Selection & Implementation of a New POC Device

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Where we were....

1. Sales rep visits MD
2. MD decides to purchase
3. Implementation per MD orders
4. TJC / CAP / CMS / COLA inspection
   – DEFICIENCIES CITED
5. POCC instructed to
   FIX IT NOW!
1. Sales rep visits MD
2. MD says “I want”
3. POCC spends weeks (if lucky) implementing system properly
4. MD uses for a month and decides test not useful
5. POCC blamed for unneeded costs
Where we should be....

1. Sales rep visits MD
2. MD calls in POCC
3. Justification for new POCT developed
4. Multiple systems analyzed
5. Optimal system implemented
6. Benefits observed in clinical, operational, and / or financial outcomes
How we get there.....

- CLSI POCT09
  - Selection Criteria for Point-of-Care Testing Devices
    - To be published March 2010
- Considerations for comparing POCT devices
- Checklist for evaluating requests
- Checklist of criteria as a starting point for selecting a new device for clinical use
- Overview of implementation activities
Why Consider POCT?

- Increasing trend toward decentralized testing
  - Not all tests need to be at POC
- Improved outcomes (sometimes)
  - Medical outcomes (possibly)
    - Decreased readmission rates
    - Decreased morbidity and mortality
  - Resource, Operational, and Financial Outcomes (possibly)
    - Decreased ED diversions
    - Increased clinician satisfaction
- Requires process change
Where to begin

• Formal request for new POCT
  – What is requested?
  – For which patient population?
  – Why?
    • Safety; Cost savings; Product innovation; User complaints; Standardization; Other
  – Why POCT?
  – Justification
Justification

• Let the Requester answer the questions:
  – Anticipated impact on cost of patient care
  – Anticipated impact on patient treatment
  – Personnel expected to perform testing
  – Departments expected to be impacted by testing
  – Procedures to be changed before implementation
  – Personnel to be responsible for implementation and training
Assess Clinical Needs

- Is POCT needed to meet a clinical need?
  - Is POCT fit for intended clinical purpose?
  - How much of the testing will move from lab to POC?
  - What is the intended population?
  - Why would POC be a benefit?
  - Is the Intended Use of the POCT appropriate to the targeted application/ patient population/ sample type?
  - What are the limitations of the procedure?
  - Are accuracy and precision claims sufficient for targeted use?
Assess Operational Needs

• What process and procedural changes are necessary to reap the benefits of POCT?
  – Does the POCT require the implementation of new quality systems and quality assurance (QA) programs?
  – Can current processes be changed to meet the clinical need, e.g., improve turnaround time?
  – How many different locations will need access to POCT?
  – How many devices are needed to meet the testing needs?
  – Is there a need for a connectivity solution to transfer patient and/or quality control (QC) results?
  – Who will perform the testing, and how many individuals require training, eg, nurses, patient care assistants, perfusionists?
  – Who will perform the ongoing inventory management activities?
POCT Features Required

- QC assessment
  - Built-in; External; Lock-outs
- Operator control
  - Training; Competency; Lock-out
- Test Menu
  - Sufficient for current and potential future needs?
- Test Volume
  - How many tests will be run in a given timeframe?
  - How many instruments are required to handle to expected volume?
Personnel Requirements

• Operators
• Supervisors
• Compliance oversight (Lab?)
• Providers/ Clinicians
• Support Personnel
  – IT, purchasing, materials management, etc.
Identify Candidate Devices

- Research options
  - Laboratory periodicals and buyer’s guides
  - Medical alert websites that list complaints, recalls, etc.
  - Vendor websites
  - External quality assessment (EQA) (proficiency testing) performance reports
  - Peer-reviewed literature
  - Regulatory and accrediting body websites
  - Online product searches
  - Professional trade shows
  - Local vendor fairs
  - Site visits to locations using the device
Preliminary Cost Assessment

• Implementation costs
  – Include personnel costs for training

• Ongoing operational costs
  – Include competency assessment, program oversight

• Total cost per test
  – Include costs for QC, calibration
  – Expected frequency of repeats or errors
Preliminary evaluation

• Optimally performed by expected operators
  – If performed by vendor reps, cannot be certain reflective of “true” performance
  – Vendor can provide user training
• Within and between day precision
• Method comparisons
  – Optimally using patient samples
• Verification of reportable range
• Regulatory and accreditation requirements
Device Selection

- System performance
  - Data from preliminary evaluation
- Ease of Use
  - Subjective assessments from operators
- System Calibration and QC
- Software/ firmware features
  - Lock-outs, connectivity
- Reagents / consumables
  - Storage; shelf-life; preparation
- Vendor support
- Cost
Implementation

• Installation
  – Electrical power requirements
  – Environmental requirements
  – Storage requirements
    • Temperature, Volume
    • Assay reagents, Calibrators, QC products
    • Miscellaneous supplies for sample collection and preparation
Implementation

• **System Configuration**
  – Set date and time
  – User identification/security
  – QC frequency and acceptable ranges
  – Automated electronic QC
  – Print options
  – Format of data output
Implementation

• Device calibration and QC
  – Follow vendor recommendations
  – Verify reagent, calibrator, and QC materials following vendor recommendations
  – Determine if QC is within specific assay performance guidelines
  – Follow regulatory requirements
  – Validate QC frequency policy
Implementation

• Validation studies
  – Often can use data collected during preliminary evaluation to support validation of system
  – Accuracy
  – Precision
  – Reportable range
  – Reference interval verification
  – Method comparison studies
Validation - Accuracy

- Measure of how close a measurement is to the “true” result. In terms of the target, how often a measurement is close to the bulls-eye.
- Determined by correlation to local standard
  - correlate does not mean match

\[\begin{align*}
\text{Perfect Correlation} \\
\text{Slope} = 1 & \quad \text{slope} = 2 & \quad \text{slope} = 0.5 \\
\text{Intercept} = 0 & \quad \text{intercept} = 1 & \quad \text{intercept} = -0.5
\end{align*}\]
### Validation - Accuracy

<table>
<thead>
<tr>
<th>System</th>
<th>Non-standardized Assay</th>
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<tr>
<td></td>
<td>System</td>
</tr>
<tr>
<td>System</td>
<td>POC 1</td>
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<tr>
<td></td>
<td>0.456</td>
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<tr>
<td></td>
<td>0.011</td>
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<tr>
<td></td>
<td>0.988</td>
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<tr>
<td>System</td>
<td>POC 2</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>-0.138</td>
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Slope of POC 2 is closer to 1.0
Is it more accurate?

Validation - Accuracy

<table>
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<tr>
<th>Reference</th>
<th>POC 1</th>
<th>POC 2</th>
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<tbody>
<tr>
<td>0</td>
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<td>-0.14</td>
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<td>5.0</td>
<td>2.29</td>
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</tr>
</tbody>
</table>

Two systems equivalent across critical range

Validation - Precision

- Measured as CV (%) for replicate sample testing
  - Matrix effects differ for each reagent
- Minimum CV will be observed with fresh samples
  - Whole blood for most POCT
- Next lowest CV using manufacturer’s recommended controls
  - Manufacturer ensures appropriate sensitivity
- Worst CV may be seen with Proficiency Samples
  - Different effect on every assay
Validation - Reportable Range

- Use controls, calibrators, patient samples
  - Spiked samples can be used IF consistent with manufacturer’s recommendations
  - Patient samples clearly optimal, where possible
- CLSI EP06 provides protocol
Validation - Reference Interval

- Vary by analyte
- May vary by manufacturer
- Often different for POC versus laboratory
  - Different clinical decision points
- Labeling may indicate as LoQ or 99th percentile, etc.
  - LoQ – limit of quantitation
    - Concentration with specified CV (%)
    - Usually 10 or 20%
  - 99th percentile
    - Determined from 100 patient reference group study
      - Values listed in increasing order, 99th value is 99th percentile
      - Approximated as the mean value of the normal reference group plus three standard deviations.
Validation - Method Comparison

- Optimally span the reportable range
- Special attention to clinical decision points
  - May require different decision points for POC and lab
    - Evaluate correlation across range
    - Set new decision points
    - Evaluate clinical agreement
Implementation

- Documentation
  - Procedures
    - Step-by-step directions CLSI document GP02
    - Many vendors will supply draft CLSI formatted procedures
  - Logs
    - Device troubleshooting references
    - Maintenance records
    - QC records
    - Method validation records
    - Training records
  - Results Reporting
Continuing Process Improvement

Corrective Actions  Evaluation

Regulatory Requirements

Monitoring  Implementation

Supplier inputs
Health care provider and patient expectations
Consensus decision on device selection; Robust implementation of POCT