Quality Control in POCT:

Liquid…Electronic…Built-In…IQCP Now what?

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Learning Objectives

- Modify current QC processes as the need arises
- Implement new QC practices when implementing new POC devices
- Develop individual quality control plans that answer both laboratory and clinician needs

CLIA Definition of QC

- Process which:
  - monitors the accuracy and precision of the **complete** analytical process
- 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

QC & POCT – Reagent issues

- Traditional QC may not be relevant
  - Unit use devices
    - Testing may not reflect reagent for next test
  - QC material differs from patient sample
    - Whole blood analogs do not behave like whole blood
  - Process may differ from patient samples
    - Rehydration and incubation requirements
    - Especially true of proficiency samples

QC & POCT –Process issues

- Value of POCT QC varies by location
  - High volume sites recognize potential erroneous results
    - Daily QC does not improve patient care
  - Low volume testing allows operators to forget important steps
    - QC each day of patient testing may mitigate operator error

QC and POCT- Optimization

- Risk assessment process can define QC frequency
  - Manufacturer fail-safes understood
    - Improved clinician buy-in with participation
  - QC frequency based on risk mitigation
    - Reduced operator grumbling
- Risk defined QC procedures
  - Patient care
  - Safety optimization

IQCP

- Individualized Quality Control Plan
  - Optional alternative to CLIA requirements
- Includes:
  - Risk Assessment (RA)
  - Quality Control Plan (QCP)
  - Quality Assessment (QA)
- Only CMS approved alternative QC procedure
  - Required for any test not adhering to CLIA defined QC frequency

CLIA defined frequency

- Subpart K--Quality Systems for Nonwaived Testing
- Sec. 493.1256 Standard: Control procedures

- For each test system, perform control procedures … At least once each day patient specimens are assayed
  - Hematology and Blood Gas at least once per eight hour shift
- Each quantitative procedure, include two control materials of different concentrations
- Each qualitative procedure, include a negative and positive control material

IQCP Maintenance

- IQCP review frequency defined as part of the QC Plan
  - Routine review as per all procedures
- Problems identified with existing equipment
  - IQCP needs revision
- Change locations using IQCP?
  - Sites with dramatic volume changes
  - Non-compliant sites
  - Sites with high operator turn-over

IQCP Revision

- Quality Assessment
  - Problem indicates a non-mitigated risk
    - Or not sufficiently mitigated
- Risk Assessment
  - Add new risk to assessment
    - Pre-, Analytic or post?
  - Why was it missed?
    - Other potential unmitigated risks?

Ask operators and clinicians

IQCP is a Continuous Process

Each change is documented
and signed as per original IQCP

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

Implementing a New System

- Installation
- Validation studies
  - Accuracy, Precision
  - Reportable range (AMR)
  - Reference interval verification
  - Method comparison studies
  - Calibration and Calibration Verification
- QC Plan
- Enrollment in Proficiency Program
- Documentation
  - Test Policy and Procedure
- Training
  - Competency Assessment

IQCP of a New Device

- Manufacturer is a key resource
  - Likely has an IQCP template
  - Has specific QC recommendations (usually)
  - Can answer questions about built-in mitigations
    - Often has suggested mitigations for known risks
- According to CLIA
  - **lab** must establish the number, type, and frequency of testing control materials
    - Cannot just implement from manufacturer template

New Device Risk Assessment

- Get clinician / operator involved
  - Especially pre- and post-analytic risk
  - How wrong is clinically wrong?
  - What clinical presentation might indicate an erroneous result
  - How can risks be mitigated?
- Demonstrate appreciation for clinician expertise
  - Get input for specific mitigations
  - QC may not be the answer

Analytic Risk Mitigation

- QC of the test system
- CLIA requires that QC

  (1) Detects immediate errors that occur due to
  - test system failure
  - adverse environmental conditions
  - and operator performance

  (2) Monitors the accuracy and precision of test performance over time

QC for POCT -LQC

- External liquid QC
  - Surrogate sample testing
  - Evaluates instrument, reagent and operator
    - Presumably
  - CLIA QC needs:
    - test system failure √
    - adverse environmental conditions √
    - operator performance ?
    - accuracy over time ?
    - precision over time ?

QC for POCT - EQC

- Dry cartridge / Electronic QC
  - Built-in or external disposable "end-point"
  - Simulates result
  - CLIA QC needs:
    - test system failure √
    - adverse environmental conditions
      - Instrument √
      - Reagent X
    - operator performance X
    - accuracy over time ?
    - precision over time ?

QC for POCT – On-board QC

- On-board QC
  - Generally refer to internal reagent controls
  - Manufacturer can verify all functions
    - Some are more complete than others
  - CLIA QC needs:
    - test system failure √
    - adverse environmental conditions √
    - operator performance √ / X
    - accuracy over time √ / X
    - precision over time √ / X

Most Common Manufacturer's Recommendation

- Electronic daily/ LQC monthly
  - Generally based on reagent stability studies
- Is it sufficient?
  - Must have some local validation
  - Many options such as:
    - LQC daily for 2 weeks / 1 month / 6 months
    - Then Q 2 weeks for 2 months / 6 months / 1 year
    - Then Monthly
  - IQCP states procedure verified frequency

Manufacturer's Recommendations

- On-board QC

  test system failure — adverse environmental conditions
  operator performance — accuracy & precision over time

  - Frequency?
    - every sample, preset intervals?
    - automatically?
- No IQCP needed?
  - CMS deems equivalent to CLIA requirement
  - Written statement on company letterhead
    - or copy of letter from CMS
- No QC available
  - Develop alternative QC

Alternative Quality Control

- Can include LQC (but not necessarily)
  - Blind samples Leftover lab samples
  - Delta checks Comparisons with lab
  - Population statistics Scheduled precision studies
- Evaluate if, with built-in mitigations, this will
  - Detect
    - test system failure
    - adverse environmental conditions
    - operator performance
  - Allow trending of performance over time
- If yes, appropriate Quality Control

Blind Samples

- Any sample with known value
  - QC Proficiency
  - cal/ver de-identified patient samples
- Independently labeled
  - Non-operator keeps key
- Operators test as per patient sample
  - As much as possible
- Can be used as QC or alternative proficiency samples
  - PT not commercially available
  - Investigate PT failure / trending

QC and Proficiency Testing

- §493.1256 Standard: Control procedures
  - (d)(7) Over time, rotate control material testing among all operators who perform the test.
- §493.801(b) Standard: Testing of proficiency testing samples
  - (b)(1)The samples must be examined or tested with the laboratory's regular patient workload
    - by personnel who routinely perform the testing in the laboratory
    - using the laboratory's routine methods.

Operators

- Not trained in laboratory testing
- Not trained to question results
- Not trained on importance of QC and PT

- Trained in patient care
- May resent need to run QC and / or PT

- How can this be improved?

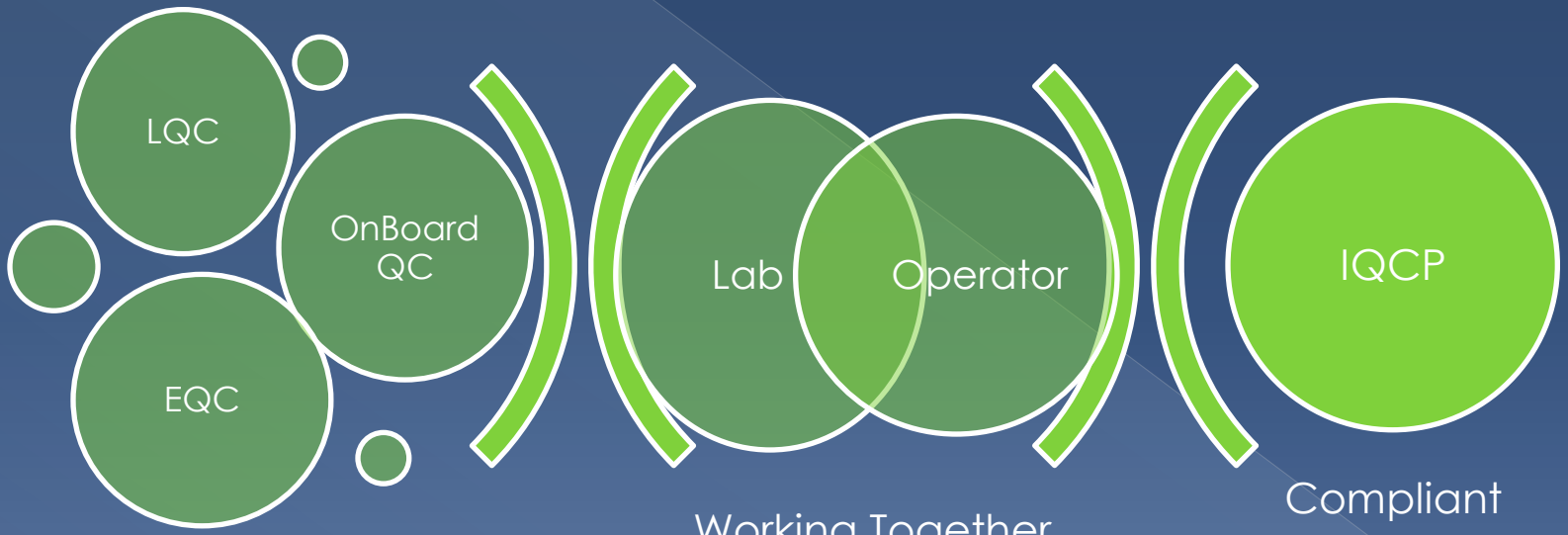
Use Risk Assessment

- Demonstrate risk reduction through quality practices
  - QC mitigates risk of erroneous result (hopefully)
- Step by step evaluation of risk reduction through training and competency assessment
- There are reasons for interruptions of routine
  - Alter workflow to minimize disruption

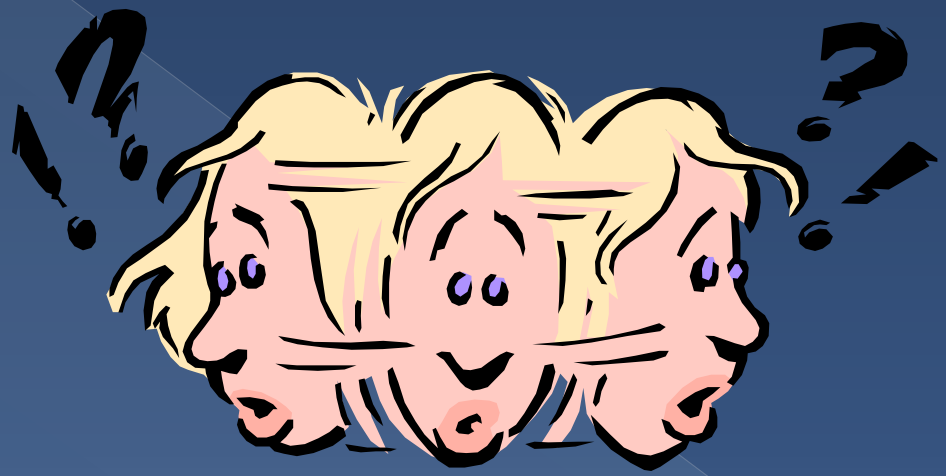
Clinician Participation

- Improved recognition of unlikely results
  - Tests repeated
  - Questions asked
  - Process changes suggested
- Improved communication
  - Operator can identify need for policy changes
- Direct correlation of quality test results and improved patient care

Quality Control in POCT



QUESTIONS?



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