"IQCP for POCT in the Analytic Stage: Decentralized Testing Specific Risk Management and Mitigation"

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Objectives

- Discern the references available to identify potential sources of error for POCT risk management
- Extrapolate viable risk mitigation procedures from test methodology
- Differentiate risk mitigation for POCT versus traditional laboratory setting

VARIABLES IN PHASES OF TESTING

Many variables can affect the accuracy and precision of laboratory test results. Laboratories must be aware of these variables in order to minimize them, as the diagnosis and treatment of patients can be impacted. These variables are divided into preanalytical, analytical, and post-analytical.[1]

- **Preanalytical** variables include specimen collection, transport, and processing
- **Analytical** variables include testing
- **Postanalytical** variables include results transmission, interpretation, follow-up, and retesting

Why is this a problem?

- The laboratory is traditionally the central hub of all testing activities
- With Point of Care Testing, the laboratory is not only decentralized, testing is performed by a wide variety of healthcare professionals
- Risk mitigation varies greatly for all of the five elements of IQCP as well as across the three phases of testing.

The Five Rights

- Right Patient
- Right Drug
- Right Dose
- Right Route
- Right Time

What about identifying the right risks?

Why is this important to me?

- Medical Assistants/Phlebotomists/Nurses/Collection Techs, etc. collect samples for laboratory testing and perform the testing
- January 1, 2016 Centers for Medicare and Medicaid Services (CMS) Individualized Quality Control Plan (IQCP) Interpretive Guidelines went into effect [3]
- Ensure proper understanding of the five elements to be reviewed: Test system, testing personnel, specimen, reagents, laboratory environment

CMS IQCP Definition

- *An IQCP is composed of three parts: a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. The RA is the identification, evaluation, and documentation of potential failures and errors in a testing process. The QCP documents a laboratory's standard operating procedure that describes the practices, resources, and procedures to control the quality of a test process. The QA consists of the laboratory's written policies and procedure for the ongoing monitoring of the effectiveness of their IQCP.*

Why is this important to me?

- POCT testing teams need to work diligently to ensure that there is a clear guideline that is created and utilized system-wide for proper IQCP compliance

- The following summarizes analytical errors in specimen collection that can affect laboratory test results and/or cause injury to the patient.

What do we need to review?

The QCP must at least include the **number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s).** If indicated by the evaluation of the risk assessment, the QCP may also include:

- Electronic controls
- Procedural controls
- Training and competency assessment
- Other specified quality control activities

Electronic controls

ensuring the electronic controls are accurate for testing protocols, specific to analytes and instruments

- Are the electronic controls properly documented?
- Are they plotted over time as a calibrator?
- Is proper maintenance performed and documented? Daily/monthly/as needed?

Procedural controls

commercial or in-house controls should be utilized for the appropriate patient population

- Are the procedural controls performed by testing personnel or a POCT Coordinator?
- Are the controls reflective of the patient population being tested to create a realistic reference range? (Ex. Applicable ranges for neonates, post-surgical patients, ethnic or genetic considerations)

Training and competency assessment

- formal training on testing procedures
  - provided and/or approved by manufacturer,
  - standard SOP created and utilized by all testing personnel

- competency assessment within 6 months of beginning test performance, annually thereafter

Other specified quality control activities

this is unique to your testing facility, especially your **testing population and locations**

POINT OF CARE TESTING SPECIFIC CONCERNS

- Many testing personnel – medical assistants, nurses, phlebotomists, collection techs, etc.
- Many testing devices
- Many testing locations
- Many patient populations

A proper Risk Assessment is the only way to identify all of the concerns and more will always arise!

SPECIMEN	Potential Error	Risk Assessment Can this be detected or prevented by existing controls or practices?	Risk Level	Risk Mitigation (Included in QC Plan)
	The specimen isn't accurately identified throughout the testing process?	YES	ACCEPTABLE	• An approved requisition is the patient's encounter completed by the provider. Testing personnel will collect the appropriate specimens. • Specimen identification – verify by checking printed labels against the information on the encounter. Verify the following: o Patient name, sex, age o Patient ID o Time and date of collection o Phlebotomist ID o Doctor's Name

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  - Patient ID
  - Time and date of collection
  - Phlebotomist ID
  - Doctor's Name

SPECIMEN	Potential Error	Risk Assessment Can this be detected or prevented by existing controls or practices?	Risk Level	Risk Mitigation (Included in QC Plan)
	Criteria for specimen rejection are not established and followed?	YES	ACCEPTABLE	Specimen rejection criteria is clearly outlined in Procedure manual • Specimen acceptability is at the discretion and responsibility of the testing personnel performing the tests. A test not performed (TNP), is utilized in the LIS if testing is not performed. o Common problems are: ▪ Evidence of clotting ▪ Specimens for ACT or PT/INR collected in glass syringes or tubes with anticoagulant of any kind ▪ Other sample types such as urine, CSF and pleural fluid.

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REAGENTS	Potential Error	Risk Assessment Can this be detected or prevented by existing controls or practices?	Risk Level	Risk Mitigation (Included in QC Plan)
	Manufacturer's instructions for reagent preparation are not followed? (e.g. reconstitution of reagents or bringing to room temperature)	YES	ACCEPTABLE	1. Refrigerated cartridges must equilibrate to room temperature prior to opening the protective pouch. a. A box of cartridges must stand at room temperature for 1 hour before use. - Individual cartridges may be used after standing at room temperature for 5 minutes. b. Do not return cartridges to the refrigerator once they have been at room temperature. Be sure and place a new expiration date on the package once it is removed from the refrigerator, if not used right away. 2. Cartridges should be used immediately after they have been removed from the foil pouch.

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TEST SYSTEM	Potential Error	Risk Assessment Can this be detected or prevented by existing controls or practices?	Risk Level	Risk Mitigation (Included in QC Plan)
	The test is performed outside of its intended use as described in the manufacturer's instructions?	YES	ACCEPTABLE	Test is not performed outside of intended use as described in the manufacturer's instructions. The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%. A level surface includes running the handheld in the downloader/recharger.

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POCT Analytical Solutions

Effective Communication

- Ensure that ALL Testing personnel are aware of IQCP requirements
- Ensure proper training of Testing Personnel on all applicable aspects of testing
- Ensure proper documentation of all applicable aspects of testing

POCT Analytical Solutions

Quality Matters Day to Day

- How are testing devices stored?
- Has everyone been formally trained on how to use instruments? Not just OTJ training or shadowing
- How often are devices cleaned? After each use, end of day, start of day?
- Are devices properly charged for use? End of shift, between patients? Is it in someone's pocket?

Summary

- The majority of errors in laboratory testing occur in the Preanalytic phase of testing, ***but*** the POCT testing the same personnel who collects the sample performs the test as well. [4]
- By being aware of what errors may happen you are preparing yourself to proactively prevent them
- January 1, 2016 each stage of laboratory testing is being assessed and must be compliant according to CMS Interpretive Gudielines

References

1. *Phlebotomy Order of Draw. WHO, WHAT, WHEN, WHERE, WHY, & HOW* National Center for Competency Testing. August 2013
2. Preanalytical Variables: Room for Improvement http://www.specimencare.com/main.aspx?cat=711&id=3085#R1
3. Individualized Quality Control Plan (IQCP) http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
4. Preanalytic Error Tracking in a Laboratory Medicine Department: Results of a 1-Year Experience. Giuseppe Lippi, Antonella Bassi, Giorgio Brocco, Martina Montagnana, Gian Luca Salvagno, and Gian Cesare Guidi. Clin. Chem., Jul 2006; 52: 1442 - 1443.

Thank you!

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