Taking Quality Assurance to the Next Level:

New Tools for Managing Quality Control and Quantifying their Impact on Lab Quality Metrics

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Hematology Technical Specialist,
MultiCare Health System, Tacoma, WA

Scott Lesher
Director, Technical QA
Sysmex America Inc.
BeyondCare℠ Quality Monitor is a revolutionary new way to monitor analyzer performance, minimize downtime and maximize efficiency. This simplified approach to real-time quality assurance monitoring can detect slight changes in analyzer performance as they happen, which can impact not only laboratory performance but hospital performance as well.
HAS YOUR QUALITY CONTROL PROCESS FAILED YOU?

- Significant change in calibration during a routine 6 month calibration verification event
- Bias exceeding ±3SDI when reviewing a peer comparison report
- Unsatisfactory rating on a CLIA Proficiency Test Survey
- Increased repeats or reviews on patient samples, affecting staff productivity or TAT
- Complaints from physicians or having to revise patient results
- Difficulty maintaining correlation between analyzers
HEMATOLOGY CALIBRATOR & QC

- Biological Calibrator & QC
  - Each batch of cells are different
  - Minimized matrix effect
    - Cells react to analyzer reagents and hardware
    - Similar to whole blood, cells continue to change in the vial
CONTROLLING A CHANGING MATERIAL

Is it the QC material changing or the analyzer?

Is the reduced error detection on the low side acceptable?

Effort to get QC to pass throughout lot life
A study from S.J. Kim et al. found MCV drift can exceed 4SD by the 5th week of a control life [1]. The study also found re-establishment of the target mean value frequently might be a solution. The paper does identify frequent target mean establishment might be “inefficient as it may considerably increase both the workloads and the expense of the laboratory”.

BeyonDCare℠ Quality Monitor

- Automated real-time application that pushes information and instructions for consistent QA process
  - Consistent process for service team and laboratory
- Integrated QA application
  - Traceability to international conventional reference measurement procedures
  - IQAP Peer comparison
  - Analyzer diagnostics data
  - 13 algorithms for immediate error detection every time QC is run
- Partnered approach in analyzer quality assurance
Quantifying the Impact on Lab Quality Metrics

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Hematology Technical Specialist,
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OBJECTIVES FOR TODAY

- Gain an understanding of the BeyondCareSM Quality Monitor
- Describe how the use of the BeyondCareSM Quality Monitor can positively impact laboratory metrics such as TAT
- Discuss how the BeyondCareSM Quality Monitor can have a positive impact on the laboratory budget
- Explain how the change in laboratory metrics can impact hospital metrics such as ER length of stay
Quality Control

What is Quality Control?
ESTABLISHING AN EFFECTIVE QUALITY SYSTEM IS CHALLENGING

- **What to monitor?**
  - QC shifts
  - Coefficient of Variation (CV)
  - Drift parameters
  - Hardware

- **How to monitor it?**
  - Total error goals (TEa)
  - Correct Documentation
    - What is required?
    - How long to keep?

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*Laboratories must be able to demonstrate that there is an effective ‘quality system’ in place and not just a series of uncoordinated activities.*

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1. [Footnote reference]
Test method Quality

• The first step to building a control plan is to understand the test quality
  – Six Sigma is a great process to understand test method quality
  – The higher the sigma score (σ) the easier to control
  – Test methods with sigma scores <3σ require rigorous control processes to ensure clinical goals are met

• The presentation is focused on automated cell counters with sigma score >5σ
  – Easy to control with high probability to achieve clinical goals
MANUAL DOCUMENTATION AND REVIEW IS OUTDATED....AND FRUSTRATING

- Monthly QC review
- Incomplete Corrective Action Logs
- You re-ran QC how many times??
- Was the background in?
- Binders, binders and more binders
- The control has been running low for 3 weeks?
BeyondCare℠ Quality Monitor will transform the way laboratories manage quality control
WHAT IS IT, EXACTLY, AND WHAT DOES IT DO?

- BeyondCare℠ Quality Monitor is a unique and innovative quality control management program that replaces traditional QC processes with automated monitoring and identification of potential errors that may adversely affect patient test results
  - Balances Error Detection with Low False Rejection Rate
  - Provides real-time assessment that proactively detects quality control (QC) issues as they happen, then notifies and advises the user of what mitigation is required
  - Maintains the integrity of the test method and quality of the results while minimizing analyzer downtime
    - Standardizes the troubleshooting process and eliminates unnecessary use of controls

BeyondCare℠ Quality Monitor represents a HUGE paradigm shift in how quality control is managed.
HOW BEYOND CARE℠ QUALITY MONITOR WORKS

QC is Analyzed
Multi-algorithm QC analysis
*Insight*™ peer group/EBQC
Calibration Verification
QC Pass/Fail
**BEYONDCARE℠ QUALITY MONITOR DASHBOARD**

- Color-coded analyzer tabs for at-a-glance status updates
- **Green** = good to go
- **Yellow** = more information or action required
- **Red** = unresolved problem requires service intervention
TROUBLESHOOTING QC ISSUES

- How to resolve a QC issue when detected?
  - Repeat of QC vial? Open new vial?
  - Recalibrate?
  - Perform maintenance?
  - Call service engineer?

- Does everyone in the lab have the same level of knowledge regarding QC?
  - Are troubleshooting processes for QC standardized and documented? Are they followed?
  - How is new staff trained on QC practices?

- This can be a time and resource consuming activity
  - Service calls
  - Instrument availability
  - QC material usage
  - Lab workflow interrupted
  - Time away from other activities
BEYOND CARE® QUALITY MONITOR DASHBOARD

Easy identification of action required
BEYONDCARE℠ QUALITY MONITOR DASHBOARD

Information & instructions at time of need
**STREAMLINED REPORTING AND DOCUMENTATION**

**Controls analyzed 3 times a day**
- QC and Backgrounds failed, Service event, Calibration and QC passed

**Intermittent QC failures monitored and proactive service event to resolve issue**
- Exceeded time between QC analysis

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DETAILED DAILY VERIFICATION REPORT

Normalizes control levels to view in one chart

Daily Pass/Fail

RBC

Number of QC runs each day

Easy pattern identification means earlier identification of shifts, trends & errors.
EXAMPLE OF ERROR IDENTIFICATION

Control product Open Vial Stability (OVS) is 7 days

Found handling issues and lab staff is exceeding the OVS 5 out of 8 times

Automatic identification of problem and details can find cause within minutes
DAILY CALIBRATION VERIFICATION

- No time-based calibration verification events
- Real-time identification and resolution of issues
- Eliminates waiting 6 months to identify and resolve shifts, trends or errors.

- Calibration verification done (and documented!) every time QC is analyzed
- Traceable to international reference methods
- Peer group integration
- Reports are printable on demand to streamline inspections.
WHY THE RIGHT NUMBER MATTERS

Essential laboratory knowledge for the clinician

Laboratory testing forms an integral part of patient management.

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Consultant Chemical Pathologist, University of Cape Town, Groote Schuur Hospital National Health Laboratory Service
Fierdoz Omar qualified as a chemical pathologist in 2009 (FCPath (Chem)) and obtained her MMed (ChemPath) in 2010. She is a lecturer at the University of Cape Town, where she is involved in undergraduate and postgraduate training. Her current field of interest includes molecular diagnostics and quality assurance.

Correspondence to: Fierdoz Omar (Fierdoz.omar@nhls.ac.za)
Six Sigma

Defined as how many Defects Per Million (DPM)

Scale: 0 to 6 (Sigma short-term scale)

6 Sigma = World Class Performance = 3.4 DPM

3 Sigma = Minimal Performance = 66,806 DPM

How do we measure 6 Sigma Performance in the laboratory?
Six Sigma

Sigma-metric equation for analytical process performance

**Sigma metric** = \((\text{TEa} – \text{bias observed}) / \text{CV observed}\)

- Imprecision = CV of quality control materials
- Inaccuracy (Bias) = CAP surveys or peer comparisons
- TEa = EP Evaluator or Westgard Website
Sigma Quality Monitoring

• Patient Results Quality
  • Patient sample test method should have highest sigma possible
    \[ >3\sigma \]
  • High sigma score indicates small accuracy and precision changes do not affect result quality

• QC Monitoring (error detection)
  • Sigma process allows for control limits placed at normal QC distribution
  • Quick detection of accuracy or precision changes
  • Sigma for error detection between 3 to 4\(\sigma\)
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Blank cells above indicate the control is not run for that analyte. Only 2 rather than 3 levels of control run.

- **World Class** = Six Sigma Performance
- **Excellent** = Five Sigma Performance
- **Good** = Four Sigma Performance
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MCV DELTA FLAG IN WAM
EMERGENCY ROOM TURNAROUND TIME

Length of Stay in the Hospital Emergency Department: Does Every Minute of Laboratory Test Turnaround Time Count?

Author: Victor Khangulov // Date: FEB 4 2016 // Source: NACB

“a 10-minute reduction in test turnaround time was associated with a nearly 7-minute reduction in length of stay in the ED.”
EMERGENCY ROOM TURN AROUND TIME
Various costs are hidden along the total testing process.

Through the use of Six Sigma, there are opportunities to reduce cost by improving the quality in laboratory.
SIX SIGMA AND COST

Health care organizations are now beginning to use Six Sigma to monitor error rates.
COST BREAKDOWN

BCQM can affect the analytical phase.

- **Preanalytical phase**
  - Ask clinical questions
  - Select appropriate test
  - Order test
  - Collect specimen
  - 61.9% of errors

- **Analytical phase**
  - Prepare sample
  - Perform test (analysis)
  - Verify results
  - 15.0% of errors

- **Postanalytical phase**
  - Report results
  - Answer clinical questions
  - Take action
  - Determine effect on patient care
  - 23.1% of errors
WHAT TO DO WITH AN ERROR

Once an error is detected, what is done by the laboratory to make sure the error doesn’t happen again?
YOU GET WHAT YOU PAY FOR?

- It is traditionally assumed that higher quality means higher costs or “you get what you pay for”.

- The beauty of BeyondCare is that the cost is minimal by using software and algorithms to achieve this higher quality.
SUMMARY

- The BeyondCare Quality Monitor can decrease your laboratory’s turnaround time by maintaining high Sigma values, which can decrease length of stay in the ED.
- The BeyondCare Quality Monitor can have a positive impact on your laboratory’s budget by detecting errors immediately.
THANK YOU