Quality Control in POCT: Liquid / Electronic / Alternate / Equivalent / IQCP Where do we go from here?"

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Quality Control

- Set of procedures designed to monitor the test method & results to ensure appropriate test system performance
- QC includes:
  - testing of normal and abnormal control materials
  - charting the results and analyzing them to identify sources of error
  - evaluating and documenting any remedial action taken as a result of this analysis;
- Main objective:
  - Ensure day-to-day consistency of measurements
    - if possible, in agreement with an indicator of truth, such as a control material with end-user assigned values

excerpted from CLSI Harmonized Terminology Database

What is Required?

- CLIA Regulations
  - Subpart K--Quality Systems for Nonwaived Testing
  - Sec. 493.1256 Standard: Control procedures
    - monitor the accuracy and precision of the complete analytical process
    - lab must establish the number, type, and frequency of testing control materials
    - control procedures must–
      - (1) Detect immediate errors that occur due to
        - test system failure
        - adverse environmental conditions
        - and operator performance.
      - (2) Monitor over time the accuracy and precision of test performance

What is Required?

- CLIA Regulations
  - Unless CMS approves a procedure…
    - For each test system, perform control procedures … At least once each day patient specimens are assayed
      - Hematology and Blood Gas require at least once per eight hour shift
    - Each quantitative procedure, include two control materials of different concentrations

POCT QC – in the beginning

- Two levels of liquid QC available from manufacturers
  - Recommended frequency often missing
  - End users often unaware that QC is required
  - Process not reflective of patient test performance
    - Still true for many systems
- Haphazard implementation

1990's

- POCT awareness increased
  - Inspectors take active look at POC processes
  - Increased implementation of QC programs
    - Compliance difficult
    - Expense of POCT greatly increased
- Introduction of Electronic QC
  - 1994 ESVT cleared for Hemochron tube system
  - 1998 HepTrac cleared for HMS system
  - Others cleared with instrument

Alternative QC Expansion

- QC designed to replace liquid controls
  - Generally only a partial replacement
  - Designed to insure system performance without surrogate sample (LQC) testing
    - QC performed using prepared samples in a manner similar to that used for patient testing
- Electronic QC
  - Internal or external
  - Evaluates instrument function only
  - Includes dry cartridge QC alternatives

Other Alternative QC

- On-board
  - Generally references internal liquid controls
  - Evaluates instrument and reagent function
  - Some also evaluate operator technique
- Built-in
  - Electronic and / or on-board
- Equivalent QC
  - Term coined by CMS to reference any non-surrogate sample QC

CMS Interpretive Guideline

- APPENDIX C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services
  - http://www.cms.gov/CLIA/downloads/apcpolicy.pdf
    - Requires review of QC policies and validation of these procedures
- CLIA Brochure #4 - Equivalent Quality Control Procedures
  - http://www.cms.gov/CLIA/downloads/6066bk.pdf

Equivalent Quality Control Procedures

- Published 2003 jointly by the CDC and CMS
  - Initially defined as “educational”
    - Became the default policy, despite being educational as no other system existed
  - Requires equivalent QC procedure evaluation
    - demonstrate that a test system is stable and can g enerate correct test results over time.
    - If results are acceptable OK to reduce the frequency of external QC
  - Defines three levels of controls

Equivalent QC Options

	Test System Description	Evaluation Process:		Equivalent QC Procedure Testing Frequency
		Internal QC	Test 2 Levels External QC	
Option 1	Test systems with internal monitoring that checks ALL analytic components	Daily testing with acceptable results	Results acceptable for 10 consecutive testing days	Testing external controls at least once per calendar **month** and **daily** testing by the internal monitoring system
Option 2	Test systems with internal monitoring that checks SOME analytic components	Daily testing with acceptable results	Results acceptable for 30 consecutive testing days	Testing external controls at least once per calendar **week** and **daily** testing by the internal monitoring system
Option 3	Test systems WITHOUT internal monitoring System	N/A	Results acceptable for 60 consecutive testing days	Testing external controls at least once per calendar **week**

Option 4

- CLSI undertook the charge to develop a risk based method for determining QC procedures and frequency
  - EP-23 Laboratory Quality Control Based on Risk Management
    - Published October 2011
    - Forms the basis for IQCP
      - CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline.* CLSI document EP23-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Individualized Quality Control Plan (IQCP)

CLIA

- ✔ **Customizes** QC Plan for each test in its unique environment
- ✔ **Optimizes** use of electronic/integrated controls
- ✔ **Offers** laboratories **flexibility** in achieving QC compliance
- ✔ **Adaptable** for future advancements in technology
- ✔ **Incorporates** other sources of Quality Information
- ✔ **Strengthens** Manufacturer/Laboratory partnerships
- ✔ **Formalizes** risk management data already maintained within the laboratory
- ✔ **Provides** equivalent quality testing to meet the CLIA QC regulations

The Right Quality Control

CMS

EP23 and IQCP

- Memorandum issued November 2011
  - CMS' adoption of EP-23 for CLIA QC as a QC option.
  - Date to be announce in 2012
    - Laboratories may begin to implement EP-23
  - EP-23 will be voluntary
  - Default QC requirement will be 42 CFR 493.1256(d)(3):
  - Equivalent Quality Control (EQC) will be phased out

Don't Panic

- Lots of help available:
  - CMS
    - FAQ: www.cms.gov/clia
    - questions: IQCP@cms.hhs.gov
  - CLSI
    - Workshops Webinars
    - Workbook Worksheet
    - FAQ: http://www.clsi.org/Content/NavigationMenu/Education/EP23QA/EP23_Q_A.htm
  - POCC group webinars
    - Whitehat Communications
      - http://www.whitehatcom.com/POC_Group_Webinars_2012.htm

It's easier than you think

- Requires review of current practices
  - Risk identification
  - Risk Assessment
  - Risk Mitigation
- No QC tool consistently prevents or detects all failures.
  - What is needed for your site?

Look at the Process

Process Mapping

Preexamination (Preanalytical) Processes	Examination (Analytical) Processes	Postexamination (Postanalytical) Processes
• Examination ordering • Sample collection and labeling • Sample transport • Sample receipt and accessioning • Preexamination sample processing	• Examination • Results review and follow-up • Medical review	• Results reporting • Results archiving • Sample archiving • Charging for examinations, where applicable

Look at the Process - POCT

Preexamination (Preanalytical) Processes	Applies ?	Risk/ Mitigation
• Examination ordering	• Yes	Standard ordering process? Part of a predefined algorithm? Training required
• Sample collection and labeling	• Yes	Wrong sample type; delay in testing; unlabeled sample Training required
• Sample transport	• No	
• Sample receipt and accessioning	• No	
• Preexamination sample processing	• ?	Sample tube not mixed; Multi-step analysis not performed correctly Training required

Preanalytical Processes

- All risks mitigated by training
  - Does training cover all identified risks?
  - Does competency cover all identified risks?
  - Are errors found in clinical use that suggest training needs to be modified?

Look at the Process - POCT

Examination (Analytical) Processes	Applies ?	Risk/ Mitigation
• Examination	• Yes	Quality Control processes must be designed specific to each system
• Results review and follow-up	• Yes	Does operator recognize results inconsistent with patient presentation? Are repeats performed as defined by policy? Training required.
• Medical review	• Yes	Was clinician notified as per policy? Training required

QC for Analytical Process

- Evaluate current procedures:
  - If using Built In Controls
    - Information on effectiveness in risk mitigation should be obtained from the manufacturer.
    - Often does not control for entire process
  - Liquid QC
    - Is frequency sufficient to identify problems with reagent?
  - Proficiency studies
    - Does performance suggest accurate results being obtained

QC for Analytical Process 2

- Evaluate current procedures:
  - Evaluate Complaint history
    - Do end users / clinicians question the results?
    - Does frequency suggest problems with system?
  - Evaluate validation performed when current procedure implemented
    - Has frequency of errors changed?
    - Is there reason to believe there are risks that can be better mitigated?

Look at the Process - POCT

Postexamination (Postanalytical) Processes	Applies ?	Risk/ Mitigation
• Results reporting	• Yes	Electronic data transfer or manual? How is accuracy of transfer controlled? How are errors kept from the EMR?
• Results archiving	• Yes	
• Sample archiving	• No	
• Charging for examinations, where applicable	• Yes	Work with IT personnel to ensure transfer to proper billing personnel

Developing a Final QC Plan

- Hazard Identification
- Risk estimation
- Risk evaluation
- Risk Control

Sample table format to document findings in EP-23

Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)

Post-implementation

- Evaluation of effectiveness
  - Verify identification of errors
  - Review complaints
  - Track complaints and investigations
- Corrective Actions
  - If problem with built-in controls, increase frequency of external controls
  - If operator errors, modify training and procedures

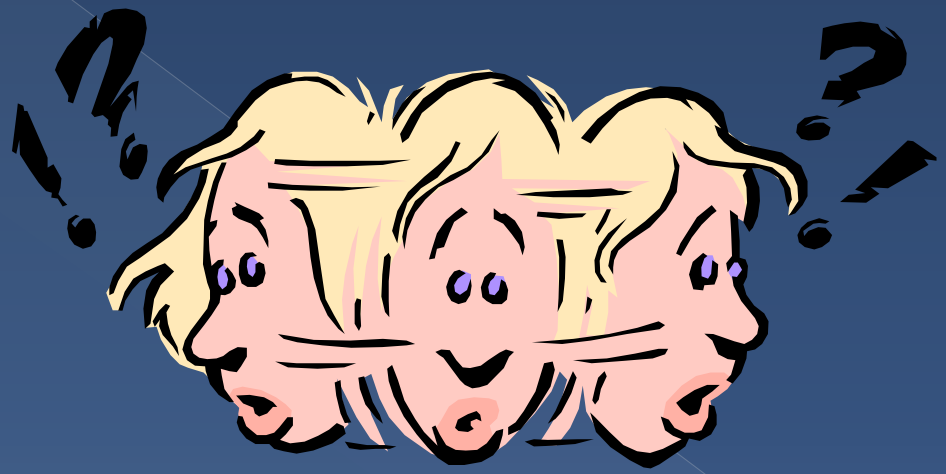
Impact on your program

- It will take time
- Requires:
  - detailed knowledge of system functions
    - ask manufacturer's for information
  - detailed understanding of clinical applications
    - ask clinicians for information to aid in identifying risks
      - how "wrong" must a result be to increase risk?
  - Documentation of findings and decisions

IQCP

- Individualized QC Policy
  - Allows the definition of a policy that fits your institution
    - *e.g.*, Different QC programs for high and low volume tests
  - May not differ from current processes
    - Need to assess efficacy of current processes in light of identified potential risks
    - May need minor revision if additional risks identified or non-value added steps noted

QUESTIONS?



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