EDUCATIONAL COMMENTARY – RISK ASSESSMENT IN THE CLINICAL LABORATORY AND HOW IT APPLIES TO A LABORATORY QUALITY-CONTROL PLAN

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LEARNING OBJECTIVES

On completion of this exercise, the participant should be able to

- explain risk assessment as it relates to federal regulations.
- explain the three parts of an individualized quality control plan (IQCP).
- list the five components that must be evaluated in a risk assessment for IQCP.
- describe the methods used in a risk assessment.

Risk assessment has been used for several years in many industries to evaluate safety risks in the work environment and to identify strategies to mitigate those risks and put safety procedures in place. Risk assessment and management are used in the clinical laboratory in a similar way when developing a robust quality plan for the testing process. Risk assessment helps clinical laboratories recognize potential adverse events, be proactive and forward thinking, and establish appropriate measures to prevent or minimize negative outcomes to patient care. With new federal regulations set forth by the United States government, it is essential that each clinical laboratory approach their quality processes in a more structured and systematic way.

"The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the United States through the Clinical Laboratory Improvement Amendments (CLIA)." CMS is implementing a new quality control option based on risk management, referred to as an individualized quality control plan (IQCP). The IQCP must include a risk assessment, a quality control plan, and quality assessment. IQCP is described in CMS’s Survey & Certification Letter 13-54 CLIA and is currently in the Education and Transition period until January 1, 2016. During this time, laboratories will have the opportunity to develop a quality control system based on the IQCP principles that includes all phases of testing in the risk analysis for each laboratory test system. After that date, there will be two acceptable quality control (QC) options for nonwaived testing in all CLIA specialties and subspecialties with the exception of Pathology, Histopathology, Oral pathology, and Cytology.

The first option that laboratories may choose is to follow the CLIA regulatory requirements as written in the Code of Federal Regulations (CFR) under the title of 42CFR 493 in subpart K, Quality System for Nonwaived Testing. Essentially, two levels of QC must be performed per day of patient testing unless the manufacturer requires it more often.
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The second option is to implement an Individualized Quality Control Plan as described in Attachment 1 to the CMS letter. This plan requires three elements: a risk assessment, a quality control plan, and a quality assessment protocol. The initial risk assessment applies to all phases of testing (preanalytic, analytic, and postanalytic) while addressing five essential components of the testing process. These five areas identified by CLIA for potential testing failures are sample collection, operator (testing personnel), reagents, laboratory environment, and measuring system. The IQCP procedure is meant to validate an analytic systems control procedure that is less stringent than the regulatory requirements specified by CLIA of two levels of control per day of patient testing. However, laboratories are not permitted to perform quality control on a less frequent basis than recommended by the manufacturer.²

A risk assessment in the clinical laboratory is an action or series of actions taken to identify and evaluate potential failures or sources of errors in the entire testing process. The risks identified are evaluated, scored, and prioritized in terms of severity and frequency of potential harm. A QCP is developed with the intention of mitigating or preventing the potential failure or error from occurring, with error detection strategies that are immediate and measurable. Finally, applying a routine review of these quality assurance strategies ensures that the QCP is effective for risk management.

The initial step in performing a risk assessment is gathering information and data. There are several possible sources that may be useful³:

- Regulatory requirements
  - Mandated QC procedures
  - Required quality assurance activities
  - Regulatory agency recall and device failure notifications
- Measuring system information from the test system manufacturer
  - Manufacturer’s package insert (to include intended use, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances, performance specifications, etc.)
  - Manufacturer’s test system operator manual
- Laboratory information
  - Environmental conditions (temperature and humidity monitoring of physical space as well as reagent storage in refrigerators/freezers)
  - Verification or establishment of performance specifications for the test system (manufacturer and performing laboratories test validations, proficiency testing evaluations, QC performance)
  - Testing personnel qualifications, training and competency records
  - Review of prior failures in testing (incident reports, proficiency testing failures, QC failures, etc.)
- Publications and reports from laboratory peers
  - Published performance evaluations
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- Published clinical studies
- Informal feedback from other users

• Clinical information
  - Clinical applications for use of a test result
  - Reference intervals and clinical decision levels
  - Potential medical errors that could result from incorrect, delayed, or no results
  - The severity of patient harm that would result from the potential failure

These data are evaluated to identify sources of potential failures and sources of error in the entire testing process. This evaluation should include identifying the potential for error in five main areas:

1. Specimen: The specimen may be at risk for error in the preanalytic phase. Evaluate critical steps in specimen collection, labeling, storage requirements, stability and transport to the testing lab, processing, acceptability, and rejection criteria.

2. Environment: The environmental conditions in the laboratory can affect the test system’s performance, for example, temperature, airflow/ventilation, light intensity, noise and vibration, humidity, altitude, dust, water quality, electrical failure/power supply variance or surge, and adequate space.

3. Reagent: The reagents, quality control materials, calibrators, and similar materials required for test processing are susceptible to failure with shipping/receiving, storage conditions, expiration date (unopened/opened state), and preparation.

4. Test System: This risk assessment will primarily cover the analytic and postanalytic phase of testing and must consider function checks and maintenance as required by the manufacturer. This may vary with the laboratory’s test volume and intended use of the test results (i.e., screening or diagnostic). Factors in this category are quite variable:
   - Sampling issues—inadequate sampling, clot detection capabilities, capability for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
   - Calibration-associated issues
   - Mechanical/electronic failure of test system—optical, pipettes, sample probes, barcode readers
   - System controls and function checks failure—built-in procedural and electronic controls, liquid quality controls, temperature monitors and controllers
   - Software/hardware issues
   - Transmission of data through an interface to the LIS/EMR
   - Result reporting format

5. Testing Personnel: This potential risk relates to training and competency assessment. The impact of inadequate training, ongoing competency, appropriate education and experience qualifications of staff, and adequate staffing resources can be significant in test systems that are highly complex.

After identifying the areas where potential failures and sources of error may exist, evaluate the risk severity. Ask the question: If the error or failure event occurred, what is the severity of harm and probability of harm to the patient?³
The severity of harm should be considered as the worst-case scenario. This can be assessed in the following terms:

- Negligible: inconvenience or temporary discomfort
- Minor: temporary injury or impairment not requiring professional medical intervention
- Serious: injury or impairment requiring professional medical intervention
- Critical: permanent impairment or life-threatening injury
- Catastrophic: results in patient death

The probability of the error or failure event occurring can be assessed in the following terms and should consider such things as test volume/frequency when applying this grading:

- Frequent: once/week
- Probable: once/month
- Occasional: once/year
- Remote: once every few years
- Inconceivable: once in the life of the measuring system

If potential failures are identified as moderate to high risk for harm to a patient, these are the areas of the test system that should be targeted as a priority for a QCP. The process of developing a plan to mitigate the error risk or prevent it entirely is essential to a robust IQCP. The QCP is a document that describes what the laboratory does to ensure the accuracy and reliability of test results. The QCP addresses each risk identified in the entire testing system and provides for immediate detection of errors that may occur due to test system failure, adverse environmental conditions, and operator performance at each phase of the testing, from preanalytic to postanalytic processing. It must at least include the number, type, frequency of testing, and criteria for acceptable results of the QC. If the evaluation of the risk assessment called for additional measures to reduce significant errors, it may also address electronic controls, procedural controls, training and competency assessment, and other activities essential for reporting a reliable test result.²

Finally, a QCP must include a process for reviewing the effectiveness of the documented quality plan. If there are changes in the test system, reevaluation of the QCP is necessary. This quality assessment monitoring should include the following components and respective documents:

- Testing personnel—Training and competency records
- Environment—Records of maintenance, corrective actions, and follow-up
- Specimens—Specimen rejection logs, patient results review, and turnaround time reports
- Reagents—QC review and proficiency testing records
- Test System—Records of maintenance, preventive measures, and repairs

When the laboratory discovers an error or failure event, an investigation must be conducted to identify the cause of the failure and the severity of the impact on patient care. The investigation must be documented by the laboratory and must include the failure, corrective actions, impact to patient(s), and plan to reduce
the future risk for recurrence of the failure. The test system may require an updated risk assessment and modification to the QCP.²

Laboratories have been performing risk assessment in many ways, including method validation, QC requirements, maintenance records, and written procedures. What is needed now according to the new IQCP guidelines is a formalized, documented approach to risk assessment, and QC practices that do not fall into the traditional quality control of two levels of QC performed each day of patient testing. IQCP addresses the test systems that have advanced to internal QC and electronic monitoring of test system performance referred to as EQC in the current CLIA regulations. A documented IQCP will include a comprehensive risk assessment, a procedure addressing error detection in terms of a QC plan, and a policy of periodic assessment to ensure the established QCP is an effective tool in producing accurate and reliable test results.

References


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