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!

Where we are…..

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…..

- Develop a process for selection and implementation of POCT
  - CLSI POCT-09A can help
    - Selection Criteria for Point-of-Care Testing Devices
  - › Include formal request policy
    - Not every test needs to be POC
  - › Include formal justification
    - Improved outcomes?
      - Medical outcomes
      - Resource, Operational, and Financial Outcomes
    - Requires process change

Request for POCT

- What is requested?
  - New or replacement?
  - If new:
    - Which analyte(s)?
    - For which patient population?
    - Why POC?
  - Why?
    - Safety; Cost savings; Product innovation; User complaints; Standardization; Other
- 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
  - Procedures to be changed before implementation
    - Personnel to create new procedures
    - Personnel to participate in IQCP development
  - Personnel to be responsible for implementation and training

Assess Need for Novel POCT

- Clinical:
  - Why would POC be a benefit to current processes?
  - Are accuracy and precision claims sufficient for targeted use?
- Operational:
  - Can current processes be changed to meet the clinical need
    - *e.g.*, improve turnaround time?

Define New Test Environment

- Locations
  - How many?
  - Which personnel?
  - How many devices per location?
- Is new connectivity required?
- Who will perform training?
- Who will perform the ongoing inventory management?

Define Required Features

- QC assessment
  - Built-in; External; Lock-outs
- Operator control
  - Training; Competency; Lock-out
- Risk Assessment
  - How will the system fit with IQCP requirements?
- 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 the expected volume?

Personnel Requirements

- Operators
- Supervisors
- Compliance oversight (Lab?)
- Providers/ Clinicians
- Support Personnel
  - IT, purchasing, materials management, etc.

Identify Candidate Devices

- Resources
  - Clinicians
  - Other POCC
  - Laboratory periodicals and buyer's guides
  - Medical alert websites
  - Vendor websites
  - Trade shows / Vendor fairs
  - Site visits to locations using the device

Evaluate Candidates

- Select 2 or 3 devices to compare
  - Optimally performed by expected operators
    - If performed by vendor reps, cannot be certain reflective of “true” performance
- Precision
  - Controls and / or patient samples
- 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

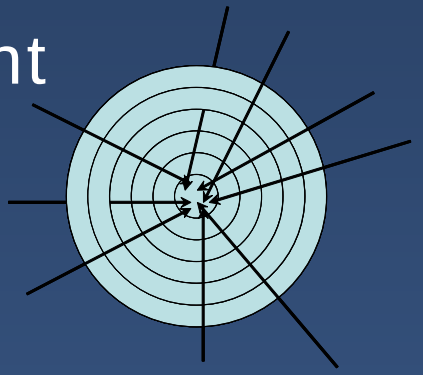
- Installation
- System Configuration
- Device calibration and QC
  - CMS Brochure # 3 – Calibration and Calibration Verification
    - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6065bk.pdf
  - Implement / Validate IQCP
    - CMS Brochures 11-13
      - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

Implementation continues….

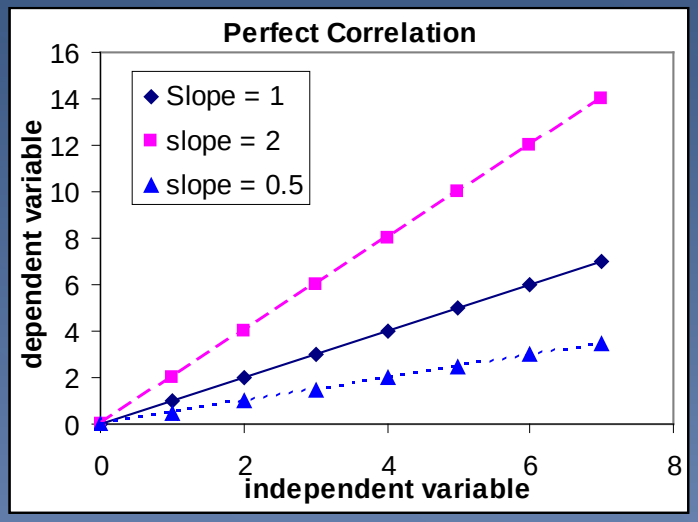
- Validation studies
  - CMS Brochure #2 - Verification of Performance Specifications
    - http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6064bk.pdf
  - CLSI has guidelines for every step of system validation studies
    - Accuracy (quantitative and qualitative)
    - Precision
    - Reportable range
    - Reference interval verification
    - Method comparison studies

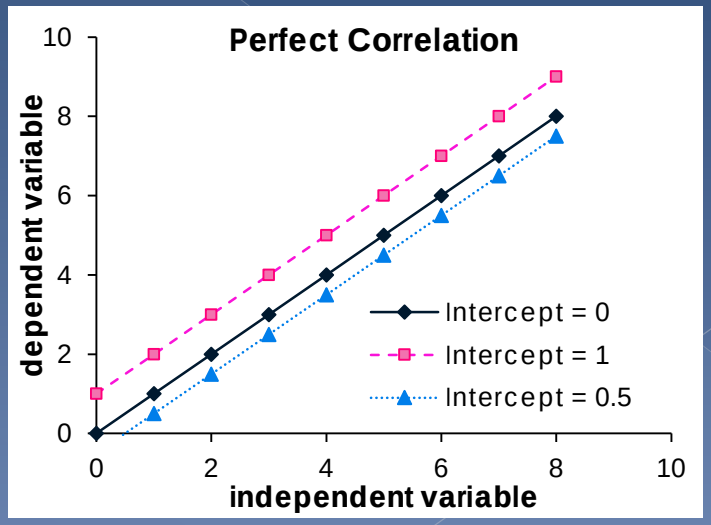
Validation - Accuracy

- Measure of how close a measurement is to the "true" result.
  - how often a measurement is close to the bulls-eye.



- Determined by correlation to local standard
  - correlate does not mean match





Accuracy - 2

Non-standardized Assay		
System	POC 1	POC 2
Slope	0.456	0.718
Intercept	0.011	-0.138
R	0.988	0.974

Slope of POC 2 is closer to 1.0

Is it more accurate?

Reference	POC 1	POC 2
0	0.01	-0.14
0.2	0.10	0.01
0.5	0.24	0.22
1.0	0.47	0.58
5.0	2.29	3.45

Two systems equivalent across critical range

Adapted from Wu, et. al. Clinica Chimica Acta 346: (2004) 211-219

Accuracy - Qualitative

		"true" Result		
		Positive	**Negative**	
Result being evaluated	**Positive**	True positive (TP)	False Positive (FP)	*(PPV) - Positive Predictive Value*
	Negative	False Negative (FN)	True Negative (TN)	*(NPV) - Negative Predictive Value*
		Sensitivity	*Specificity*	*Concordance*

$$Sensitivity = \frac{TP}{TP+FN}$$

$$Specificity = \frac{TN}{TN+FP}$$

$$PPV = \frac{TP}{TP+FP}$$

$$NPV = \frac{TN}{TN+FN}$$

$$Concordance = \frac{TP + TN}{Total\ Number\ Samples}$$

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 performance
- Worst CV may be seen with Proficiency Samples
  - Different effect on every assay

Validation - Reportable Range

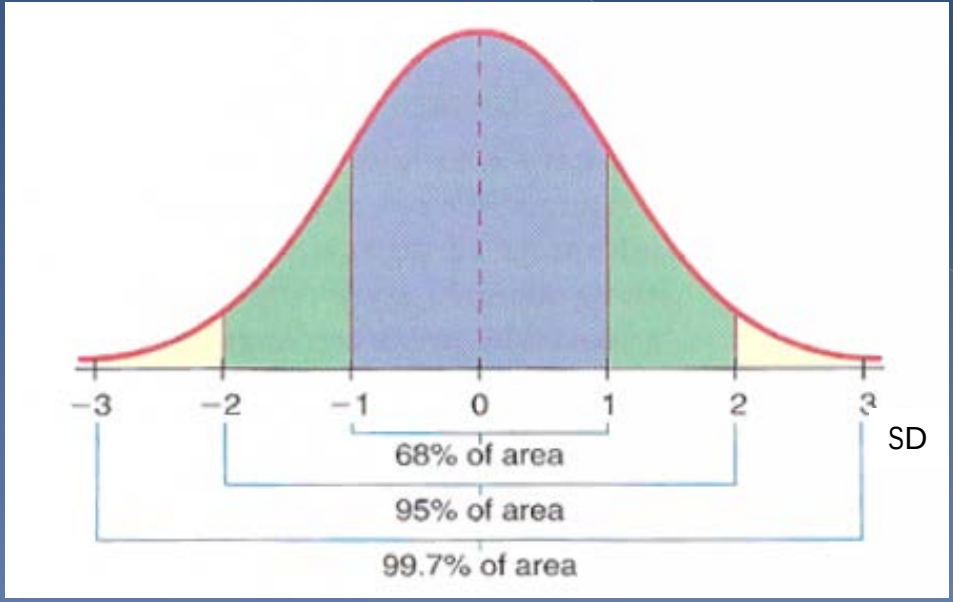
- Use controls, calibrators, patient samples
  - Spiked samples can be used IF consistent with manufacturer's recommendations
  - Patient samples optimal, where possible
- Only samples within the validated range should be used for patient assessment / treatment

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

- Often the same as Accuracy
- 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
  - IQCP
  - Procedures
    - Step-by-step directions
  - Logs
    - Device troubleshooting references
    - Maintenance records
    - QC records
    - Method validation records
    - Training records
  - Results Reporting

Conclusion

- Spend the time up front
  - Don't implement a system that won't work
- Lean on your supplier
  - Get draft protocols, IQCP templates, etc.
  - Get free or reduced price supplies for evaluation and implementation
- Get buy in from everyone in house
  - Manage expectations!

QUESTIONS?

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