Plan for Quality to Improve Patient Safety at the POC

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In 2013, POCT’s focus must be on planning for:

Patient Safety and Quality Outcomes
Testing Criteria for POC:

**Quality** test results
On the **right** patients

Performed simply by **trained, competent** (and caring) operators

AND

Delivered in a **timely manner** to caregivers for **good patient outcomes**
“Things” happen
Your Health

- Hospital errors cause 100,000 deaths yearly.
- These are preventable deaths.
- What’s wrong, and can it be made right?

The Worst Place to Be If You’re Sick

U.S. surgeons operate on the wrong person or body part as often as 40 times a week.

One study of Medicare patients found that 1 in 7 died or were harmed by their hospital care.

The number of patients who die each year from hospital errors is equal to 4 jumbo jets crashing each week.

“We” need “Quality” Results and Quality Practices!
2013 Quality Strategies

- Implement a Quality Management System
  - Ensure quality of ALL testing processes
  - Detect and eliminate/reduce errors
  - Improve quality continuously (CQI)
- Build a Patient Safety Culture
- Select the right “smart” technology
  - Ensure ongoing quality of test results
    - Let the instrument, when possible, perform the tasks!

All are part of Quality (RISK) Management
Central Laboratory and POCT Relationship…

Fred Astair
and
Ginger Rodgers
Circa 1938...Fred and Ginger
In 2013……

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

Everything said about safety in the central laboratory also applies to POCT…however…
Ginger Rogers, representing POCT: “I do everything Fred does except [I do it] backwards and in [red] high heels”

POCT has challenges!
POCT *Amplifies* the Challenges facing Clinical Testing … and adds *More*

- Multi-test menu
- Multiple test sites
- Multiple testing devices
- Fewer quality checks and balances
- Immediate result availability
- Immediate therapeutic implications
- Often multiple, non-laboratory, trained analysts with other healthcare responsibilities

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

- Alternate site 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
    - Analysts may not ID testing problems
  - No CLIA oversight of waived; CAP/TJC includes oversight
  - Often minimal QC; different QC; limited quality checks

Source: Judy Yost, CMS
Most cited POCT (analytical) 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

Okay - What’s the Plan for Quality?
…“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.”

Current Healthcare Culture is Contradictory to Patient Safety

“Health care must come to see itself as a high hazard industry, which is inherently risky.”* 

“Professional and organizational cultures in healthcare must undergo a transformation …[to promote] …safer patient care.”*

“…without culture change, it is difficult to reorganize work or implement safety practices, because people are not playing in the sandbox together.”**

Culture

Set of shared attitudes and practices that characterize an organization

Culture of Patient Safety

- Patient Safety Training
- Open Communication
- Quality Improvement focused on patient outcomes
- Competency Assessment
- Informed and Flexible Organization
- Knowledgeable, caring staff
- Feedback
- Common goals
- Effective Leadership
- Patient-centered care
- Faulty system; not faulty staff
- Patient-centered care
Patient Safety Culture Requires Shift in Thinking

<table>
<thead>
<tr>
<th>Not Effective Thinking</th>
<th>Effective Thinking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who did it?</td>
<td>What happened? Why?</td>
</tr>
<tr>
<td>Punitive</td>
<td>Fair and just</td>
</tr>
<tr>
<td>Bad people</td>
<td>Bad systems</td>
</tr>
<tr>
<td>Penalize the reporter</td>
<td>Thank the reporter</td>
</tr>
<tr>
<td>Confidential</td>
<td>Transparent learning</td>
</tr>
<tr>
<td>Investigation</td>
<td>Root cause analysis</td>
</tr>
<tr>
<td>Independent silos; no/little communication</td>
<td>Inclusive and interdisciplinary team; lots of communication</td>
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</tbody>
</table>

## Patient Safety Culture Requires Shift in Thinking

<table>
<thead>
<tr>
<th>Not Effective Thinking</th>
<th>Effective Thinking</th>
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</thead>
<tbody>
<tr>
<td>Thinking that errors are rare</td>
<td>Realizing that errors are everywhere</td>
</tr>
<tr>
<td>Great care</td>
<td>Great care in a high-risk environment</td>
</tr>
<tr>
<td>Lack of direction; staff make it up as they go along</td>
<td>Principles of fair and just culture, guidelines algorithms, flow charts</td>
</tr>
<tr>
<td>Risk of disclosure/confidentiality</td>
<td>Moral duty, risk of non-disclosure</td>
</tr>
<tr>
<td>Great staff; poor systems</td>
<td>Great staff; great systems</td>
</tr>
<tr>
<td>Deliver care to patients</td>
<td>Partner with patients and families</td>
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“Quality and Patient Safety NOT associated with mismanagement, hostilities, “in-fighting,” disorganization”

Anne Belanger, former inspector and Laboratory Accreditation director, TJC
Quality is made or broken by warmware!*

Dr. Henk Goldschmidt, Quality in the Spotlight Conferences, Antwerp, Belgium, 2010
We do know:

Hardware
Software
Middleware

but you ask, what about

Warmware?
Warmware?
Why Testing Fails?

- Lack of test management
- Lack of documentation
- Human error (the “people” factor)

*To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press; 2000*
“Things” happen!

Quality is made or broken by warmware!

The “people” factor!
<table>
<thead>
<tr>
<th>Common Factors for Errors*</th>
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<tbody>
<tr>
<td>Incompetence</td>
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<tr>
<td>Neglecting patient safety culture</td>
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<tr>
<td>Behavior is insufficiently monitored and quantified</td>
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<tr>
<td>Patient safety competing with other goals</td>
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<tr>
<td>Unclear communication about quality improvement</td>
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<tr>
<td>Normalization / acceptance of deviant behavior</td>
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<tr>
<td>Multi-tasking / fatigue combination</td>
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<tr>
<td>Disconnect between work: “lab” versus patient care</td>
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<tr>
<td>Favoring weak interventions because they are easier</td>
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</table>

Interventions to “treat” errors*

**Strongest** - Major physical plant changes, software enhancements, elimination of steps, standardization, automation, getting staff involved

**Intermediate** - Reduce distractions, computerize reminders, enhance software, auto-fax, read back communication, checklists, workflow to match staffing

**Weaker** (there is a limit) - Training, call for increased vigilance, double checks, warning labels, memos

Weak Interventions –
The elephant that never forgets

As I get older,
I find I rely more and more on these sticky notes
POCT: Quality and Patient Safety

Buy Right!
Use New and Smart POCT Technologies

Re-engineering the test process; not just automating it – intelligent (automating)!

Quality and Patient Safety approaches designed into systems!
POCT: Quality and Patient Safety

Don’t Forget the Team!
BOY! THE CURRENT IS TOUGH TODAY!
Teamwork is Essential

WE MIGHT AS WELL TURN BACK—THIS IS GETTING US NOWHERE!
Good POCT Relationships for Good Patient Outcomes requires **Teamwork**
Teamwork!

Hospital administration provides:
- Support/validity

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
POCT: Quality and Patient Safety

Learn from the Experts!

Don’t reinvent the Wheel!
10 Key Factors for Quality POCT*

- Start with a plan, e.g., Quality Management System
- Establish a framework, e.g., Quality System Essentials
- Train, train, train
- Make procedures easy to follow
- Make any needed “tools” understandable and available
- Automate where possible
- Assess overall quality – feedback from indicators for CQI
- Have a very “visible” POCT coordinator
- Nurture a quality and 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
Key Strategies (Murphy, KS, Daley AT, Hess, N)

- Make quality a core organizational value
- Develop a quality management systems approach
- Subscribe to benchmarking program 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.

POCT: Quality and Patient Safety

Managing Risks!
(the future?)
Criteria for Quality POCT

- 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
August 16, 2013

Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option

IQCP’s Purpose – “QC” Strategy for Quality Test Results

- Covers the **entire testing process** to ensure quality test results
- Test sites assess risks and include quality practices/ checks to eliminate/ reduce significant errors
- POC’s current policies and procedures fulfill many most of the strategy
CMS Brochure for More Information

Additional Resources


- **CMS CLIA Central Office:** 410-786-3531


- **CMS IQCP Questions:** Any questions about IQCP should be forwarded to [IQCP@cms.hhs.gov](mailto:IQCP@cms.hhs.gov)

- **CLSI Link:** [http://www.clsi.org](http://www.clsi.org)
CLN's – Patient Safety Focus
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