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 2012, 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.
2012 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
2012 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

All are part of Risk (Quality) Management
The Central Laboratory and POCT are like…….

Fred Astair
and
Ginger Rodgers
Circa 1938...Fred and Ginger
In 2012……

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
Ginger says: “I do everything Fred does [at POC] except I do it backwards and in [red] high heels”
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 (2012)
- Technology is dynamic & robust?
  - 8 waived tests in 1992; >100 analytes in 2012 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

Astion M. Patient safety: Find the error behind the error. May 2005.
http://acutecaretesting.org/journalscanner?Tld=61290154281; Patient safety 2007, Sept. 2007,
http://acutecaretesting.org/journalscanner?Tld=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
- Feedback
- Common goals
- Faulty system; not faulty staff
- Patient-centered care

Patient Safety Training
- Open Communication
- Quality Improvement focused on patient outcomes

Culture of Patient Safety

Competency Assessment

Focused on patient outcomes
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”

Weak Interventions

As I get older,
I find I rely more and more on these sticky notes
A lab’s strategy to reduce errors depends on automation

By Denise L. Uettwiller-Geiger, PhD, DLM(ASCP)

Six years ago, the Institute of Medicine (IOM) issued its report *To Err is Human: Building a Safer Health System*. The monograph’s conclusion was so startling that one of its statistics still reverberates throughout healthcare today: Up to 98,000 Americans die annually from medical errors. In terms of number of deaths, medical errors represent a far greater threat to Americans than traffic accidents.

The medical laboratory plays a major role in helping to prevent medical-error tragedies. Most of the information that physicians depend upon for diagnosis and treatment of their patients — as the Joint Commission on Accreditation of Healthcare Organizations or JCAHO has emphasized — originates in the lab. Appropriate diagnosis and treatment, therefore, depends upon results that are not only accurate but also delivered immediately.

In fact, the IOM report identified “delay in diagnosis” as one of the most critical forms of medical error. And delayed treatment is the downstream result of a delayed diagnosis. For patients whose conditions are life threatening, faster-than-normal test turnaround time (TAT) can mean the difference between living and dying.

Drastic reduction in error potential...as a result of advanced technology, regardless of lab size or test volume

Even at POC
Evolution of POCT

Manual to Automation to Automation – intelligent automation

Meier F, Jones B, 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 (EQC) to meet CLIA QC

CLIA said “OK” for now, but laboratories should expect change!

CLSI formerly known as NCCLS; www.clsi.org
Government’s Solution for meeting CLIA QC

EP23
Using Risk Management

Develop Right Quality Control Plan (QCP) or (iQCP) designed for each test

CLIA 2012
Assess the Path of Workflow for risks/hazards to eliminate or reduce
Gather Information for Risk Assessment

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<td>Collection technique (interstitial fluid contamination)</td>
<td>Training</td>
<td>Shipping</td>
<td>Temperature</td>
<td>Dirty optics</td>
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<tr>
<td>Drug interferences</td>
<td>Competency</td>
<td>Storage</td>
<td>Humidity</td>
<td>Software failure</td>
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<td>Delayed sample application (clotting)</td>
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<td>Expiration date</td>
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<td>Electronic instability</td>
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<td>Bubbles</td>
<td>Short staffing</td>
<td>Control preparation</td>
<td>Error codes</td>
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<td>Inadequate volume</td>
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<td>Delay in strip insertion</td>
<td>Contamination</td>
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<td>Sample detection error</td>
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<td>Wrong calibration code</td>
<td>Scratches</td>
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**Sample Integrity**
- Collection technique (interstitial fluid)
- Drug interferences
- Delayed sample application (clotting)

**Sample Preparation**
- Bubbles
- Inadequate volume
- Sample detection error

**Operator Capacity**
- Training
- Competency

**Operator Staffing**
- Short staffing

**Atmospheric Environment**
- Temperature
- Humidity

**Utility Environment**
- Electrical
- Water Quality
- Pressure

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**Identify Potential Hazards**

**Reagents**
- Shipping
- Storage
- Expired
- Preparation

**Calibrator**
- Wrong calibration code

**Inadequate Instrument Maintenance**
- Dirty optics
- Contamination
- Scratches

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EP23-A
Implementation Workbook
CLSI.org
Develop iQCP from information

1. **Electronic Controls:**
   a. Shall be run on each instrument once every eight hours.

2. **Liquid-based QC Samples:**
   a. Analyze two levels of QC samples before and after each change in reagent lot. Do not use QC that was shipped with the reagent being tested.
   b. Analyze two levels of QC after each calibration.
   c. Analyze two levels of QC samples at least weekly.

3. **Proficiency Testing:**
   a. Participate in proficiency testing program two times per year.

4. **Maintenance:**
   a. Clean the instruments after each use with alcohol wipes, following the instructions in the user's manual.
   b. Check the laboratory refrigerator monitors daily.
   c. Check the room temperature monitors in the **outpatient clinic** daily.

5. **Training:**
   a. Nurses and laboratory technicians – document proper training for:
      i. Sample collection
      ii. Sample placement on reagent test strip
      iii. Testing procedures
      iv. Cleaning procedures
      v. Documentation of results
   b. Receiving personnel – document proper training for:
      i. Checking the condition of the cold packs upon receipt
      ii. Procedure to follow when cold packs are not present or are no longer cold
      iii. Procedure for storing of the reagents

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**EP23-A Implementation Workbook**

**CLSI.org**
Monitor iQCP for Effectiveness: CQI

- Is the iQCP actually working?
  - Continue to monitor errors, controls, failures
    - 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
Good Risk (Quality) Management Strategy??

“I think we need to take another look at your quality plan”
Summary – CLSI EP23A iQCP Option?

- A new QC option under CLIA
  - Current EQC option to **solely** meet QC will be phased out over the next 2 – 4 years, but EQC can be part of QCP

- POCT develops iQCPs that are **right** for each test
  - Use risk management techniques to ID risks that potentially impact test quality throughout testing process
  - Mitigate harmful hazards
    - Testing device’s built-in quality assessments, additional “control” mechanisms, training, etc.
  - Ensure that medical requirements and regulatory, accreditation, and organization requirements are met
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

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”**

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 patient’s 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
Ginger says: “I do everything Fred does [at POC] except I do it backwards and in [red] high heels”

And I do much more!
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)
Thanks from Wisconsin’s State Animal