MARCH / APRIL '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 third 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.

Analytic Phase, QC Scenario: In this article, we will use the QSE: Occurrence Management to investigate a specific error in the analytic phase of the path of workflow. This error is a problem with Quality Control (QC).

QC is a tool to help identify problems with the expected operation of the test system, the environment in which testing is performed, and the competency of the testing personnel. If QC is out of range, there could be a problem with the test system, the testing environment and/or testing personnel. However, regardless of the reason, this deviation in performance will affect the accuracy of patient test results and must be investigated. To ensure that performance deviations are detected, QC samples (controls) should be run in the same manner as patient samples. As stated in the second article in this series, when testing patient samples (with any test system), you should:

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*

Be 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)*

continued on page 2

Quality

FROM THE CHAIR

Since quality permeates the clinical laboratory atmosphere, it is emphasized in this issue of *Insights*. From test system Quality Control to quality performance, we hope this issue has something that will interest each of you. To start, the main article, the continuation of our Occurrence Management series, focuses on investigating an unacceptable QC result.

Because quality laboratory practice is not limited to Quality Control within the test system, another article provides a list of the resources COLA offers that address quality throughout the lab. Regardless of whether you are just opening your laboratory or have been practicing for several years, we are confident that you will find something to help you manage the overall quality of the testing you provide.

Whether we interact on-site, on the phone or online, we continually strive to excel in providing quality service to you. Our latest efforts are illustrated in the final article, which announces upgrades to our COLAcentral portal.

As we institute improvements to our service, our intent is to address your issues, so we encourage you to contact us with any questions or comments. We look forward to hearing from you.

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

OCCURRENCE MANAGEMENT continued from page 1

To ensure that the test system is measuring accurately over the full range of possible results, different levels of controls should be run. Consult the package insert to see how many levels are required. *Qualitative* tests (those that provide "either/or" results such as positive or negative, or reactive or nonreactive) will usually require two levels of controls, i.e. a positive control and a negative control. *Quantitative* tests (those that provide numerical results reported with units of measure such as IU or mg/dl) may require three or more levels of controls, e.g. a low control, a "normal" control, and a high control.

Control results should be reviewed to ensure they are within acceptable limits prior to reporting patient results. For quantitative tests, the acceptable range is usually ± 2SD (standard deviations) from the mean. In addition to the review for acceptability, control results for quantitative tests should be evaluated over time to see if there are any shifts, trends or other signs of instability. Shifts and trends both signify a change in the mean; although, trends occur more gradually than shifts. See figures 1a & 1b for examples of Levey Jennings charts which show shifts and trends.

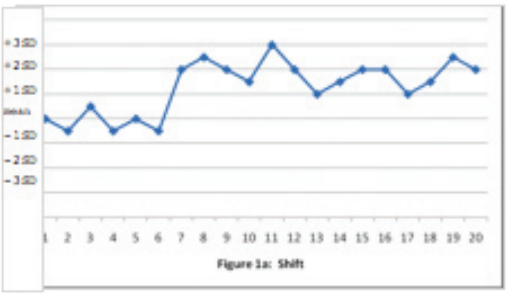

Figure 1a: Shift

Figure 1b: Trend

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 it's 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 it's publication standards. COLA and it's 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.

OCCURRENCE MANAGEMENT continued from page 2

The test system manufacturer also sets the requirements for the frequency of Quality Control. Some relatively simple test systems may require QC to be run only when the kit is first put into use or when the reagent lot changes. These systems have internal failsafe mechanisms performed at the same time as each patient test that confirm the system is operating as expected, no environmental changes which could affect performance are detected, and the personnel performing the test have followed the appropriate steps. Some even prevent the system from producing a result if it is not performing correctly. These mechanisms take the place of running controls more frequently. Other more complicated systems may require QC to be run daily or once per shift (every 8 to 12 hours).

For this scenario, our test system is a quantitative chemistry instrument that requires two controls (low and high) be run daily for each analyte. We perform testing for five different analytes. The "low value" analytes are all contained in one low control; the "high value" analytes are all contained in a single high control. We do not have to keep track of 10 different controls for the five analytes that we test.

For the last several weeks, the controls have been run daily and have been reviewed prior to reporting patient results. Any out of range values were handled appropriately according to protocol. All reviews and corrective actions have been documented and tracked. Routine maintenance procedures have been performed as scheduled. The instrument manufacturer performed annual maintenance, including complete recalibration, one month ago. No QC irregularities have occurred as a result of any maintenance procedures. However, today, we have a problem with the high control for CRP (C-reactive Protein) which is greater than 4SD above the mean. Even though we have just one value that is out of the acceptable range, the fact that it is so far from the mean warrants an investigation. Patient testing must not be performed until the reason for this occurrence can be determined.

The past articles in this series have listed several questions to be asked during the investigation of an occurrence, in an attempt to determine its root cause. The investigation is different when the occurrence involves QC, since statistically, QC errors can be random errors. This means that a control can be out of range simply because of the odds; one in 20 control values will be beyond the commonly accepted ± 2SD range.

Step 1: Because of this fact, one of the most common initial corrective actions performed when QC is out of range is to repeat the control. Confirm that you are using the correct QC material and rerun the unacceptable control. If the value of the repeat run is within range and nothing else has changed, the original was probably out due to random error, indicating that no test system, instrument, environment, or operator problem exists. Patient results can be reported, in accordance with your laboratory policy. If the repeat run is still out of range, further investigation is needed and all patient results should be held pending the outcome of the investigation. As with other investigations, all QC values and all actions taken during the investigation have to be properly documented.

Step 2: The next step is to determine if there is a problem with the control itself. Has something changed? Was a new vial opened? Was a new lot started? If it was necessary, was the bottle reconstituted correctly? Has it been stored under the proper conditions? Has the bottle been tightly closed (to prevent evaporation)? Are there signs of deterioration or contamination (cloudiness, precipitation, change in consistency or color, etc.)? Is it near or past the expiration date? Remember that the viability range may shorten when the bottle is opened. Note that these questions assess the control itself, the environment affecting the control and testing personnel's use of the control. All are factors that can affect controls and cause QC to be out of range.

If the control is used for several analytes, it is likely that a problem with the control itself will affect most or all of the analytes involved. However, this is not always the case. For example, if only one of four control analytes is light sensitive, that will be the only one that is affected if the control is improperly stored under bright lights.

If you suspect that your QC problem lies with the control, open a new vial and rerun QC. If the new vial result is within acceptable limits, patient results can be reported in accordance with your laboratory policy. If the new result is not within the acceptable range, further investigation is needed. All patient results should be held pending the outcome of the investigation, as the investigation may show that patient samples have to be retested. If so, the results of the repeated tests would be reported.

Step 3: Now, we turn our attention to the test system, starting with the reagents. The same questions we asked about the control can be asked about the reagents.

continued on page 4

OCCURRENCE MANAGEMENT continued from page 3

Again, be sure to ask environmental and testing personnel questions. If you suspect that the problem lies with one (or more) of the reagents, replace the reagent(s) and rerun *all* levels of QC. Since a component of the test system changed, the *system* has to be rechecked to ensure that it is still functioning properly. Thus, all levels of QC have to be repeated. If the QC is out of range due to the reagent, previous patient samples may have been affected. Following your laboratory protocol, you will have to evaluate samples run since the last acceptable QC, which may mean that you pull these samples and repeat the testing.

If the repeated QC values are within acceptable limits, patient samples can be tested using the new reagent and results can be reported. If the repeated QC values are not within the acceptable range, further investigation is needed. Again all patient results should be held pending the outcome of the investigation.

Step 4: Even though we checked and changed the reagent, we have not evaluated the entire test system. The instrument itself is another component of the test system and needs to be checked. The type of instrument involved will dictate what is actually evaluated. You may have to inspect, clean or replace individual components such as tubing, filters, lenses, cups, cartridges, batteries, syringes, motors, scanners, etc. In general, though, the main things to check are maintenance and calibration. Periodic maintenance includes inspecting, cleaning or replacing individual components. Calibration is required periodically and when certain maintenance is performed.

This would be a good time to confirm that personnel are properly following testing procedures, since not following procedure can cause QC to be out of range. Then, complete any missing maintenance and/or calibration and rerun all controls for all affected analytes. If the repeated QC values are within acceptable limits, patient samples can be tested and the results can be reported. If the repeated QC values are still not within the acceptable ranges, further investigation is needed. Continue to hold all patient results until the investigation is complete.

Step 5: As just stated, calibration is required after some maintenance procedures. It is also possible for parts of the test system to gradually deteriorate or change over time causing variations in the test system that warrant recalibration. However, this may not be noticeable until QC results are out of range. Once other possible causes are ruled out, recalibrate the instrument and rerun all affected controls. If the repeated QC values are within acceptable limits, patient samples can be tested and the results can be reported. If the repeated QC values are not within the acceptable ranges, further investigation is still needed and all patient results should continue to be held.

Common steps to follow when QC is out of range

Step 1	Rerun the control
Step 2	Open new control and rerun
Step 3	Check, change reagents Rerun controls
Step 4	Check, perform maintenance Rerun controls
Step 5	Recalibrate the instrument Rerun controls
Step 6	Contact the manufacturer

With each step, be sure to address personnel and environmental concerns

Step 6: If after all these steps, QC values are still not acceptable, it is time to check with the manufacturer. The manufacturer's representative may be able to suggest steps to take that are specific for the test system. They may be aware of issues seen in other laboratories as well as the corrective actions taken by those labs. They may have had complaints about the particular kit or reagent lot that you are using. (If this is the case, they should send replacements free of charge.) They can make suggestions as to what else could affect the QC results, how it should be evaluated, and how to correct the problem.

As with any other occurrence, corrective action must be instituted and a follow-up evaluation must be performed to ensure that the action taken has been effective. Everything must be properly documented.

Let's apply these steps to our scenario. We reran the original high control and our repeat result was still outside of the acceptable range. We then checked the control, including how it was stored and handled. We

continued on page 5

OCCURRENCE MANAGEMENT continued from page 4

replaced and reran it. Since the repeat value was still unacceptable, we did the same with the CRP reagent. Both the low and high controls were repeated after the reagent change. The low control was within range, but the high control remains unacceptable. As mentioned earlier, all routine maintenance procedures, including annual maintenance, have been performed and documented, as scheduled. We tried recalibrating the instrument and ran both the high and low controls after recalibration. The CRP high control still remains unacceptable. All control values and all the actions we have performed have been properly documented.

When we called the manufacturer, one of the first things they suggested was something that we overlooked: check for clerical errors.

Clerical errors can occur at any time, during any procedure. In our scenario, a new control lot was just put into use. According to protocol, the manufacturer control ranges were verified when the new lot was received. The old lot was continued until it was depleted, so the new lot was first used today. The new control ranges for all analytes were updated in the QC files, except for the CRP high control range. It appears that the person entering the new ranges got called away while she was entering the data. When she returned to finish the task, she did not double check her entries to ensure that all the ranges were updated.

Clerical error is quite common with Quality Control issues. Checking and rechecking data entry should be incorporated into routine protocols. It should also be one of the first things considered during an investigation of any occurrence, especially if a new control or reagent lot was recently placed into use.

Once the control range was updated in the QC files, we discovered that all of the control values were actually within the acceptable range. Our corrective action is to add clerical checks to the procedure we follow when new control lots are started. These checks include having a second staff member ensure that the correct reagent and QC lots are in use, that the correct calibration factors are in use, that all of the control ranges have been verified and that all of the QC files have been updated with the new ranges.

We hope that you have been finding these articles helpful. The series will continue in the next Insights *issue when we address management of an occurrence in the post-analytic phase.*

EDUCATIONAL RESOURCES

COLA wants to provide all the help we can when it comes to Quality Assurance and Quality Control. We offer many educational resources to help meet your QA / QC needs. Since we know that it is sometimes difficult to keep track of everything that's offered, we created this table to direct you to the available assets that address these topics. The table provides a brief description as well as the online location of the product. Most of the downloadable resources are free to COLA labs and many of the online courses are available at discounted prices.

All of the following information can be accessed via www.COLAcentral.com or from the "Member Site" at www.cola.org. Use the navigational buttons to access "Educational Resources" and/or "COLA Store."

DOWNLOAD / HARD COPY PRODUCTS

CLIA Fact Sheets

#14: Quality Systems–General Laboratory Practices
http://www.cola.org/storage/c14.pdf
"Quality Systems" is a term that refers to all of the laboratory's policies, processes, procedures and resources needed to achieve quality testing. This fact sheet contains an introduction to the Quality Systems concept.

#15: Quality Systems–Pre-Analytic Phase
http://www.cola.org/storage/c15.pdf
CLIA Facts 14 introduces the Quality Systems concept. This fact sheet (15) discusses the pre-analytic phase of testing.

#16A: Quality Systems–Analytic Phase–Procedure Manual & Test Systems
http://www.cola.org/storage/16a.pdf

#16B: Quality Systems–Analytic Phase–Performance Specifications & Calibration
http://www.cola.org/storage/16b.pdf

#16C: Quality Systems–Analytic Phase–Maintenance & Function Checks & Test Records
http://www.cola.org/storage/16c.pdf

#16D: Quality Systems–Analytic Phase–Comparison of Test Results & Corrective Actions
http://www.cola.org/storage/16d.pdf

#16E: Quality Systems–Analytic Phase–Control Procedures
http://www.cola.org/storage/16e.pdf
CLIA Facts 14 introduces the Quality Systems concept. These fact sheets (16A -16E) discuss components of the analytic phase of testing, as indicated in the titles.

#17: Quality Systems–Post-Analytic Phase
http://www.cola.org/storage/cf17.pdf
CLIA Facts 14 introduces the Quality Systems concept. This fact sheet (17) discusses the post-analytic phase of testing.

The following fact sheets provide control procedures based on the CLIA regulations for the indicated specialties.

#18: Control Procedures for Chemistry
http://www.cola.org/storage/cf18.pdf

#19: Control Procedures for Hematology
http://www.cola.org/storage/cf19.pdf

#20: Control Procedures for Microbiology
http://www.cola.org/storage/cf20.pdf

#21: Control Procedures for Immunohematology
http://www.cola.org/storage/cf21.pdf

Cytology Fact Sheets – The following fact sheets provide control procedures based on the CLIA regulations for the indicated aspects of cytology.

#4: Cytology Quality Control: 10% Rescreen of Negative Gynecologic Cases
http://www.cola.org/storage/cytology_final4.pdf

#5: Cytology Quality Control: 5-Year Retrospective Review
http://www.cola.org/storage/cytology_final5.pdf

#6: Cytology Quality Control: Correlation of Cytology Reports
http://www.cola.org/storage/cytology_final6.pdf

#8: Cytology Quality Control: Comparison of Each Individual's Case Reviews to the Overall Laboratory Statistical Values
http://www.cola.org/storage/cytology_final8.pdf

#9: Cytology-Specific QA Monitors
http://www.cola.org/storage/cytology_final9.pdf

Lab Facts

#50: Quality Control Primer
http://www.cola.org/storage/elf50.pdf
This focuses on Quality Control (QC) as an essential element of all test systems in your laboratory.

#70: Quality Assurance in the Laboratory
http://www.cola.org/storage/LG70.pdf
This is a primer for Quality Assurance; how to define it, the type of documentation to maintain, what to include in a QA Plan and how to implement it in your laboratory.

Information Packet

QA Help Packet
http://www.cola.org/storage/QAHelpPack.pdf
Guide to writing Quality Assurance plans and conducting written Quality Assurance reviews.

Quality Assurance

Quality Assessment Plan: A Simplified Approach
http://www.cola.org/product.html?ProductID=331
CLIA regulations emphasize the need to assess quality across the entire path of workflow. This QA Plan allows you to do this efficiently and effectively, by incorporating QA into your laboratory's daily routines.

Quality Management Systems Collection from CLSI

A Quality Management System Model for Health Care; Approved Guideline—Second Edition
http://www.cola.org/product.html?ProductID=253
This guideline provides the necessary information to develop a quality management system. It also provides a structure for a comprehensive, systematic approach to build quality into the healthcare organization's processes, assess the organization's performance, and implement quality improvements.

Application of a Quality Management System Model for Laboratory Services: Approved Guideline—Third Edition
http://www.cola.org/product.html?ProductID=252
This guideline expands on the guidance presented in the above document. It describes the path of workflow and provides information that will help your laboratory improve its processes, and meet governmental and accreditation requirements.

Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition
http://www.cola.org/product.html?ProductID=256
This guideline defines Continuous Quality Improvement (CQI) and explains how to implement CQI through important quality system management approaches. To achieve CQI, the clinical service needs to synchronize five quality system components including Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.

Quality Specialty Collection
http://www.cola.org/product.html?ProductID=257
The collection includes the three guidelines listed above as well as two additional tools: "Laboratory Documents: Development and Control; Approved Guideline-Fifth Edition (2006)" and "Training and Competence Assessment; Approved Guideline -Third Edition"

COLA offers online courses that can be accessed through the Member site at www.cola.org. Click on "COLA Store" and "On-line Courses." Then browse the subcategories of Laboratory Science and Quality Management Systems. CEexpress 3 also addresses Quality Systems.

COLA QUALITY

COLA is revolutionizing the way clinical laboratories deliver patient care. Utilizing experienced, COLA-dedicated surveyors who want you to succeed, our approach to accreditation is educational and consultative, rather than confrontational. Our multitude of educational products (including the biennial Symposium for Clinical Laboratories, online courses, and printed or down-loadable manuals and guides) is further evidence of our emphasis on education. With this core strength in accreditation and education, and our focus on quality, COLA empowers your laboratory to provide quality patient care and prevent citations that could jeopardize your CLIA status.

Our online portal, COLAcentral (www.colacentral.com) is designed to help you better manage your laboratory, improve the quality of your services, and increase your profitability. Using COLAcentral will help you achieve compliance prior to your first survey and/or maintain compliance throughout the accreditation cycle.

The following features showcase our commitment to providing quality service to you:

- Online form completion: most of your laboratory information can be submitted and updated online
- A 2GB Document Repository: you can easily upload and safely store your important documents, including compliance materials, CLIA certificates, personnel records and other laboratory documents
- Cost savings: by updating these documents and your laboratory information online, you save money by reducing postage and paper usage
- An Inventory Control module created specifically for your lab: you are able to monitor and manage your supplies, equipment (including maintenance) and all of your inventory
- A color-coded dashboard to easily oversee your Proficiency Testing results
- Educational products matched to your specific concerns and citations
- Personalized alerts and email warnings to notify you of what is most important to you (accreditation, PT, etc.)
- Consultants and managers: view and manage all of your labs using one COLAcentral user log-in

These aspects of COLAcentral are in addition to our educational products designed to help you with all of your laboratory medicine needs and our outstanding team of Technical Advisors who provide "the personal touch" as they answer your questions and discuss your concerns when you call our Customer Support line (1-800-981-9883).

Together, as partners in prevention, performance and profitability, we can excel in providing quality patient care.

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 to get started or call 1-800-981-9883.

COLAcentral℠

COLA
Lab Accreditation Through Education

9881 Broken Land Parkway, Suite 200
Columbia, MD 21046-1195
www.cola.org | www.COLAcentral.com

PAID SUBSCRIPTION

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