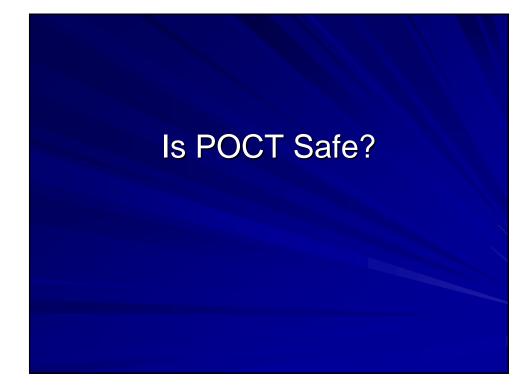
# Point of Care Testing and Quality Management Systems

Brendon Sato, MLS(ASCP) Avera McKennan Hospital Sioux Falls, S.D.

## 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 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 nonclinical 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.

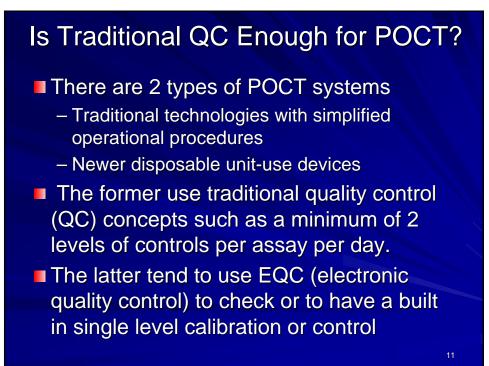
### Real Life Tragedy

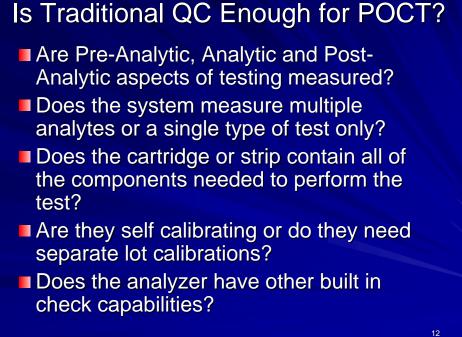
- 1/3 0920 MD orders insulin drip put on "hold"
- 1/3 0930 Bed side staff try other pack of strips and still get high readings.
- 1/3 1030 Bedside staff test themselves with strips and get high readings – determine that test strips "malfunctioned".
- 1/3 1032 MDs begin treating for "low blood sugar".
- Later in AM, patient determined to be "unresponsive 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?







#### 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

- 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.



#### 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

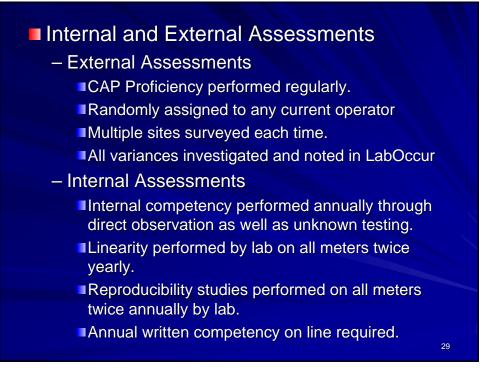
- All POCT testing information is electronically collected using middleware and is interfaced to the LIS.
- The LIS and middleware together allow the POCT Technical Specialist to monitor the program, personnel, equipment and their individual and over-all performance.
- The LIS is integrated into the 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.



#### 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 nonlaboratorians abide by the standards that are so ingrained in us.
- 4. OUR PATIENTS DESERVE NOTHING LESS THAN OUR VERY BEST.

# **QUESTIONS?**

Contact Info: brendon.sato@avera.org