Anticipating IQCP: 
What We’ve Learned about QC and More by Using QMS, Lean and Continuous Improvement

Lab Quality Confab
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Lou Ann Wyer, MS, MT(ASCP), CQA (ASQ)
Sentara Healthcare
Objectives

- Explore key points of quality journey to current state
- Describe risk assessment principles and list components to evaluate within a POCT process
- Identify strategies to prepare for the development of a risk-based quality control plan for a POCT system
- Define quality assessment plans for post-implementation monitoring for effectiveness
Sentara Healthcare

Williamsburg, VA

Hampton, VA

Norfolk, VA

Suffolk, VA

Woodbridge, VA

Virginia Beach, VA
Quality Journey

- Lab Quality Department
  - CLSI Key to Quality
  - 6 CQA(ASQ)
  - QMS
    - Document Control
    - Safety Culture
    - Internal audits
- System Assessments
  - CAP
  - AABB
  - DNV
Stage 1
Low Maturity Quality Culture
Immature QMS
Nonconforming to ISO

Potential Issues:
Understanding what the standard requires; why NC is being raised, and/or what needs to be done in order to meet the requirements of ISO 9001.

Action:
Advice on "how to" implement the QMS and/or resolve any non-conformities raised.

Stage 2
Mature Quality Culture
Immature QMS
Nonconforming to ISO

Potential Issues:
While a mature quality culture, NC are still seen & CA are not sustained or are ineffective

Actions:
Explore how effective current methodologies used to meeting the requirements of ISO 9001
Explore Gaps in the way the tools are being deployed.
Identify any systematic problems and address appropriate non-conformities

Stage 3
Low Maturity Quality Culture
Mature QMS
Conforming to ISO

Potential Issues:
May not have a "quality culture" throughout the organization.
The QMS might have been implemented under pressure from customers or external parties, and built around the requirements of the standard rather than on the organization's own needs and expectations.
The QMS may be operating in a parallel way with the way the organization carries out its routine operations, generating redundancy and inefficiency.

Action:
Focus on "Opportunities for Improvement"

Stage 4
Mature Quality Culture
Mature QMS
Conforming to ISO

Potential Issue:
The organization may feel that routine surveillance visits are superfluous and not value added

Action:
Obtain a better understanding of the leadership's expectations and how the surveillance visits can add value
Sentara Lean

- Standardized work
  - Processes, P&Ps
- User friendly
  - 5S
  - Kanban
- Unobstructed throughput
Lab Safety Initiatives

- Specimen Management
- Safety Stand Down
- Specimen Logs
- Courier Services
  - Lab location scanning
  - Standardized courier orientation & training; unannounced audits (eliminate transport bags, drop all)
- Man Overboard
- It’s all about trash....
- Leadership rounding with intent
Safety First!

5S Specimen Boxes

Locked Transport Boxes
Kanban, Leadership Rounding

WE IMPROVE HEALTH EVERY DAY !!!
Batch Tracking Logs
Vantage Tracking
Specimen Receipt Logs / Accession Logs
Problem Resolution Logs

Transport Logs
Barcode Tracking

Wingman Verification Transport Logs
Destination Barcodes

Hospitals

Couriers

Laboratories

Pathology

Processing

Embedding
Microtomy
Slide Distribution

Batch Tracking Logs
Vantage Tracking
Wingman Verification Batch Tracking Logs
Quality Assurance Forms

Lab Quality Confab 2014
Individualized Quality Control Plan

Alternative CLIA quality control (QC) option that will meet the CLIA regulations for nonwaived tests (42CFR493.1250)

Includes:
- Risk assessment
- Quality control plan
- Quality Assurance plan
Why IQCP?

- Changes in healthcare environment & delivery of services
- Advances in technology
- QC no longer fits all
- EQC too limited
- IQCP provides a flexible program/plan for the future that includes the entire testing process
Case Study for Risk Assessed QC Plan

- Sentara POC Program
  - 350 i-STATs
  - 12 facilities
- Lactate, POC method
- Lactic acidosis - forerunner of major medical illnesses
  - High mortality rate
    - values > 4mmol/L
Measuring System Information

- Medical Requirements for the Test Results
- Regulatory and Accreditation Requirements
- Measuring System Information:
  - Provided by the manufacturer
  - Obtained by the Laboratory
- Information about Health Care and Test Site Setting

**PROCESS**: Risk Assessment

**OUTPUT**: Quality Control Plan

**PROCESS**: Post-implementation Monitoring

<table>
<thead>
<tr>
<th>Quality Program Element</th>
<th>Strengths</th>
<th>Weaknesses</th>
<th>Does My System Have This?</th>
</tr>
</thead>
</table>
| LQC Liquid based quality control materials | • Readily available  
• Sequestered lot number  
• Long out-date  
• Ranges already established  
• Know if performance is acceptable | • Cost | • Yes, LQC materials provided by the manufacturer  
• Establish in-house ranges  
• Perform 1H/1L each analyzer monthly |
| Function Checks | • Internal and automatic  
• Monitors electronics of test system  
• Quality checks prevent reporting of results | • May not monitor the entire process (i.e., sample)  
• Does not detect hemolysis or interferences | • Yes, except for hemolysis index and interferences |
| Calibration Verification | • Identifies that calibrators, reagents, instrument, and calibration algorithm are working | • Labor intensive | • Yes, material provided by manufacturer  
• Perform with each new/replacement device  
• Perform on each cartridge type twice per year |
| Proficiency Testing | • Confirms proper technique by testing personnel  
• Confirms proper operations of test system | • Does not carry over to individual patient samples | • Yes, provided by CAP  
• 40 measurements (2011) |
## Types of QC in our QC Toolbox

<table>
<thead>
<tr>
<th>Internal Proficiency-Method Comparisons</th>
<th>Identification of Implausible Values</th>
<th>New employee orientation</th>
</tr>
</thead>
</table>
| • Confirms comparison of methods for random selected tests  
• Ensures POC method is aligned with lab method or another analyzer | • Informs operator/POCC of results outside established ranges  
• Software rules stop values from automatically posting to the chart | • All new employees who will be using test system  
• Direct observations  
• Conducted by POCC for consistency  
• Identify learners who need more 1:1  
• First impressions of POCT |
| • Does not carry over to each patient test (unit-use) | • Does not determine reason for value (operator, specimen, etc)  
• May delay results from getting to chart | • Resource heavy |
| • Yes, conducted by POCC  
• Perform patient sample for each sensor type monthly  
• Perform LQC for each analyzer monthly | | • Yes, conducted by POCC |

- **POCC monitors daily**
Information for Risk Assessment

- Regulatory and Accreditation Standards
- Measuring system
- Literature Search
- Lab and testing unit information
- Medical requirements for test results
- Known interferences
Process Map

START

Method Validation: precision, accuracy, methods, reference ranges, procedures

Equipment and supply acquisition and storage

Medical Director approval

Test System Ready

Operator training and competency

MD order/protocol in EMR

Collect Venipuncture Sample

Patient identification

Label Specimen

Charge cartridge

Select test/panel

System quality check code?

Evaluate Results

Yes

Troubleshoot

Repeat test

No

Evaluate Results

Match clinical picture?

Yes

Send specimen to the Laboratory for testing

Release results to EMR

END

No
Fishbone Diagram – POC Lactate

**Samples**
- Sample Integrity:
  - Collection Technique
  - Hemolysis
  - Correct tube/fill
  - Time to test
  - Specimen Labeling
  - Interferents

**Operators**
- Sample Preparation:
  - Mix well prior to loading
  - Correct cartridge type
  - Bubbles
  - Over/under fill
  - Cartridge handling
- Operator Capacity:
  - Orientation/Training
  - Competency
- Data Entry:
  - Sample type
  - Test Select
- Operator Staffing

**Measuring System**
- Instrument Failure:
  - Dead Battery
  - EQC failure
  - Software failure
  - Quality check codes
- Maintenance Failure:
  - Pin Conditioning
  - Blood/liquid contamination

**Reagents**
- Cartridge, QC Materials:
  - Shipping
  - Storage
  - Expired
  - Preparation/handling
  - Acceptance
  - Availability
- Cal Ver Materials:
  - Shipping
  - Storage
  - Expired
  - Preparation/handling

**Identify Potential Hazards**

**Lab Environment**
- Atmospheric Environment:
  - Temperature
  - Humidity
  - Dust
- Utility Environment:
  - Electrical
  - IT/networks

**Incorrect/Delayed Test Result**
- Instrument availability
<table>
<thead>
<tr>
<th>Steps</th>
<th>Failure Mode</th>
<th>Causes</th>
<th>Internal Controls</th>
<th>External Controls</th>
<th>Engineering Controls</th>
<th>Operator Training</th>
<th>General Comments or Other Laboratory-Implemented Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measuring System Error Message or Malfunction</td>
<td>Instrument Failure</td>
<td>Electronic instability</td>
<td>Internal QC performed every 8 hrs. FAIL message displays on screen</td>
<td>External electronic simulator performed as needed</td>
<td>Lock-out for failures</td>
<td>Train operators to perform external simulator when needed. Contact POCC for assistance.</td>
<td>POCC's review EQC results daily</td>
</tr>
<tr>
<td></td>
<td>Dead Battery</td>
<td>Battery status displayed on analyzer screen</td>
<td>NA</td>
<td>Battery status displayed on analyzer screen</td>
<td>Train operators to routinely observe battery status.</td>
<td></td>
<td>Two 9-volt lithium batteries, or rechargeable battery available in the laboratory</td>
</tr>
<tr>
<td></td>
<td>Quality Check Codes</td>
<td>Each code is indicative of a type of error</td>
<td>No</td>
<td>Guardian reports</td>
<td>Contact POCC for assistance. Review troubleshooting tips with operators.</td>
<td>Train POCC's on software applications and identification follow-up to quality check codes. Review quality check codes monthly for trending.</td>
<td></td>
</tr>
<tr>
<td>Targeted Failure Mode (Hazard)</td>
<td>Measuring System Feature or Recommended Action</td>
<td>Known Limitation of Feature or Recommended Action</td>
<td>Control Process Effective?</td>
<td>The IQCP Actions Required to Address Known Limitations</td>
<td>Residual Risk Acceptable? (Yes/No)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------------------</td>
<td>---------------------------------------------------</td>
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<td>-------------------------------------------------------</td>
<td>----------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operator Competency</td>
<td>Operator Lock-out (mandatory Operator ID required for trained staff)</td>
<td>Provide multiple forms of competency to address testing &amp; QC procedures, maintenance, troubleshooting, proficiency samples</td>
<td>Y</td>
<td>Operator Lock-out QC Lock-out Transmission Lock-out Skills Fairs E-learning interactive modules Direct Observations Proficiency testing Results review</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping (Cartridges)</td>
<td>Temp control card with a four-window indicator to monitor temp during transit.</td>
<td>Perform LQC with each shipment</td>
<td>Y</td>
<td>Perform LQC # and patient samples with each shipment</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Data to Support QC Plan

- LQC
- Old lot vs. new lot
- Acceptance studies
- Internal proficiency with patient samples
- CAP acceptable limits
i-STAT Lactate QA by Risk Management Power Analysis

Power Curve for Paired t Test

Difference (mmol/L)

Power

Alpha 0.05
StDev 0.13
Alternative Not =

Sample
Size
3
4
5
6

Assumptions
i-STAT Lactate Proficiency Testing with Laboratory Instrument

Laboratory Method (mmol/L)
i-STAT (mmol/L)
Regress
Lowess
Fits
T10330
W11245
Y10352
Y11074
Y11146
Y11167
Lot Number
OLS Lowess
i-STAT Lactate Proficiency Testing with Laboratory Instrument
Power Curve for 2-Sample t Test

- Sample Size
  - 3
  - 6

- Assumptions
  - Alpha: 0.05
  - StDev: 0.2
  - Alternative: Not =

i-STAT Lactate QA by Risk Management Power Analysis Control Level 1
## Lactate Testing – QCP

<table>
<thead>
<tr>
<th>QC Toolbox</th>
<th>QC Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic QC</td>
<td>• Every 8 hours</td>
</tr>
<tr>
<td></td>
<td>• QC, Operator, Transmission Lock-outs</td>
</tr>
<tr>
<td>Acceptance studies</td>
<td>• 2H/2L LQC, 5 patients with each shipment old vs new lot</td>
</tr>
<tr>
<td>Monthly LQC</td>
<td>• 4H/4L (min), each cartridge type</td>
</tr>
<tr>
<td>Calibration Verification</td>
<td>• 3 levels in triplicate, every 6 months</td>
</tr>
</tbody>
</table>
## Lactate Testing – QCP

<table>
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<tr>
<th>QC Toolbox</th>
<th>QCP</th>
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<tr>
<td>Internal proficiency for comparative methods</td>
<td>● 1 patient monthly for each sensor type vs Lab analyzer</td>
</tr>
<tr>
<td>External Proficiency program</td>
<td>● CAP survey sets</td>
</tr>
<tr>
<td>New/replacement devices</td>
<td>● LQC (2 H/2 L x10)</td>
</tr>
<tr>
<td></td>
<td>● Patient sample (1)</td>
</tr>
<tr>
<td></td>
<td>● Calibration verification</td>
</tr>
<tr>
<td></td>
<td>(3 levels in triplicate)</td>
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## Lactate Testing – QCP

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<th>QCP</th>
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<tr>
<td>Orientation/Training</td>
<td>Provided by POCCs</td>
</tr>
<tr>
<td>Competency</td>
<td>Interactive e-learning</td>
</tr>
<tr>
<td></td>
<td>Direct Observations</td>
</tr>
<tr>
<td></td>
<td>Proficiency surveys</td>
</tr>
<tr>
<td></td>
<td>Skills Fairs</td>
</tr>
<tr>
<td></td>
<td>Results review</td>
</tr>
</tbody>
</table>
Alternative IQCP Solution

*i-STAT 1 Activated Clotting Time (ACT) (Pre-analytic)*

Abbott i-STAT ACT EZ-QCP

**PRE-ANALYTIC:**

- **SECTIONS (1-4)**
  - Patient ID
  - Sample Collection
  - Sample ID
  - Sample Presentation

- **RISK MITIGATION REPORTS**
  - Patient ID
  - Sample Collection
  - Sample ID
  - Sample Presentation

- **RESIDUAL RISK SCORES**
  - Patient ID
  - Sample Collection
  - Sample ID
  - Sample Presentation
  - Residual Risk Scores by Category

**PRE-ANALYTIC SUGGESTION REPORT**

- Pre-analytic Suggestion Report

**PRE-ANALYTIC ACTION PLANS**

- SOP
  - Training Checklist
  - Direct Observation
  - Competency Quiz
  - Problem Solving

**IQCP**

- Individualized Quality Control Plan

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*i-STAT 1 Activated Clotting Time (ACT) (Analytic #1 of 2)*

Abbott i-STAT ACT EZ-QCP

**ANALYTIC, 1 of 2: SECTIONS (5-11)**

- Access
- Operation
- Cleaning
- Configuration
- Cartridges
- Quality Control
- Linearity

- **RISK MITIGATION REPORTS**
  - Access
  - Operation
  - Cleaning
  - Configuration
  - Cartridges
  - Quality Control
  - Linearity

- **RESIDUAL RISK SCORES**
  - Access
  - Operation
  - Cleaning
  - Configuration
  - Cartridges
  - Residual Risk Scores by Category

- **ANALYTIC SUGGESTION REPORT**
  - Analytic Suggestion Report

**ANALYTIC ACTION PLANS**

- SOP
  - Training Checklist
  - Direct Observation
  - Competency Quiz
  - Problem Solving

**IQCP**

- Individualized Quality Control Plan
Generates Action Plans

<table>
<thead>
<tr>
<th>Responsible party</th>
<th>Target completion date</th>
<th>Actual completion date</th>
<th>Signed off by</th>
</tr>
</thead>
</table>

- ensue that testing personnel perform ACT proficiency testing in i-STAT 1 analyzer Proficiency Testing mode. *The prewarmed or non-prewarmed calibration is not applied to ACT tests performed in the Proficiency Testing mode.*
- alternate instruments when testing PT, if applicable.
- alternate testing personnel when testing PT.
Generates IQCP Report

Proficiency Testing:

We perform educational Proficiency Testing with 2 challenges three times per year.

Training:

- Standard Operating Procedure (SOP) covers:
  - Test result review
  - Limitations and interferences
Post-Implementation Monitoring - QA

- Evaluate the effectiveness
- Unacceptable findings?
  - Troubleshoot
  - Determine cause
  - Assess the risk to the patient
  - Corrective action
    - Modify QC Plan to prevent recurrence
- Document, document, document
Lessons Learned

- Start early
- Consider all current processes
- Review current data
- Monitor for effectiveness
- It’s a journey
Questions?