Point of Care Testing and Quality Management Systems

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Key Points To Ponder

1. Is today's POCT safe?

2. Is traditional QC for POCT enough?

3. What is a Quality Management System?

WHY THE BIG DEAL??

Is POCT Safe?

Is today's POCT safe?

- Instrument design and reliability
  - The core technologies used in POC testing and their presentation formats have developed to the extent that the products can now be used by moderately trained non-clinical staff.
  - POCT devices are essentially "black boxes" which compress the analytical process to (a) collecting the specimen (b) inserting the sample into the device and (c) receiving a quantitative result. All this happens with a minimum of operator involvement.

Is today's POCT safe?

- Since there is little or no operator involvement in the analytical process, one should be able to assume that there is little or no opportunity for error.

  A critically thinking professional would immediately reject this logic!

  – However, our society generally assumes, with little question, the superiority of "black boxes".

  – If the quality or process can't be easily assessed, it MUST be right.

Is today's POCT safe?

- **Real Life Tragedy**
  – Patient- post renal transplant w/complications
    - UTI, cerebral edema, respiratory failure, fluctuating glucose levels (not uncommon)
  – Patient is monitored from a remote eICU to provide "second level of specialists".
  – Primary bedside care done on-site by nurses and physicians with oversight by AICU staff.
  – Bedside Glucose Monitoring done by on-site nursing staff.

Real Life Tragedy

- Time Line:
  - 12/21 Pt. Admitted
  - 1/1 MDs order patient be treated for “high blood sugar” based on POC results.
    - BSG results 480 mg/dl (several times)
  - 1/2 MDs order insulin drip increased
    - BSG results 480 mg/dl (several times)
    - insulin drip increased from 14.7 to 52.6 u/hr over several hours
    - BSG still 480 mg/dl-insulin injection given.
    - Confirmatory Lab Tests show “critically low glucose levels” on 1/3 at 4 AM (x3) – nurse does not communicate to MDs treating patient.

Real Life Tragedy

- 1/3 0920 MD orders insulin drip put on “hold”
- 1/3 0930 Bed side staff try other pack of strips and still get high readings.
- 1/3 1030 Bedside staff test themselves with strips and get high readings – determine that test strips “malfunctioned”.
- 1/3 1032 MDs begin treating for “low blood sugar”.
- Later in AM, patient determined to be “un-responsive due to prolonged hypoglycemia that met brain death criteria”
- 1/6 Patient dies

Issues?

- Was daily QC run on meters? Was it EQC or Aqueous QC?
- Was there an automatic “lab confirmation” of very high patient or very low BSG results?
- Did anyone at the bedside look at the lab results that had been ordered and received at 4 AM on 1/3?
- Did the lab call a critical value?
  - If so, to whom?
- Why did staff rely on BSG when they admit “serum lab glucoses were more accurate”.

Where was the lab POC oversight?

Traditional Approach

Is Traditional QC Enough for POCT?

- There are 2 types of POCT systems
  - Traditional technologies with simplified operational procedures
  - Newer disposable unit-use devices
- The former use traditional quality control (QC) concepts such as a minimum of 2 levels of controls per assay per day.
- The latter tend to use EQC (electronic quality control) to check or to have a built in single level calibration or control

Is Traditional QC Enough for POCT?

- Are Pre-Analytic, Analytic and Post-Analytic aspects of testing measured?
- Does the system measure multiple analytes or a single type of test only?
- Does the cartridge or strip contain all of the components needed to perform the test?
- Are they self calibrating or do they need separate lot calibrations?
- Does the analyzer have other built in check capabilities?

PRE-ANALYTICAL CONSIDERATIONS

- Patient ID confirmation
  - How is the patient positively identified?
  - Are 2 points of ID utilized?
- Sample Quality
  - Is puncture site clean? Dry? Healthy? Appropriate?
- Aseptic Technique
  - Free from contaminants? Alcohol free (from sterilizing pads/swabs)?
- Correct collection tubes (if applicable)
  - Is the correct capillary tube used?
  - Is it tested immediately or must it be mixed?

Analytic Considerations

- Operator Identification
  - Can the operator, date and time of test be clearly documented?
- Operator Competence
  - Is there annual documentation of demonstrable competence with the system.
- Analyzer Maintenance
  - Is there documented maintenance per the manufacturers recommendation. Is the analyzer clean?
- Analyzer QC/Calibration
  - Is the Calibration and QC performance documented and is it verified and monitored? Frequency?

Post Analytic

- Correct sample disposal
  - Use of sharps, biohazard containers
- Cleanliness and tidiness
  - Spill clean up, patient clean up, analyzer cleanup
- Examination & interpretation of results
  - Does the operator understand what the results mean? Do they know what is normal or what to expect? Do they know when to repeat a test? Do they know what error codes mean? What to do when they get an error code?
  - Do they know when and how to get confirmation?
- Notification of abnormal results
  - Are they relayed to the appropriate caregiver (nurse, doctor)
  - How are they documented? Is the notification documented?
- Inclusion in patient record
  - How does the result placed in the patients record? Is it accurate?

External Quality Assessment and Proficiency Documentation

- Proficiency and Competence are regulatory requirements.
  - External Proficiency should be randomly assigned to the various operators.
    - Multiple proficiency samples will be required depending on the frequency and the number of operators and systems in use.
  - Annual competence verification is mandatory
  - How is QC reviewed and how often?
    - By whom? Is review clearly documented?

Quality Management Systems

QUALITY MANAGEMENT SYSTEMS

- A QMS provides a comprehensive approach in the development of standards and guidelines which applies a core set of Quality Systems Essentials (QSEs).
  - Documents and records, Organization, Personnel, Equipment, Purchasing and Inventory, Process Control, Information Management, Occurrence Management, Assessments (both internal and external), Process Improvement, Customer Service and Facilities and Safety

CAP, ISO-15189 and POCT

- ISO-15189 currently does not assess POCT. It is addressed in ISO-22870.
  - They are intended to be used together.
- CAP Lab Accreditation Program (LAP) requires the laboratory to have a "comprehensive QMS" which must include POCT if it is provided under the lab CLIA license and CAP #.
- JCAHO requires a comprehensive QMS for the hospital and it too should include POCT if the lab is JCAHO deemed.

Avera McKennan's POCT QMS

- It is part of the total lab QMS and follows all of the criteria required of the main lab.
- We are ISO-15189 accredited and designed our POCT QMS program using those guidelines.
- Non-Laboratory personnel have a hard time understanding why the QMS standards are so strict.
  - In this sense, they are no different than other facilities and non-laboratory professionals.
  - All waived Quantitative tests are held to the same standards as non-waived

QSE Components

- Documents and Records
  - Complete procedures following ISO/CLSI format that are available and used by all testing personnel.
  - Documentation of Competency by operator
  - Documentation of daily QC (2 levels) by meter
  - Documentation of EQC/cartridge QC as appropriate
  - Documentation of positive patient ID
  - Documentation of analyst, date and time
  - Documentation of maintenance by meter including date, time and by whom

  ALL ELECTRONICALLY CAPTURED

- Organization-
  - An organizational chart of the POCT management is maintained with responsibilities and authority designated.
- Personnel
  - Program is run by a laboratory supervisor and the Point of Care Technical Specialist, with oversight by a designated POC Pathologist.
  - Nursing provides a Diabetes Educator who works in conjunction with the laboratory to ensure compliance and provide a “nursing point of view” and assisting in communications with the nursing staff.

Testing Personnel Training

- POCT technical specialist trains all new users in order to ensure standardized training.
- All procedures are available in electronic format and require an annual read and assessment by each individual authorized to perform POC testing.
  - This is documented electronically without any other intervention.

- Equipment
  - Laboratory approves any POC testing and equipment. It is provided by the laboratory to ensure quality and accuracy. Laboratory can deny POC testing to any area if appropriate.
- Purchasing and Inventory
  - Laboratory orders all supplies and equipment.
  - All supplies/reagents follow our LEAN inventory protocols.
  - All supplies are provided by laboratory and issuing controlled following LEAN principles.
    - Outdates are virtually non-existent. Any reagent with an outdate is clearly marked before leaving lab.

- Process Control
  - Standard Work Document is used throughout the hospital for POCT.
  - It is specific for the POCT analyzer/assay.
  - All personnel who do POCT are trained using the Standard Work Document and its importance is stressed and why.
  - Ensures that all tests are performed in the same manner by all performing staff
  - Failure to follow Standardized Work Documents results in counseling for first offense and afterwards in corrective action.
  - A process map showing how POCT information and processes flow provides visual education.

- Information Management
  - All POCT testing information is electronically collected using middleware and is interfaced to the LIS.
  - The LIS and middleware together allow the POCT Technical Specialist to monitor the program, personnel, equipment and their individual and over-all performance.
  - The LIS is integrated into the EMR and the POCT information flows seamlessly to the EMR with no technical manipulation.

- Occurrence Management
  - When BSG exceeds 400 mg/dl, automatically a laboratory glucose is ordered, label prints in phlebotomy and stat collection performed.
  - Lab routine TAT for glucose is 35 min from collection to availability in EMR.
  - Lab is required to call all “critical” value results of Lab performed Glucose to nurse taking care of the patient and make notation.
  - Any deviations are documented and investigated by POC and QMS. All are logged in to Laboratory’s LABOCCUR program.

Compliance Enforcement

- Most POC instruments are on a “QC Lockout” so compliance is assured.
  - In those areas that don’t have lockouts, a designated individual is responsible to see weekly QC is done and sends the data to POC Tech Specialist on a weekly basis.
  - Any deviation results in loss of POCT for the individual, continued deviation means loss of POCT for the area.

- Internal and External Assessments
  - External Assessments
    - CAP Proficiency performed regularly.
    - Randomly assigned to any current operator
    - Multiple sites surveyed each time.
    - All variances investigated and noted in LabOccur
  - Internal Assessments
    - Internal competency performed annually through direct observation as well as unknown testing.
    - Linearity performed by lab on all meters twice yearly.
    - Reproducibility studies performed on all meters twice annually by lab.
    - Annual written competency on line required.

- Process Improvement
  - As part of our QMS and LEAN initiatives, POCT is evaluated periodically, issues identified, corrected and documented.
- Customer Service
  - Lean commitment to customer service is key.
  - Voice of the Customer is second nature.
- Facilities & Safety
  - All areas are surveyed for safety and cleanliness by Hospital as well as POC on a regular, random basis.

Why The Big Deal?

1. We are committed to ISO and QMS
2. Good POCT contributes to Positive Outcomes for our patients
3. It takes constant vigilance to ensure that non-laboratorians abide by the standards that are so ingrained in us.
4. OUR PATIENTS DESERVE NOTHING LESS THAN OUR VERY BEST.

QUESTIONS?

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