Patient Safety: A Quality System Approach To POCT QC/QA

Ellis Jacobs, Ph.D., DABCC

New York University School of Medicine
Coler-Goldwater Specialty Hospital & Nursing Facility
New York, New York
Point-of-Care Testing
Characteristics

A broad based process. Unrestricted to location, personnel or test menu.

A collective, multi-disciplinary effort.
Simple to use technology
Potentially low volume testing
<table>
<thead>
<tr>
<th>POCT versus Central Lab Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing personnel</strong></td>
</tr>
<tr>
<td>Pathologists, PhDs, Med. Lab Technologists</td>
</tr>
<tr>
<td><strong>Primary duties</strong></td>
</tr>
<tr>
<td><strong>Knows laboratory testing</strong></td>
</tr>
<tr>
<td><strong>Understands instrument’s quality checks</strong></td>
</tr>
<tr>
<td><strong>Can interpret QC data</strong></td>
</tr>
<tr>
<td><strong>Skills to resolve problems, troubleshooting</strong></td>
</tr>
<tr>
<td><strong>Recognizes quality testing</strong></td>
</tr>
</tbody>
</table>
Potential Analytes for POCT

- Bilirubin
- Blood Gases
- BUN
- Cardiac Markers
- CBC
- Cholesterol/Triglycerides
- Drugs
- Fecal Occult Blood
- Gastric Occult Blood
- Glucose
- Gram Stains
- HgB/Hct
- HgB A1C
- Infectious Diseases
- Lactate
- Na, K, Ca++, Cl, Mg++
- O2 Sat
- Platelet Function
- Pregnancy
- PT/PTT/ACT
- Urinary microalbumin/creatinine
- Urinalysis/Specific Gravity
Point-of-Care Tests (POCT)

- NOT considered laboratory testing
  - Breath alcohol
  - Continuous glucose monitors
  - Pulse oximeters
  - Transcutaneous bilirubinometers
  - *Ex vivo* ABG
  - Biosensor Technologies (monitors)
Trends in Healthcare Provision

POCT

Home

Primary Care Centre

Community Treatment Centre

Laboratory

Local Hospital

Referral/Specialist Hospital

trend in care?
The Truth about POCT

- POCT introduces an additional technology
  - Different precision
  - Biases
  - Unique interferences

- POCT results do not necessarily agree with core laboratory results

- Quality concerns if manufacturers instructions and controls are not performed as required

- Additional testing is ordered when POCT results do not match core lab results or questions about the quality of results present
Growth in POCT

- 2008 Worldwide IVD Market - $42.1 Billion (46B in 2010)
- 2008 Worldwide POCT Market - $13.1 Billion (31%)
- 2010 Worldwide Professional POCT Market - $4 Billion
- ~10-12% annual growth
Moderators of POCT Growth

- Quality Assurance
- Quality Control - Matrix/Electronic
- Regulatory Requirements
- Record Keeping/Data Management
- Finances
What is Quality

- **Laboratory**
  - Delivery of test results within a specific timeframe with specified precision and accuracy

- **Physician**
  - Reliable test results that meet medical needs

- **Patient**
  - A test that tells the physician what is wrong

- **Manufacturer**
  - Stable test systems which perform within required accuracy and precision specifications

**THE CORRECT RESULT, ON THE CORRECT PATIENT, REPORTED IN THE CORRECT TIMEFRAME TO EFFECT PATIENT MANAGEMENT**
Quality Issues

- There is no “perfect” device, otherwise we would all be using it.
- Any device can and will fail under the right conditions.
- Any discussion of risk must start with what can go wrong with a test (errors).
- Laboratory tests are not foolproof.
Quality System

Organizational structure, resources, policies, processes and procedures needed to implement quality management

(ISO, NCCLS)

In other words... all activities which contribute to quality of testing, directly or indirectly.
Quality Assurance

All planned and systematic actions necessary to provide adequate confidence that goods or services will satisfy the customer’s needs.
POC Testing Knowledge Flow

Health Care Provider Determines Need for Data

- Sample Obtained
- Sample Processed At POC
- Sample Received & Processed in Lab
- Data entry into LIS

Sample Transported To Satellite Lab
Due to the rapid availability of results with POCT, data can often be seen and acted upon prior to any QA checks or other external mechanisms for assuring test results can be applied to these systems.
What is Risk

Combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51).
## Risk Acceptability

<table>
<thead>
<tr>
<th>Probability of Harm</th>
<th>Negligible</th>
<th>Minor</th>
<th>Serious</th>
<th>Critical</th>
<th>Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Probable</td>
<td>acceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Occasional</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>unacceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Remote</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>unacceptable</td>
</tr>
<tr>
<td>Improbable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
<td>acceptable</td>
</tr>
</tbody>
</table>

Quality Control

- Operational techniques and activities used to fulfill requirements for quality (ISO)
- Internal quality control (IQC) – set of procedures for continuously assessing laboratory work and the emergent results; immediate effect, should actually control release of results (WHO, 1981)
Process to Develop and Maintain (CQI) a Quality Control Plan (QCP)

Key Processes in the Laboratory Path of Workflow

<table>
<thead>
<tr>
<th>Preexamination (Preanalytical) Processes</th>
<th>Examination (Analytical) Processes</th>
<th>Postexamination (Postanalytical) Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Examination ordering</td>
<td>• Examination</td>
<td>• Results reporting</td>
</tr>
<tr>
<td>• Sample collection and labeling</td>
<td>• Results review and follow-up</td>
<td>• Results archiving</td>
</tr>
<tr>
<td>• Sample transport</td>
<td>• Medical review</td>
<td>• Sample archiving</td>
</tr>
<tr>
<td>• Sample receipt and accessioning</td>
<td></td>
<td>• Charging for examinations, where applicable</td>
</tr>
<tr>
<td>• Preexamination sample processing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Quality System Hierarchy

- TQM
- Quality Management
- Quality Systems
- Quality Assurance
- Quality Control
POCT as a TQM Project

- Multidisciplinary team approach
- Looking at entire system, rather than individual performance
- On-going evaluation & refinement (CQI)
- Cost savings
- Improvement in delivery of critical laboratory services
Quality Management System Model

Laboratory’s Path of Workflow

Preanalytical  Analytical  Postanalytical

QSEs encompass the entire path
Quality Service Essentials (QSEs)
Quality Service Essentials (QSEs)

Facilities & Safety
- The Lab
  - Equipment
  - Organization
  - Personnel
  - Purchasing & Inventory

Information Management
- Documents & Records
- The Work
  - Process Control
  - Information Management

Process Improvement
- Customer Service
- Occurrence Management
- Assessments External & Internal

Process Improvement
- Occurrence Management
- Assessments External & Internal

Customer Service
- Process Improvement
- Occurrence Management
- Assessments External & Internal

The Work
- Process Control
- Information Management

Documents & Records
- The Work
  - Process Control
  - Information Management

Assessments External & Internal
- Process Improvement
- Occurrence Management
- Assessments External & Internal

Occurrence Management
- Process Improvement
- Occurrence Management
- Assessments External & Internal

Process Improvement
- Occurrence Management
- Assessments External & Internal

Customer Service
- Process Improvement
- Occurrence Management
- Assessments External & Internal

The Lab
- Equipment
- Organization
- Personnel
- Purchasing & Inventory
Quality of Health Care in U.S.

- Institute of Medicine
  - Medical errors cause 44,000 to 98,000 deaths each year
    - Equivalent to 200 deaths each day in airline crashes
    - Fifth leading cause of death in U.S.
  - Ahead of diabetes, breast cancer, HIV
    - Lab testing certainly contributes to deaths
  - Lab is looking for built-in safeguards to prevent errors

To Err is Human: Building a Safer Health System.
Washington, DC, National Academy Press; 2000
Laboratory Testing
Potential Sources of Errors

- Prepare request form
- Phlebotomy
- Record result
- Transmit result
- Prepare sample
- Register sample
- Report result
- Analyse sample
- Quality control
- Validate result

Doctor

Patient
<table>
<thead>
<tr>
<th>Sources of Testing Error</th>
<th>1997</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preanalytical</td>
<td>68%</td>
<td>62%</td>
</tr>
<tr>
<td>Analytical</td>
<td>13%</td>
<td>15%</td>
</tr>
<tr>
<td>Postanalytical</td>
<td>19%</td>
<td>23%</td>
</tr>
</tbody>
</table>

Potential Impact of POCT on Laboratory Errors

**Pre-Analytical**
- Patient Identification
- Specimen Identification
- Improper result validation (QC)

**Post-Analytical**
- Routing
- Excessive turn-around time

**Analytical**
- Method Calibration
- Interferences
- Results out of measurement range
- Quality Assessment (EQA/PT)
Fishbone Diagram of Potential Failure Modes

1. Samples
   - Sample Integrity
     - Lipemia
     - Hemolysis
     - Interfering substances
     - Clotting
     - Incorrect tube
   - Sample Presentation
     - Bubbles
     - Inadequate volume

2. Operator
   - Operator Capacity
     - Training
     - Competency
   - Operator staffing
     - Short staffing
     - Correct staffing

3. Reagents
   - Reagent Degradation
     - Shipping
     - Storage
     - Used past expiration
     - Preparation
   - Quality Control Material Degradation
     - Shipping
     - Storage
     - Used past expiration
     - Preparation

4. Laboratory Environment
   - Atmospheric Environment
     - Dust
     - Temperature
     - Humidity
   - Utility Environment
     - Electrical
     - Water quality
     - Pressure

5. Measuring System
   - Calibrator Degradation
     - Shipping
     - Storage
     - Used past expiration
     - Preparation
   - Instrument Failure
     - Software failure
     - Optics drift
     - Electronic instability
   - Inadequate Instrument Maintenance
     - Dirty optics
     - Contamination
     - Scratches

Identify Potential Hazards

Sources of Quality Errors in POCT

N = 225

- Postanalytical: 3%
- Preanalytical: 32%
- Analytical: 65%
# POCT Quality Errors by Test

<table>
<thead>
<tr>
<th>Test Type</th>
<th># of Tests</th>
<th># of defects</th>
<th>% of defects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood gas/electrolytes</td>
<td>22,687</td>
<td>119</td>
<td>0.52</td>
</tr>
<tr>
<td>Blood gas/electrolytes/troponin I</td>
<td>5,809</td>
<td>10</td>
<td>0.17</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>8,879</td>
<td>14</td>
<td>0.158</td>
</tr>
<tr>
<td>Glucose</td>
<td>30,389</td>
<td>71</td>
<td>0.02</td>
</tr>
<tr>
<td>Drugs of Abuse</td>
<td>247</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Hb A1c</td>
<td>1,236</td>
<td>8</td>
<td>0.65</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>64,370</td>
<td>2</td>
<td>0.003</td>
</tr>
<tr>
<td>Blood Ketones</td>
<td>1,087</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### Impact of POCT Errors

<table>
<thead>
<tr>
<th>Score</th>
<th>Acutal n (%)</th>
<th>Potential n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>116 (51.2)</td>
<td>6 (2.7)</td>
</tr>
<tr>
<td>2</td>
<td>109 (48.4)</td>
<td>175 (77.8)</td>
</tr>
<tr>
<td>3</td>
<td>0 (0)</td>
<td>3 (1.3)</td>
</tr>
<tr>
<td>4</td>
<td>0 (0)</td>
<td>33 (14.7)</td>
</tr>
<tr>
<td>5</td>
<td>0 (0)</td>
<td>8 (3.6)</td>
</tr>
</tbody>
</table>
POCT & Patient Safety: Quality Testing Criteria

- Correct test ordered
- Correct patient
- Correct time for collection
- Correct specimen and processing
- Correct (accurate) test result
- Correct patient record
- Correct clinical interpretation of POCT result(s)
- Correct and timely clinical response
Best Practices for Glucose POCT

- Positive Patient ID - two identifiers
- Operator Certification
- Regular Calibration & QC
- Use Fresh Reagents
- Prevent Reagent Contamination
- Prevent Substance Interference
- Prevent Blood Sampling Errors
Evolution of POCT

1. **Manual**
   - A process or system operating automatically

2. **Automation**
   - Intelligent automation – detects single defective operation and automatically stops

---

Managing Sources of POCT Errors

- Designed out of the product
- Tested for
- Warned about
Evolution of Glucose POCT Technology

Manual Testing
- Incorrect sample amount
- Incorrect reagent amount
- Incorrect mixing
- Wrong position of testing device
- Wrong wait time
- Color blindness
Evolution of Glucose POCT Technology

1st/2nd Generation Instruments
- Wipe/Wipeless technology
- Operator ID / Patient ID
- Reduced operator intervention
- Operator prompts
- Check on reagent viability
- QC lock-outs
- Rudimentary Data Management

Manual Methods
Evolution of Glucose POCT Technology

Manual Tests

1st/2nd Generation Instruments

Current Technology
- Electrochemical Technology
- Ability to use universal specimen types
- Extended linearity
- Minimally Invasive Technology ( <3 uL Sample Size)
- Consolidated Testing Platforms
- Real Time Data Management and Connectivity
Patient/Sample Identification

- Pre-barcoded arterial syringe for positive patient identification
- Establishes and Maintains Sample ID throughout testing process
Preanalytical Error Reduction

- **Reduced Analytical Risks**
  - Glucose-specific strip technology
  - Individually foil wrapped and bar-coded strips –
    » reduces risk of contamination
    » assure fresh reagents for each test
    » only approved lots can be used

- **Reduced Risk of Sampling Errors**
  - Test begins when adequate sample is detected, reducing risk of short-sampling and over-sampling errors
Unit use and POCT devices

- It is often suggested that QC has no role in a unit use device because...
  - QC of a single unit (good or bad result) does not inform about other units [same argument would apply to non POCT analyzers in main lab that use discrete (unit use) reagent packs]
  - IMS fulfills QC role in unit use devices

- Unit use and continuous flow systems are not that different
Characteristics of Unit-Use Test

- The container where the test is performed is always discarded after each test.

- Reagents, calibrators, and wash solutions are typically segregated as one test. There is no interaction of reagents, calibrators, and wash solutions from test to test.
Nature of QC Procedures

- Use of electronic checks, including any instrument software features that serve as error detection or prevention mechanisms
- Use and number of surrogate samples, where appropriate, to be included as part of the QC procedure
- Testing of controls that are engineered into the test system
Centrifugal Analyzer – Integrated Surogate Controls
Surrogate QC doesn’t detect all errors

- Random patient interferences
- Random biases
- Long-term bias
- Imprecision

Flowchart:
- Assay a patient sample
- Determine out of control cause, rerun samples
- In control?
  - Yes: Patient results reported
  - No: Time to assay control?
    - Yes: Potential blocked detected errors
    - No: Potential undetected errors
Non-Surrogate Sample QC

Includes all forms of quality control other than the measurement of a surrogate sample, usually integrated into the device

- electronic QC (which simulates signals electronically), ex. i-STAT
- automated procedural controls (which ensure that certain steps of the procedure occur appropriately), ex. Immunochromatography test kits
- automated internal quality controls (which may, for example, ensure the quality of a raw signal), ex.
- diagnostic pattern recognition systems, ex. GEM iQM
Immunochromatography – Urine Dipstick
Blood Gas Analyzer - IMS

- Continuously monitors all critical components of blood gas testing in real time to assure accurate results
- Automatically assures that each test meets demanding quality specifications
- Immediately detects, corrects and documents errors
- Eliminates labor and material costs associated with traditional QC
- Assures that optimal quality control protocols are followed at all times, regardless of operator training
Internal monitoring systems (IMS)

- IMS are a collection of hardware and software that detect errors and prevent the effect of the error from occurring
  - Example: Noise in the signal of a patient sample is detected, the result is flagged and not reported

- IMS are not new – although always improved, they have been in systems for over 30 years
Internal monitoring systems

- Internal monitoring systems don’t detect all errors, because
  - Complexity of instrument systems prevents perfect failure mode models
  - There is management pressure to release new products quickly
  - There is insufficient knowledge to “design things right the first time”
Non-Surrogate QC and QC

Surrogate and Non-Surrogate QC

- are not completely redundant
- do not detect all errors
Thinking in the POCT Box

As automation reduces errors in the box, further reductions must occur outside the box.
Thinking Outside the POCT Box

Pre-pre: Physician must consider

» What POCT is available?
» What POCT will best serve the patient?
» Will an immediate answer improve the patient’s outcome?

Post-post: Is the Physician?

» Receptive to using an immediate POCT result
» Able to interpret result in the patient’s context
» Amenable to initiating an immediate response
Critical Factors in QC Decisions

◆ QC must be able to detect mistakes to enable immediate correction

◆ Risks and costs must be weighed

◆ QC is only one part of the quality control plan / quality management system

◆ Not all laboratories have the same competencies and organization

◆ Science and common sense must converge
Quality Control Plan

- Summarizes the potential errors for a device and how the lab will address them.

- Can be high level or very detailed - depends on the device, the laboratory, and the clinical application and can vary from lab to lab.

- Is scientifically based. It depends on the extent to which the device’s features or actions achieve their intended purpose and the laboratory’s expectations for ensuring quality test results.

- Once implemented, is monitored for effectiveness and may be modified to maintain risk at a clinically acceptable level.
The Problem with Pedestals

Congratulations! Please stand still so everyone can get a clean shot at knocking you down.
QUESTIONS