COLA FAST FACTS 35-2017

COLA Patient Safety Program – Risk Management

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. COLA is also focused on reducing the frequency of citations for criteria that impact, or can potentially impact, patient safety. Through this program, COLA will identify an existing COLA criterion or patient safety issue as the patient safety goal for each year, and provide education on good laboratory practices for implementation of that safety goal. The program has also been integrated into the COLA survey process.

The COLA Patient Safety Goal for 2017 is:

QC 31.1: For any eligible test system with a manufacturer's QC protocol which is less stringent than the CLIA regulatory requirement, has the laboratory developed and implemented an IQCP that adheres to the manufacturer's QC protocol, at a minimum?

The IQCP must include the Risk Assessment, the QC Plan, and monitoring the effectiveness as part of the laboratory's QA Plan. If IQCP is not implemented, the default CLIA regulatory requirements must be met.

In 1999 the Institute of Medicine (IOM) published a study entitled "To Err Is Human: Building a Safer Health System." The estimated number of deaths and adverse outcomes caused by medical errors sent shockwaves throughout the healthcare community as well as the general population. This information prompted members of the healthcare community to seriously look at the way healthcare is delivered and how the process could be improved to enhance patient safety.[1]

Read more: New Institute of Medicine Report Finds Diagnostic Errors Continue to Put Americans at Risk | Dark Daily http://www.darkdaily.com/new-institute-of-medicine-report-finds-diagnostic-errors-continue-to-put-americans-at-risk-1207#ixzz4WmfZisTw

The IOM then published "Improving Diagnosis in Healthcare" in 2015 which again underscored the critical importance of reducing errors. Pathologists, Lab Directors, and Clinical Consultants can be instrumental in reducing diagnostic errors through better communication with providers to ensure that physicians not only order the correct clinical laboratory tests, but also select the appropriate therapies based on test results.[2] Laboratories can contribute to reducing errors by identifying and mitigating risk throughout all phases of testing. There is likely to be continued emphasis on risk assessment within the laboratory community.

Why Risk Assessment is so important

Clinical laboratory tests play an integral role in medical decision-making. Therefore, the results must be reliable and accurate. Unfortunately, no laboratory test or instrument is without errors. These errors can occur at the pre-analytical, analytical and post-analytical phases of testing. Risk Assessment is an important part of IQCP. Using Risk Assessment, the lab can evaluate possible conditions that could lead to errors and outline the necessary steps to detect and prevent errors before they cause patient harm.[3]

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Risk Assessment is the first of three steps of the IQCP

Risk Assessment identifies and evaluates potential failures and sources of errors in your testing process. It must include an evaluation of the following components:

- Specimen
- Test system
- Reagent
- Environment
- Testing personnel
- Pre-Analytic, Analytic, and Post-Analytic Processes

You will find that some risks could fit under more than one of the risk assessment components. Identify the risks under the component that is most appropriate for your laboratory.

Performing Your Risk Assessment

To begin your risk assessment, ask yourself these questions for each Risk Assessment Component: (1) What are our possible sources of error? What can go wrong? (2) Can our identified sources of error be reduced? (3) How can we reduce the identified sources of error?

Review and assess all manufacturers' information and other applicable resources to determine sources of error. Some documents you may want to include are:

- Laboratory Procedures & Policies
- Manufacturer's Package Inserts
- Instrument Manuals
- Calibration/Calibration Verification Records
- Performance Specifications
- Proficiency Testing Records
- Complaint Records
- Testing Personnel Competency and Training Records
- Quality Assessment Reviews

There may be other records that you want to review as part of the Risk Assessment process. Keep in mind that you are not limited to what is listed above. For more information about Risk Assessment and the IQCP process, Lab Guide 53 – Individual Quality Control Plan is available on COLAcentral®

You will then develop your QC Plan based upon learnings from the Risk Assessment. The QC Plan and Risk Assessment should be reviewed at least annually, and/or when there are failures in the test performance, to confirm their effectiveness.

[1] *Risk Management in the Clinical Laboratory (*https://www.labce.com/risk_management_clinical_laboratory.aspx)
[2] *New Institute of Medicine Report Finds Diagnostic Errors Continue to Put Americans at Risk* http://www.darkdaily.com/new-institute-of-medicine-report-finds-diagnostic-errors-continue-to-put-americans-at-risk-1207#axzz4W8c8jq9u
[3] *Abstract – Risk Management in the Clinical Laboratory (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4071183/)*

Resources:

- *COLA Lab Guide 53 – Individual Quality Control Plans*
- *https://www.cms.gov/Regulations-and Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.htmlhttp://www.ncbi.nlm.nih.gov/pmc/articles/PMC3249958/*