orlando at the COLA Symposium for Clinical Laboratories, Sept. 16-19, 2009.*

## Is Your COLA Lab Located in Maryland?

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## We had a great symposium in Dallas!

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You can purchase QSE: Occurrence Management from the COLA Store at [www.cola.org](http://www.cola.org). At checkout enter the discount code: **OM30** to receive the discount. This discount code is valid for purchasing the QSE: Occurrence Management course until **July 15, 2009.**

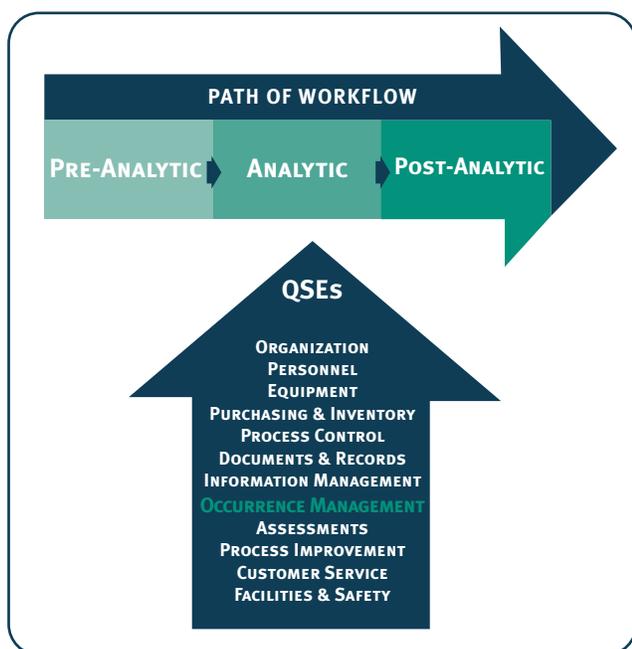
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## INSIGHT INTO QMS

### QSE: Occurrence Management

Quality Management Systems (QMS) is a systematic approach to quality management with a focus on error prevention and efficiency. The goal is to take quality and effectiveness to a higher level of performance. The Quality System Essentials (QSEs) work together to comprise a quality management system, supporting the path of workflow and forming the foundation of the laboratory's operations.



Occurrences are nonconforming events - events that shouldn't have happened if the process worked correctly. The most serious of these occurrences are sometimes called incidents, and they can produce significant consequences and negative outcomes for patients or staff. Occurrences also waste resources and time.

This QSE examines how to identify and evaluate occurrences to find the true cause to prevent the problem from happening again. In the LabUniversity® course *QSE: Occurrence Management*, written by Lucia M. Berte, MA, MT(ASCP)SBB, DLM; COA(ASQ) CMQ/OE, you will find this description:

QSE: Occurrence Management is about detecting, reporting, investigating, tracking, and trending events that do not conform with your laboratory's established policies, processes, and procedures. Much information

can be learned about how well your laboratory is functioning when you take the time to analyze where problems are occurring and why.

Occurrences can occur anywhere along the laboratory path of workflow. They may be reported by customers (physicians, patients) or staff. Lab staff should be encouraged to report occurrences without fear of blame, and they need a mechanism, such as a problem log, to report them and initiate the occurrence management process. Here are the steps for managing occurrences:

- Detect the occurrence
- Take remedial action to address the immediate concern
- Collect information for the investigation, while the details are fresh
- Document the occurrence in as much detail as possible
- Investigate the occurrence - How and why did it happen?
- Classify the occurrence as to impact, error type, and preventability
- Determine root cause and take appropriate corrective action
- Implement process improvement as needed to prevent a recurrence
- Analyze occurrences over time to look for underlying trends or patterns

In other words, learn from your mistakes, and don't repeat them! Change processes and procedures that don't work to ones that do. And remember that determining why is the key to resolutions that actually work. Don't just stab in the dark to try random solutions—find the root cause to correct problems permanently.

For details about this QSE and Quality Management Systems (QMS), see the LabUniversity® QMS courses available from the COLA Store at [www.colabio.org](http://www.colabio.org). You can also hear Luci Berte and other great speakers present QMS sessions at the COLA Symposium for Clinical Laboratories, Sept. 16-19, 2009 in Buena Vista, Florida.



## SYMPOSIUM

FOR CLINICAL LABORATORIES

The COLA symposium staff wanted to share some of the great comments we received from participants at our recent Dallas event:

- I really appreciated the interaction of all participants, vendors, and particularly the COLA staff. There were several physicians in my sessions, and I think this has to be a unique opportunity for laboratorians to see the physician's perspective and for the provider to more clearly understand the challenges faced by the laboratory in dealing with an ever-evolving regulatory and re-imburement environment.
- Extremely educational, interesting, and a great experience. Enjoyed the exhibits. Everything was provided.
- I brought a nurse and we attended different sessions and shared what we learned which was very beneficial to our office.
- I want to become a better and more informed laboratorian. For someone who is just starting as a consultant, the topics covered were informative. Now I can go back and implement many of the things I learned here. Thanks.
- I'd love to have all members of my staff be able to attend at least every other year...Always impressed with COLA's organization of the conference and the food. Everyone seems to enjoy the conference, including COLA staff.
- The resource packet in the binder was excellent. The fact that you've included all the break-out sessions on a CD is a real bonus.
- Always a very useful conference – well worth the time and expense.
- I attended the Lab Director Qualification Curriculum. Dr. Janzen is an excellent speaker. Unique to have someone who is a Lab Director and takes the time to make our introduction to LD responsibilities so smooth. Very informative!



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