

Quality Control in POCT:

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

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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

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

- QC frequency requirements vary 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 defined QC frequency needs
 - Manufacturer fail-safes understood
 - Improved clinician buy-in with participation
 - QC frequency based on risk mitigation
- Risk defined QC procedures
 - Patient care
 - Safety optimization
 - Reduced operator grumbling

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

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

What's left to say?

- Assume IQCP in place as needed
 - > Not always needed
- Problems arise with existing equipment
 - > How can IQCP be modified
- New devices are implemented
 - > Some claim no IQCP or QC required
 - > Some have no QC or proficiency materials
- Should operators be involved in QC
 - > Can operators be trusted with proficiency

Current IQCP

- Not always needed
 - > Low volume sites
 - > Non-compliant sites
 - > Sites with high operator turn-over
- Policy should include review frequency
 - > Routine review as per all procedures
- Problems arise with existing equipment
 - > IQCP needs revision

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

Revising IQCP

● Risk Assessment

- Identify mitigation(s)
 - Changes in procedure?
 - Changes to training and competency?
 - Include operators / clinicians

● Quality Control Plan

- Update processes/ procedures as needed

● Quality Assessment

- Monitor to ensure changes effective

IQCP is a Continuous Process



Each change is documented
and signed as per original IQCP

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 internal 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?

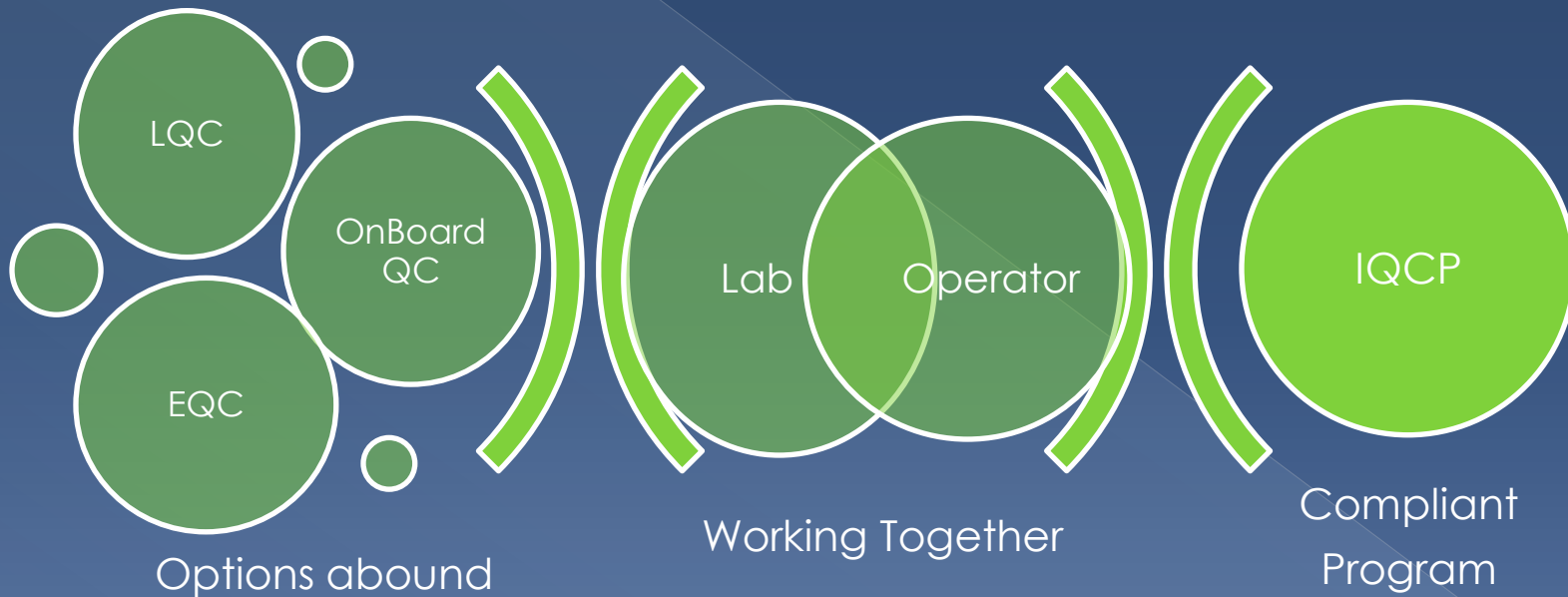
Use Risk Assessment

- 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

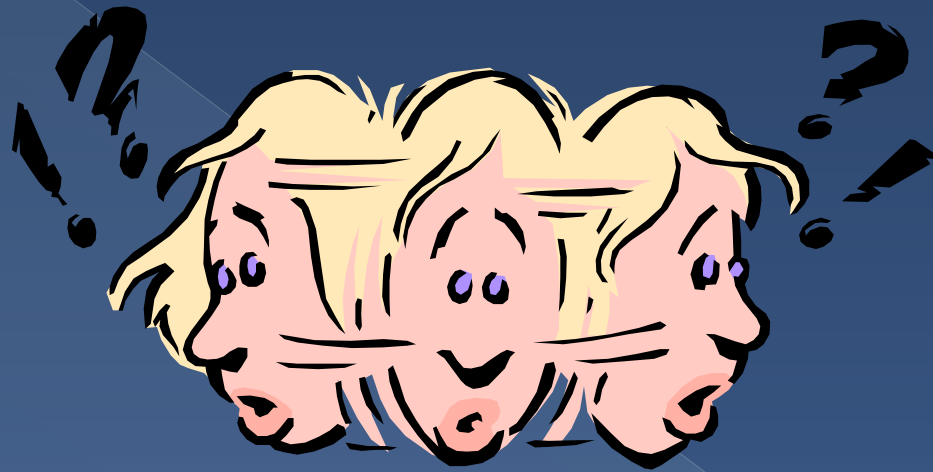
Clinician Participation

- 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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