

CLIA Corner

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In This Issue...

Risk Assessment in relation to the Individualized Quality Control Plan (IQCP)

Risk assessment is one of the three components that must be addressed in any IQCP plan. In order for the laboratory to create a successful risk assessment policy, it must consider three risk concepts: risk management, risk assessment, and risk mitigation. Risk concepts are not new to the laboratory. The laboratory is already performing risk concepts everyday by:

- Evaluating the performance of new devices;
- Troubleshooting instrument problems;
- Responding to physician complaints;
- Reporting corrected results;
- Taking actions to prevent errors; and
- Training and assessing competency of personnel

In order to successfully perform IQCP, the laboratory will need to formalize and gather data to support these risk assessment activities.

DEFINITIONS:

Risk: the probability or threat of quantifiable damage, injury, liability, loss or any other negative occurrence that is caused by external or internal vulnerabilities, and that may be avoided through preemptive action. In the context of laboratory testing, risk includes identifying factors that have the potential to cause a problem or negative outcomes relating to patient test results.

Risk Management: a three-step process which includes steps to identify and evaluate risks, implement practices to reduce risks, and monitor practices for effectiveness and adjust as needed.

Risk Assessment: the identification and evaluation of potential failures and sources of errors in a testing process.

Risk Mitigation: an action to lower or eliminate the risk associated with an adverse situation, or to prevent the occurrence of future errors.

LET'S GET STARTED!!

Risk assessment must encompass the entire testing process: **pre-analytic, analytic and post-analytic**. When performing risk assessment in regards to IQCP, the risk assessment must include (at a minimum) an evaluation of five risk assessment components: **specimen, environment, reagent, test system and testing personnel**. There

is no right or wrong way to categorize risks. One laboratory may identify a particular risk under the component “specimen,” while another laboratory may identify the same risk under the component “test system.” This is perfectly acceptable. Here is a list of the five necessary components and some possible risks to evaluate under each:

Specimen:

- Patient preparation
- Specimen collection and labeling
- Specimen storage, preservation and stability
- Specimen transportation and processing
- Specimen acceptability and rejection, and
- Specimen referral

Environment

- Temperature
- Airflow/ventilation
- Humidity
- Water
- Lighting/intensity
- Adequate space
- Utilities (electrical failure/current variations or surges)

Reagent

- Shipping and receiving conditions
- Storage conditions
- Expiration dates (may differ based on storage requirements)
- Preparation instructions/requirements

Test System

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus or turbidity)
- Use of incorrect reagents, controls or calibrators (e.g., mixing reagents from one lot number of a test kit with another lot number)
- Placement of device (e.g., placing device near a window with direct sunlight may cause instrument to over-heat causing errors with controls, calibrators and patient test results.)
- Function checks
- Control failures
 - Built-in procedural (internal controls) and electronic controls
 - External or internal liquid quality controls (assayed vs. unassayed)
- Calibration associated issues
 - Stability over time
 - Power failures
- Hardware, software and electronics integrity
 - Power failure or fluctuation
 - Incorrect voltage
 - Repeated plugging and unplugging of the device
 - Physical trauma to unit, moving the unit
- Hardware, software, mechanical and electrical failures
 - Optics
 - Pipettes or pipettors
 - Barcode readers

Testing Personnel

- Appropriate education and experience, qualifications
- Training
- Competency
- Adequate staffing
- Adequate supervision

There are numerous resources for the laboratory to use when identifying and evaluating risks. The manufacturer's package insert and operator's manual will be among the most valuable resources. When reviewing the package insert or operator's manual, pay attention to the intended use, limitations, environmental requirements, quality control frequency, specimen requirements, reagent storage, maintenance and calibration requirements, and interfering substances. Other resources which will prove to be useful while identifying potential risks include: troubleshooting guides, manufacturer's alerts and bulletins, method evaluation/verification of performance specifications, training manuals, testing personnel records, quality control data (including historical data), proficiency testing data, quality assessment information, previous survey/inspection deficiencies, and scientific publications and journals.

CONDUCTING THE RISK ASSESSMENT

After the laboratory has identified possible risks in each of the five components through all phases of testing (pre-analytic, analytic, and post-analytic), the laboratory will need to document how the risks will be mitigated and/or monitored. The laboratory will need to evaluate the frequency for potential failures and errors, and the impact of the potential failures and errors on patient testing. The laboratory must document all risk assessment activities and then collect data which supports the risk assessment. The data can be historical (e.g., equivalent quality control records) or current (e.g., performance specifications including accuracy, precision, reportable range and reference range).

Risk assessment in regards to IQCP is required for all non-waived test systems; there are no special guidelines for laboratory developed tests. Risk assessments must be performed for each test system, not each testing device. For identical devices (same make and model), a single risk assessment may be performed. The risk assessment data might suggest a different quality control plan for the same analyzer, depending on factors like testing personnel and environment. These differences must be taken into consideration when evaluating your risk assessment.

LINKING RISK ASSESSMENT TO QUALITY CONTROL AND QUALITY ASSESSMENT PLANS

After the laboratory has identified and evaluated the sources of potential failures and errors for a testing process, and evaluated the frequency and impact of those failures and errors, the resulting risk assessment is used to develop the quality control plan. Once the quality control plan is implemented, the laboratory must establish a review system (quality assessment) for the on-going monitoring of the effectiveness of the quality control plan. When the laboratory discovers a testing process failure, the laboratory must conduct and document an investigation to identify the cause of the failure, its impact on patient care and then make appropriate modifications to the quality control plan.

In summary, risk assessment is nothing new to the laboratory. However, in order for a laboratory to implement IQCP for one of more its non-waived test systems, the laboratory will be required to incorporate risk assessment processes.

EXAMPLE RISK ASSESSMENT

Below is an example of a risk assessment for a serum pregnancy test kit. *The example is for teaching purposes only and is not to be interpreted as a “CLIA-approved” risk assessment for any specific laboratory or test system. Risk assessments must be customized for each laboratory.* The laboratory may identify different risks, place the risks in a different component category, or identify different ways to mitigate risks. This example is a test kit and not an actual analyzer, therefore we did not include information about calibration, calibration verification and instrument maintenance. Finally, there is no supporting data with the example, as it is a fictional example and we don't have supporting data.

[QUALITATIVE SERUM HCG TEST KIT RISK ASSESSMENT] July 28, 2014				
Testing Phase	Component	Potential Failures and Sources of Errors	Patient Impact	Mitigation of Risks
Pre-Analytic	Specimen	Mislabeled specimen	Potential for misdiagnosis	Ensure training and competency assessment includes proper patient identification and specimen collection, labeling and handling.
Pre-Analytic	Specimen	Wrong specimen type	Potential for misdiagnosis	Ensure training and competency assessment includes proper patient identification and specimen collection, labeling and handling.
Analytic	Specimen	Improper storage or handling	Inaccurate results	Check manufacturer's package insert for proper storage and handling requirements.
Pre-Analytic	Environment	Unacceptable storage temperature & humidity	Inaccurate results	Record daily temperatures and humidity if appropriate (refrigerator and room); Take and document corrective action if out of range.
Pre-Analytic	Environment	Physical damage to test system	Inaccurate results	Ensure policies and procedures in place for discontinuing use of damaged test kits.
Pre-Analytic	Environment	Inadequate storage space	Inaccurate results	Ensure policies and procedures in place for test kit inventory and ordering of lab supplies.
Analytic	Environment	Unacceptable testing temperature	Inaccurate results	Record daily temperatures and humidity if appropriate (refrigerator and room); Take and document corrective action if out of range.
Pre-Analytic	Reagent	Improper shipping conditions	Inaccurate results	Contact manufacturer and/or distributor.
Pre-Analytic	Reagent	Improper reagent storage	Inaccurate results	Record daily temperatures and humidity if appropriate (refrigerator and room); Take and document corrective action if out of range.
Analytic	Reagent	Use of expired reagents	Inaccurate results	Record lot numbers and expiration dates on the reagent and/or QC logs. Check kit expiration dates prior to use.
Analytic	Reagent	Interchanging reagents from different kits	Inaccurate results	Ensure training and competency assessments include checking expiration dates and only opening/using one test kit at a time.

[QUALITATIVE SERUM HCG TEST KIT RISK ASSESSMENT] July 28, 2014				
Testing Phase	Component	Potential Failures and Sources of Errors	Patient Impact	Mitigation of Risks
Analytic	Test System	Inadequate sampling	Inaccurate results	Ensure testing personnel are trained and competent with test procedure.
Analytic	Test System	Incorrect reagents used or in the wrong order	Inaccurate results	Ensure testing personnel are trained and competent with test procedure.
Analytic	Test System	Control failure	Inaccurate results	Review historical data and on-going QC results to determine frequency of QC (internal and external) failures. Ensure policies and procedures are in place for taking and documenting corrective action when QC fails.
Post-Analytic	Test System	Incorrect interpretation and report of results	Potential for misdiagnosis	Review past proficiency testing records and performance to determine if there were issues with incorrect interpretation of results. Ensure that training and competency assessments include direct observation of procedural steps, performing QC, interpretation of results, and reporting patient test results.
All	Testing Personnel	Insufficient education, experience and/or training	Inaccurate results	Maintain copies of testing personnel diplomas and/or transcripts and training records.
All	Testing Personnel	Incompetent personnel	Inaccurate results	Ensure policies and procedures are in place for training all new testing personnel. Assess competency twice within the first year of employment and then annually thereafter. Review proficiency testing records and take training and technical assistance when necessary.
All	Testing Personnel	Inadequate staff	Inaccurate results	Monitor turn-around times. The lab director and administration to assess staffing needs accordingly.

REFERENCES:

Centers for Medicare/Medicaid Services (CMS), Center for Clinical Standards and Quality/Survey & Certification Group, Survey & Cert Letter 13-54, Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option, Ref: S&C:13-54-CLIA; Published 08/16/2013.

CMS CLIA Brochure #11, Individualized Quality Control Plan Introduction

Food & Drug Administration, Home Medical Devices Device Advice: Comprehensive Regulatory Assistance

Guidance Documents (Medical Devices), Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices [Issued 01/30/2008; OMB control number: 0910-0598; Expiration Date: 07/31/2016].

