Plan for Quality to Improve Patient Safety at the POC

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Meeting the requirements or needs of the POCT or laboratory’s customers -- doctors and patients -- and satisfying their expectations
“Things” happen
“We” need “Quality” Results and Quality Practices!
In 2013, POCT’s focus must be on planning for:

Quality

And

Patient safety

Quality ≠ Patient Safety
Patient Safety— is not new!

Freedom from unintentional or preventable harm due to **avoidable** adverse events *(medical errors)* that directly impact the quality of care

Hippocrates: “…do no harm”

Patient safety is jeopardized by **poor quality** at POCT
2013 POCT: Criteria for Patient Safety and Quality

- Correct test ordered
- Correct patient
- Correct time for collection
- Correct specimen and processing
- Correct (accurate) test result
- Correct patient record
- Correct clinical interpretation (leading to the)
- Correct and timely clinical response

“Wrongs” instead of “Corrects” jeopardize patients’ safety
2013 Strategies: Managing Quality Testing for Patient Safety

- Plan for Quality
  - Implement a Quality Management System
  - Ensure quality of ALL processes impacting test results
  - Detect and reduce errors
  - Improve quality continuously (CQI)

- Build a Patient Safety Culture

- Select the right “smart” technology
  - Ensure ongoing quality of test results
  - Incorporate connectivity
The Central Laboratory and POCT are like…….

Fred Astair
and
Ginger Rodgers
In 2013……

The central laboratory is like Fred Astaire – the “leader”

Everything said about safety in the central laboratory also applies to POCT…however
Everything said about safety in the central laboratory also applies to POCT…however

POCT is more like Ginger Rogers
POCT Amplifies the Challenges facing Clinical Laboratories ... and adds *More*

- Multi-test menu
- Multiple test sites
- Multiple testing devices
- Multiple non-laboratory trained operators
- Few quality checks and balances
  - Little understanding of quality assessments, CMS found
    - 19% were not trained
    - 25% did not follow manufacturers’ directions
    - 32% could not find manufacturers’ directions
    - 32% did not perform QC
- Immediate result availability
- Immediate therapeutic implications

Meier and Jones. *Arch Pathol Lab Med* 2005;129:1262-72
POCT – Challenges continually increasing!

- Alternate testing continues to increase
  - 377 pharmacies (1997); 3442 (2008); XXXX (2013)

- Technology is dynamic & robust?
  - 8 waived tests in 1992; >100 analytes in 2013 with more than 1000 methodologies

- Issues with explosion of POCT/waived testing
  - Testing personnel shortage
    - less-trained; may not ID problems
  - No CLIA oversight
  - Minimal QC; different QC; limited quality checks

Source: Judy Yost, CMS
POCT: Quality and Patient Safety - Just don’t happen!

Plan

Plan

Plan

Plan
Most cited POCT (technical) deficiencies

Failure to:

- Follow manufacturers’ instructions
- Follow a procedure manual
- Perform quality control
- Document QC
- Document and take appropriate corrective action for QC outliers
- Document personnel training and competency
- Verify accuracy for all analytes
- Document POCT results in patient record

Plebani M. www.bloodgas.org Jan 2009

Additional factors that jeopardize patient safety*

- Incompetence
- Neglecting patient safety culture
- Behavior is insufficiently monitored and quantified
- Patient safety competes with other goals
- Unclear communication about QI
- Normalization/acceptance of deviant behavior
- Multi-tasking / fatigue combination
- Disconnect between “lab” work and care providers
- Favoring weak interventions for the “cure” because they are easier

Aston M. Patient safety: Find the error behind the error. May 2005.  
http://acutecaretesting.org/journalscanner?TId=61290154281; Patient safety 2007, Sept. 2007,  
http://acutecaretesting.org/journalscanner?TId=61290154281
“the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm.”

Patient Safety Culture

- Informed and Flexible Organization
- Effective Leadership
- Patient Safety Training
- Open Communication
- Quality Improvement focused on patient outcomes
- Competency Assessment
- Feedback
- Common goals
- Faulty system; not faulty staff
- Patient-centered care

Culture of Patient Safety
Interventions to Reduce Errors*

- Weaker strength interventions
  - Increased training and competency assessment
  - Increased vigilance, double checks, warning labels, memos

“We cannot only train or ‘be careful’ our way out of errors”

http://www.aacc.org/members/divisions/cpoc/poc_forum/Documents/AstionAACC_POCsafety_submission.pdf
Weak Interventions

As I get older,
I find I rely more and more on these sticky notes
"Drastic reduction in error potential...as a result of advanced technology, regardless of lab size or test volume"
Evolution of POCT

Manual to Automation to Auto\textsuperscript{no}mation – intelligent automation

Meier F, Jones B, \textit{Arch Pathol Lab Med} 2005;129:1262-1267

Autonomation, Quality and Patient Safety

Re-engineering the test process; not just automating it!

Quality and Patient Safety must be designed into systems!
Evolution of POCT Technology

Performance errors
- Incorrect sample amount
- Incorrect reagent amount
- Incorrect mixing
- Wrong position of testing device
- Wrong wait time
- Color blindness

Evolved to include
- Operator ID / Patient ID
- Reduced operator intervention
  - Operator prompts
- Check on reagent viability
- Lock-out QC
- Data management
- Connectivity
POCT: Quality and Patient Safety - Just don’t happen!

Buy Right!
Advice from the “Experts”

Key Factors in Achieving Excellence
Key Strategies (Murphy, KS, Daley AT, Hess, N)

- Make quality a core organizational value
- Develop a quality management systems approach
- Subscribe to a benchmarking program that provides relevant numbers to corroborate claims
- Educate the workforce
- Hold people accountable
- Be inspection ready at all times

Achieving excellence in POCT
(Drs. Bowman, Nichols, Karon, Fiebig, Melnick)

- Be aware of POCT limitations
- Don’t let clinicians dictate POC tests
  - Don’t just add tests because they are available
- Stick to one vendor or one type of device
- Standardize training; check competence
- Minimize the number of POCT staff
- Centralize (lab) POCT management
- Have lab select and validate instruments
- Set up order guidelines to lead clinician to “right” test
- Train staff not to blindly rely on POCT result generated
- Use available resources
  - Websites, CLSI documents, professional societies, etc.

10 Key Factors*

- Start with a plan
- Establish a framework, e.g., QMS/Quality System Essentials
- Train
- Make procedures easy to follow
- Make any needed “tools” understandable and available
- Automate where possible
- Track events for CQI
- Assess for overall quality – feedback from quality indicators
- Have a very “visible” POCT coordinator
- Nurture a patient safety culture

Santrach P. Mayo Clinic’s 10 key factors for creating and maintaining a quality POC Program, October 2006, http://acutecaretesting.org/journalscanner?TId=61290154281
POCT – Quality and the Future

Risk (Quality) Management
New POCT technologies with built-in “quality” checks

POCT use **ONLY** the built-in “quality” checks (termed EQC) to meet CLIA QC

CLIA said “OK” for now, but laboratories should expect change!
Government’s Solution for meeting CLIA QC

Risk Management

Develop Right Quality - Individualized Quality Control Plans (IQCP) designed for each test

CMS
CLSI: GP23-A (October 2011)

CLSI EP23 translates industrial risk management principles (ISO 14971:2007) to the clinical laboratory setting

CLSI formerly known as NCCLS; www.clsi.org
Definitions associated with “Risk”*

- **Hazard (error)** - potential source of (patient) harm

- **Risk** - combination of the probability of occurrence of harm and the severity of harm

- **Risk analysis** – systematic use of available information to identify and estimate risk

- **Risk mitigation** – application of effective combinations of “activities” (QC/QA) to minimize/eliminate risks (starting with those that are potentially most harmful)

Steps for IQCP development*

1. Collect FACTS (for informed decisions)
2. Diagram testing process; and identify/analyze potential risks
3. Develop and document the plan
4. Implement and monitor the plan for effectiveness (CQI)

2. Assess the Path of Workflow for hazards/potential errors to eliminate or reduce – start with those most harmful to patients
Identify potential causes of analytical failures

Cause and Effect (Fishbone) Diagram*

1. Samples
   - Sample Integrity
     - Lipemia
     - Hemolysis
     - Interfering substances
     - Clotted
     - 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
   - Inadequate Instrument Maintenance
     - Dirty optics
     - Contamination
     - Scratches

6. Incorrect Test Result

3. Develop and Document IQCP from Information Gathered
Monitor IQCP for Effectiveness: CQI

- Is the IQCP actually working?
  - Continue to monitor errors, controls, failures, etc.
  - Investigate
  - Review complaints for other sources of failure that need to be addressed
  - Make necessary adjustments
  - Repeat the **Plan-Do-Verify-Assess** cycle

Plan – Do – Verify – Assess Cycle
IQCP Summary

- Applies to CMS-certified, non-waived testing
  - CAP, TJC, COLA, etc.) have not yet adopted the IQCP approach
- It is not mandatory
  - Default QC is 2 external controls per test per day for most tests
- It is for existing and new analytes / test systems
- After education and transition date, EQC, to solely meet CLIA QC, will be phased out
- Manufacturer instructions must be followed
- No CLIA (subpart K) regulations will change
- Key concepts for IQCP development will be in revised Interpretive Guidelines (Appendix C, SOM)
- CMS survey process won’t change

Good Risk (Quality) Management Strategy??

“I think we need to take another look at your quality plan”
For effective POCT: Don’t forget the Team!

- Administration provides:
  - Support/validity of the testing approach

- Physicians define:
  - What and where POC testing is appropriate
  - Quality needs for test results

- Laboratory/POCC focuses on:
  - Good test results
  - Instrument selection, evaluations, maintenance
  - Best POCT is when laboratory is involved

- Nursing/ healthcare providers strive for:
  - Good patient care, better patient outcomes, patient safety through POC testing
For effective POCT: Don’t forget the Team!

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We cannot overlook the “RED” criteria
Who is responsible for the “Red Corrects”

Physicians, Clinicians --

These individuals must be part of the process and concerned with medical errors and patient safety

Medical Errors and Patient Safety: A New POCT - Physician Paradigm

Before Pre-Analytical

Equipment Malfunction

Pre Analytical (46-68.2%)
- Incorrect Sample
- Insufficient Sample
- Incorrect Identification
- Sample Handling/Transport
- Sample condition

Analytical (7-13%)

Post Analytical (18.5-47%)
- Reporting or Analysis
- Improper Data Entry
- Turn Around times

Sample Mix-Ups/Interference

After Post-Analytical

Medical Errors and Patient Safety

We must **create** a new **physician paradigm** to take maximum advantage of POCT’s capabilities to better serve the patient.

We must **bring** the physician into the process and address:

Sub-optimum POCT result utilization*

“Failure to appropriately respond to a test result in a timely manner”**


*Meier and Jones. *Arch Pathol Lab Med* 2005;129:1262-72

**Plebani M. Partners in error prevention. [www.bloodgas.org](http://www.bloodgas.org) (2009)
New Physician Paradigm -- Does POCT add Value?

Before Pre-analytical, physician’s must consider:
- What POCT is available?
- What POCT will best serve the patient?
- Will an immediate answer improve the patients’ outcome?

After Post-analytical, 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?
POCT and the new Physician Paradigm

- Include interpretive comments - provide information not just results - testing generates more than just data!

  - “… new and complex tests …increasingly introduced into clinical practice,
  - … adding comments to laboratory reports, particularly when the physician is not familiar with a test or with a panel of laboratory tests, is not new,
  - Finally, … interpretative comments do not represent "a diagnosis", but a suggestion for better interpretation of the laboratory information”

Plebani  M. POCT, Partners in Prevention. (2009), www.bloodgas.org
For Quality and Patient Safety: Do “things” right from pre-pre analytical through post-post analytical
Quality Is Never An Accident!

“it is always the result of intelligent effort...

the bitterness of poor quality lingers long after the sweetness of low price is forgotten”

John Ruskin (attributed)