"IQCP for POCT in the Post-Analytic Stage: The Results are In, Now What Will Become of Them?"

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Objectives

- Follow the process of identifying and documenting a risk assessment in the post analytic phase for the five elements of IQCP
- Describe the process of results reporting for POCT on various platforms
- Relay the importance of proper results reporting at or near the site of patient care

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
- **Post-analytical** 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, perform the testing and often immediately implement treatment based on the results in conjunction with the clinician.

- 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.*

What do we need to review?

- Quality Assessment plan.
- written policies and procedures for the ongoing monitoring of the effectiveness of their IQCP.
- The monitoring should include specimen, test system, reagent, environment and testing personnel.
- Re-evaluation when changes occur

What do we need to review?

new tests = perform monitoring activities at more frequent intervals

Interpretive Guidelines §493.1290

- Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities.
- CMS Surveyors use D5800

What do we need to review?

- QC records
- Proficiency testing records (e.g. scores, testing failures, trends)
- **Patient results review**

What do we need to review?

- Specimen rejection logs
- Turnaround time reports
- Records of preventive measures, corrective actions, & follow-up
- Personnel Competency Records

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

Manufacturer Instructions

The risk assessment must include consideration of the manufacturer instructions for function checks and maintenance checks.

In addition, the risk assessment should take into consideration the laboratory's test volume, and intended use of the test results (i.e. screening or diagnostic).

Software/Hardware

- Is it up to date and the most current version provided by the manufacturer?
- Who's responsibility is it to ensure that it is up to date?
- Is there an effective collaboration with your IT Department/Manager to implement updates?

Transmission of data to Laboratory Information System

- How is data recorded for each patient?
- Is there a wireless or wired link available for data transmission?
- If traditional data transmission is unavailable how is data submitted to LIS and/or EMR?
- Is the data transfer secure? Password required, automatic with user login?

Result reporting

- Does the test system provide a hard copy printout? Does it use thermal paper and is there a secondary copy made for patient records? (Thermal paper degrades over time, making the data unreadable and therefore unusable)
- How are results recorded in patient record?
- Is there a log of patient results created and is it subject to Laboratory Director/Management review as per IQCP compliance?
- How soon after results collected are they implemented for patient care?

POINT OF CARE TESTING SPECIFIC CONCERNS

From a Point of Care Testing viewpoint there are many concerns that are specific and may not apply to other testing protocols.

- 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!

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 laboratory information system (LIS) isn't transmitting results or other information accurately?	YES	ACCEPTABLE	A hard copy is available as the instrument data log or patient report that can be submitted in the event of result transmission error to the ordering clinician. Done as per the test system criteria, that can be hand delivered (in-house) the same day as testing performed. The i-STAT System is designed to eliminate operator influence on delivered results. Results data is held in middleware software until LIS is available to transmit data.

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	The laboratory information system (LIS) isn't transmitting results or other information accurately?	YES	ACCEPTABLE	Analyzer error: The motor moved for too long and/or The motor stalled while moving Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.

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TESTING PERSONNEL	Potential Error	Risk Assessment Can this be detected or prevented by existing controls or practices?	Risk Level	Risk Mitigation (Included in QC Plan)
	Laboratory personnel make transcription errors when reporting results, either written or when using an LIS?	YES	ACCEPTABLE	Transcription errors are eliminated based on the results data being downloaded in to middleware, and then from middleware if results are not flagged they are forwarded to LIS and HIS. If results are flagged, laboratory staff reviews the results and test is repeated with new sample. Transcription review is performed every 6 months for each cartridge to ensure results data is successfully transferred from iSTAT, to middleware to LIS to HIS. All four results are printed and compared.

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POCT Post-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

§493.1291 Standard: Test report[4]

- (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner.

CMS IQCP Guidelines

- For CLIA purposes, the final report destination for test results is considered to be the authorized person and/or their designated personal representative
- Who can receive results under revised HIPAA guidelines: authorized person, their personal representative (if applicable) and others who are identified as responsible for using the test results on the requisition

Interpretive Guidance §493.1291(l)

- The laboratory must have and follow a written policy that is available to the laboratory staff and details how it handles patient requests for access to their completed laboratory reports.
- Test reports are considered to be complete when **all results associated with the ordered tests are finalized and ready for release**.

CMS IQCP Guidelines

- Example: Direct software system
- Secure, authenticated, encrypted

§493.1299 Standard: Postanalytic Systems Quality Assessment

- (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in §493.1291.

§493.1299 Standard: Postanalytic Systems Quality Assessment

- When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation.
- All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

§493.1299 Standard: Postanalytic Systems Quality Assessment

- QA of the **Postanalytic System** includes assessing practices/issues related to test reports.
- Review a cross-section
- Monitoring systems

§493.1299 Standard: Postanalytic Systems Quality Assessment

If the laboratory uses an LIS, the laboratory must have a mechanism to periodically verify the accuracy of:

- Its calculated data;
- Its results sent to interfaced systems; and
- Patient specific data.
- In the event that the laboratory becomes aware of information that reasonably suggests that an in vitro diagnostic device may have caused or contributed to a patient death or serious injury, verify that the laboratory has reported such instances to the FDA.

§493.1299 Standard: Postanalytic Systems Quality Assessment

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§493.1299(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.

§493.1299 Standard: Postanalytic Systems Quality Assessment

- The steps taken by the laboratory to identify and correct problems, and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must be noted.

POCT Postanalytical Solutions

Quality Matters Day to Day

- How are results being used – screening vs. diagnostic?
- Has there been a system check as to ensure secure and accurate data transmission?
- Have all post-analytical quality assessment activities been reviewed and documented?

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 and reports the results as well. [5]
- 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 Guidelines

References

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3. Individualized Quality Control Plan (IQCP) http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
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5. 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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