Meeting Dynamic Challenges for POCT Quality and Patient Safety

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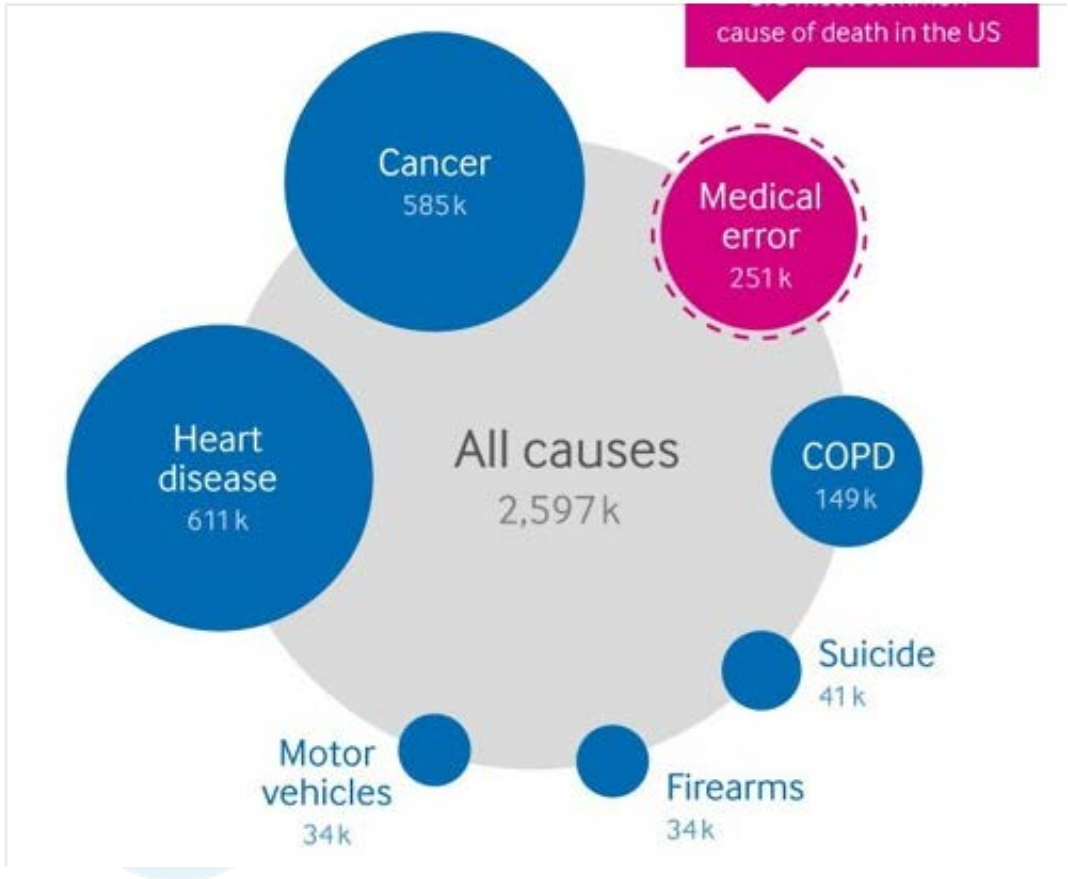
Today's Goal

Developing strategies to meet today's and tomorrow's challenges and enhance POCT's contribution to the healthcare team

Goal of POCT

Quality results for
quality patient care

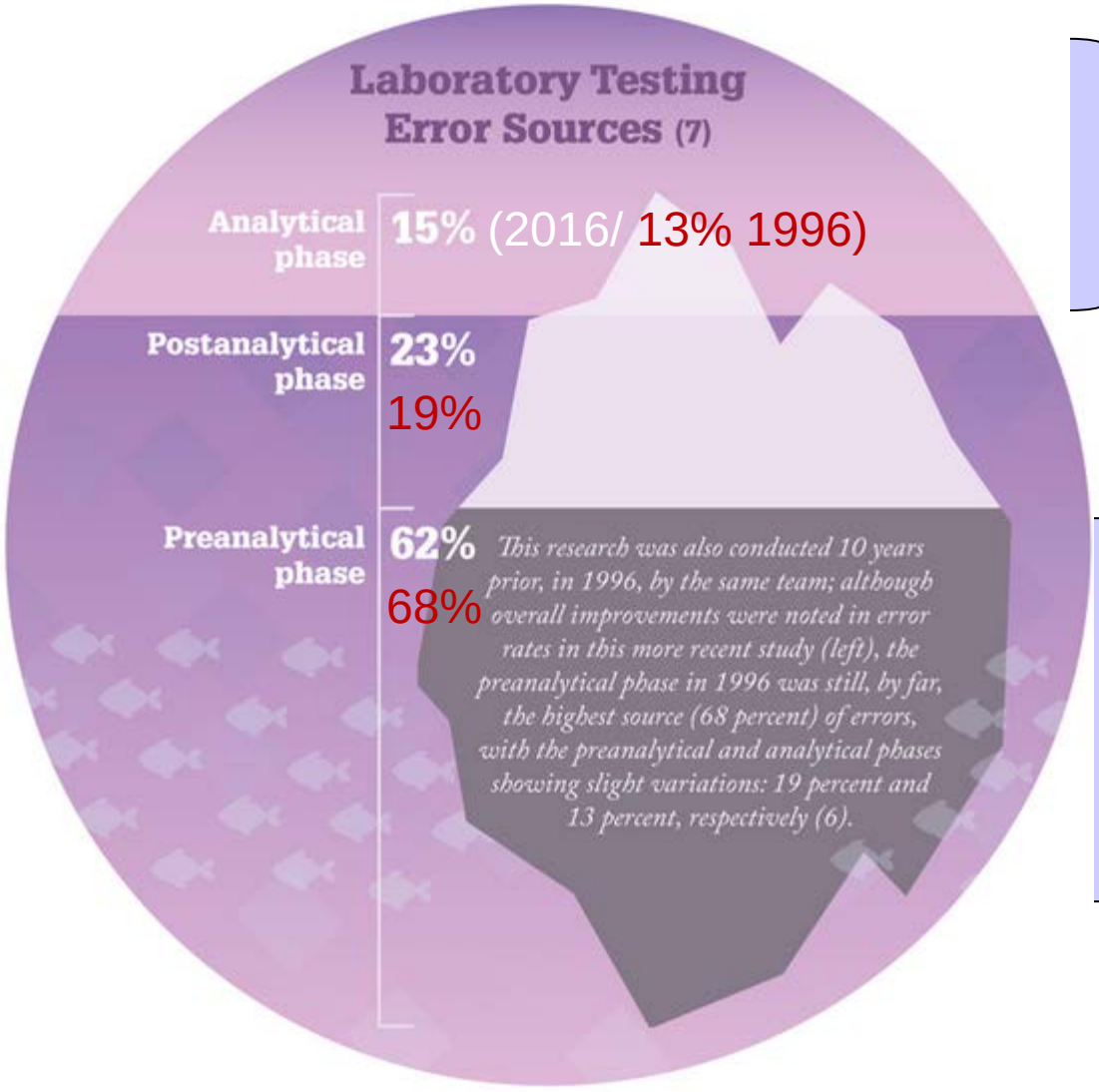
Medical Errors: Deaths from Medical Blunders and Safety Lapses*



1. Heart disease
2. Cancer
3. **Medical error**

* - National Center for Health Statistics. May 2016, BMJ

Errors (Risks) in Testing: Little Change



Analytical, often the least, but so important and *can't* be ignored!

Preanalytical still remains the largest source of error

AM Šimundić. Avoiding Titanic Errors: The preanalytical phase is subject to more error than any other part of the testing cycle – what can we do to improve it? The Pathologist - https://thepathologist.com/issues/avoiding-titanic-errors/avoiding-titanic-errors/ (08/2016)

POCT's Healthcare Role: Quality Test Results

Common quote --
60 – 70% of clinical decisions are based on laboratory/POCT results

We are part of the problem and the solution!

Quality Strategies:

As a “team” member -- where to start?

Starting Point

Be Prepared Today and Tomorrow!

Quality Strategy: Manage Risks
(know and manage POCT risks)

Simple Definition of *risk* -- possibility that something bad will happen*

Simple Definition of *risk management* -- analyzing, evaluating, controlling, and monitoring risk (ISO 14971)**

*Merriam-Webster's Learner's Dictionary
** ISO 14971: www.iso.org

Criteria for Quality Test Results
(Covers Entire Testing Process)

- Correct patient
- Correct time for specimen collection
- Correct specimen and processing

} Pre-analytical

- Correct test result generated

} Analytical

- Correct test result reported and documented in right patient record

} Post-analytical

When “wrongs” replaces “corrects” --
Quality is compromised; care may be compromised

Risk Management Example: IQCP-Individual Quality Control Plan

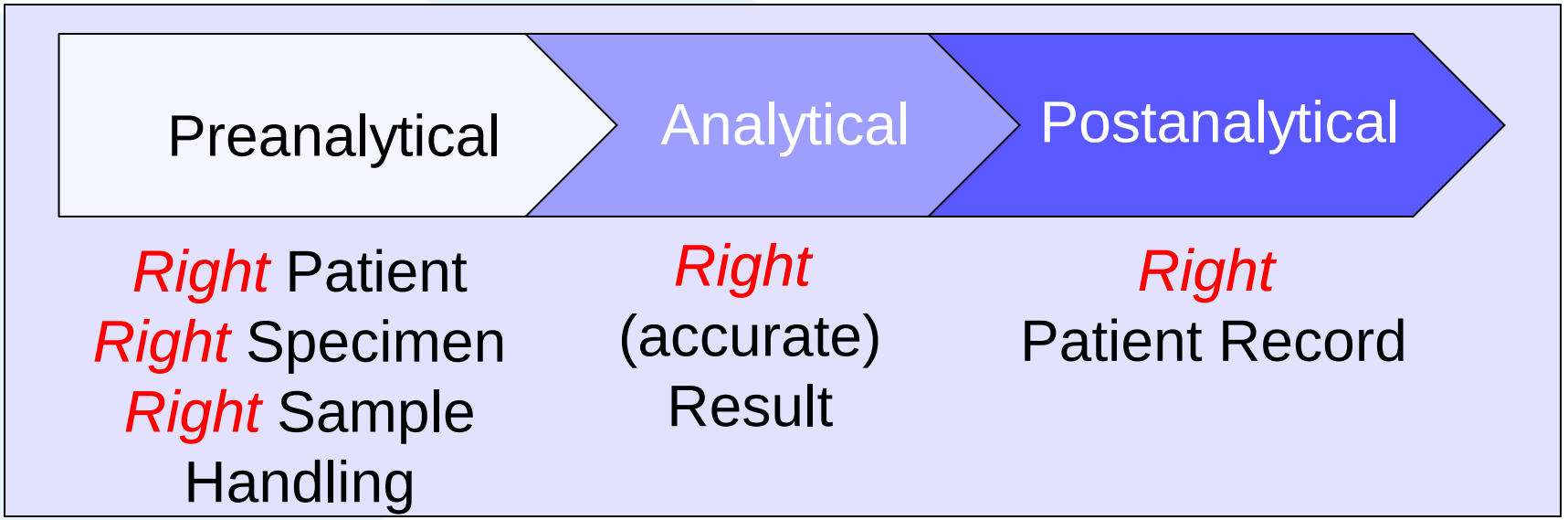
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

IQCP Intent: Manage ***risks*** (errors) in entire testing process

“Things” do happen!

IQCP Development Process

- **Gather information** - IQCP is based on facts
  - Medical, regulatory, testing device and situation
- **Risk assessment** - know processes; identify potential risks



  - Must assess -- samples, operators, test environment, testing systems, reagents
  - Review policies; remove/handle ALL significant risks

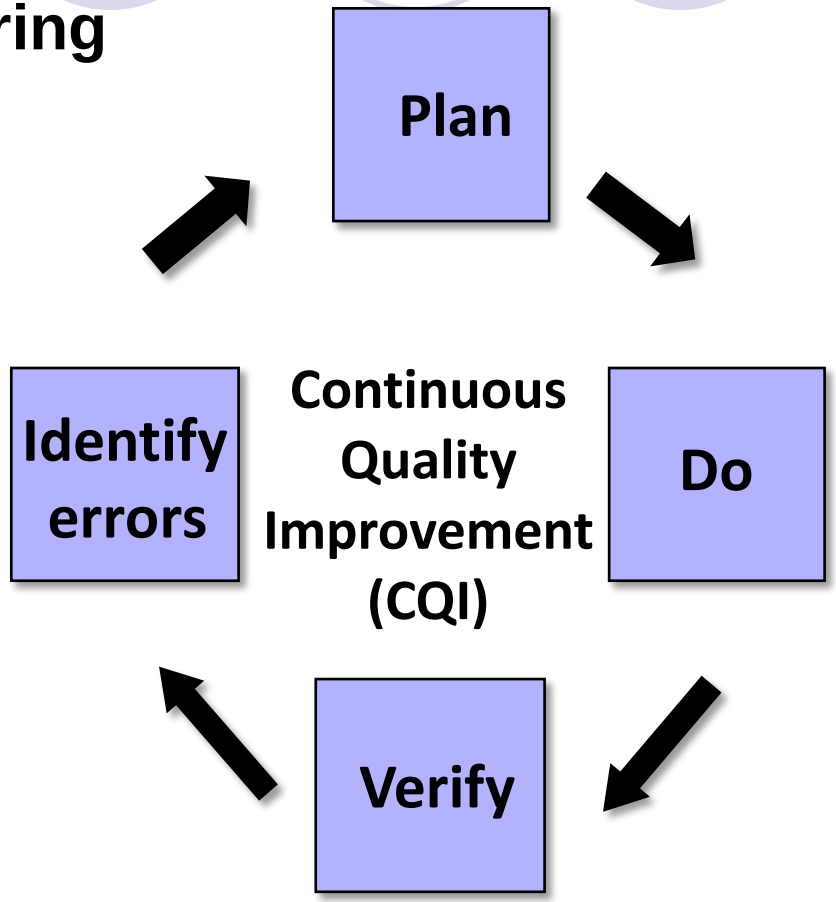
IQCP Development Process

- **Quality Control Plan**
  - CMS inspection probes, inspectors look for:
    - Written QCP for each test system, as applicable
    - QCP (at least) specifies:
      - Number, type, frequency of testing QC materials
      - Provides for immediate detection of errors
      - Criteria to determine acceptable QC results
    - QCP requires QC to follow manufacturer specifications
    - Documented evidence of lab director approval

https://www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html

IQCP Development Process

- **Post Implementation Monitoring**
  - Continually **monitor, verify** and **improve** the PLAN, when needed
  - **Ensure** (*ongoing*) final QCP is effective



Plan – Do – Verify – Assess Cycle

IQCP & your Accrediting Organization: Stay in the "KNOW"

CLIA

The Joint Commission

COLA

COLLEGE of AMERICAN PATHOLOGISTS

They (really) are here to help us!

CAP's IQCP 2016 Inspection Findings

1. No IQCP in place and EQC still in use
2. IQCP not signed by director prior to implementation
3. CAP IQCP forms not completed
4. Risk assessment missing required elements/not customized for lab/site variations
5. Quality control plan not well defined (missing frequency or type of QC, etc.)
6. External controls not performed every 31 days, at minimum
7. No IQCP for microbiology when following CLSI protocols instead of CLIA default QC (media, susceptibility, bacterial ID)

www.cap.org - Experience Clarity with the 2016 CAP Accreditation Checklist Update Focus on Compliance Webinar 9-21-2016

2016 IQCP Westgard Survey

Inspection outcomes:

- ~ 2/3 had adequate IQCPs
- ~1/3 had no IQCPs inspection
- Small minority had problems:
  - "Needed to add components to IQCP"
  - “…cited for failure to have an IQCP for XXX test…subsequently accepted our IQCP response..."
  - "TJC surveyor made recommendations related to improving the format of the IQCP's…"
  - “…not having a count of actual internal and external QC and failures documented for a particular time"

http://www.westgard.com/iqcp-user-survey.htm

Quality Strategy: Patient Safety Focus

Professional Accreditation Organizations'—
Examples of New Approaches
(IQCP is Patient Safety focused)

Quality Strategy: Patient Safety Focus

- COLA's recommendations: build systematic solutions to reduce medical errors (3rd leading cause of death)
  - Most errors due to *systemic* problems, e.g.,
    - Absence of safety nets and standard protocols
    - Poorly coordinated care
    - Human error
  - Doug Beigel, CEO of COLA, states:
    - "…ensuring quality and excellence in…lab medicine can go a long way in reducing overall adverse patient outcomes…"

http://www.cola.org/4144-2/

COLA Recommends

- ***Inter-professional Teamwork and Communication***
  - Embrace teamwork; collaboration with clinicians for appropriate protocols [test ordering to data interpretation]
  - Transform labs from passive service to active participant in patient diagnosis, treatment and management
- ***Laboratory Training and Education***
  - Pre-analytical phase accounts for 46 – 68% of errors, yet…
    - Often [staff] with limited experience/training are responsible
    - >120 unregulated [waived] POCT analytes require no specialized training…[but] contribute to diagnostic decisions
  - Have universal priority - maintaining/following highest quality standards, regardless of education requirements and test complexity
  - Need ***Increased focus on lab quality education and training*** for all involved in the testing process
- ***Increased Research***
  - More to unveil systemic problems; cultivate long-term/sustainable solutions

http://www.cola.org/4144-2/

Quality Strategy: Patient Safety Focus

CAP's QM revisions (2016) "monitor activities critical to patient outcome

****REVISED**** ~~07/28/2015~~08/17/2016

GEN.20316 **QM Indicators of Quality** **Phase II**

The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.

NOTE: Key indicators should monitor activities critical to patient outcome or that may affect many patients. ~~There~~The laboratory must ~~be records of the evaluation of~~evaluate its indicators by ~~comparison of~~comparing its performance against available benchmarks. The laboratory should also evaluate the effectiveness of each corrective action. The number of monitored indicators should be consistent with the laboratory's scope of care. Special function laboratories may monitor fewer indicators; full-service laboratories should monitor multiple aspects of the testing process appropriate to their scope of service.

For laboratories that have implemented one or more individualized quality control plans (IQCPs), the quality management program must include a review of the ongoing monitoring of the effectiveness of each IQCP.

Quality Strategy: Patient Safety Focus

CAP's increasing emphasis on preventive actions, error detection and corrective action.

REVISED* *08/17/2016*

COM.04050 ~~Unusual Laboratory Results~~Error Detection and Correction **Phase II**

There is a written procedure for the detection and correction of significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

NOTE: One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all reported data for tests that do not include interpretation. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors,

Quality Strategy: Patient Safety Focus

2017 Laboratory National Patient Safety Goals

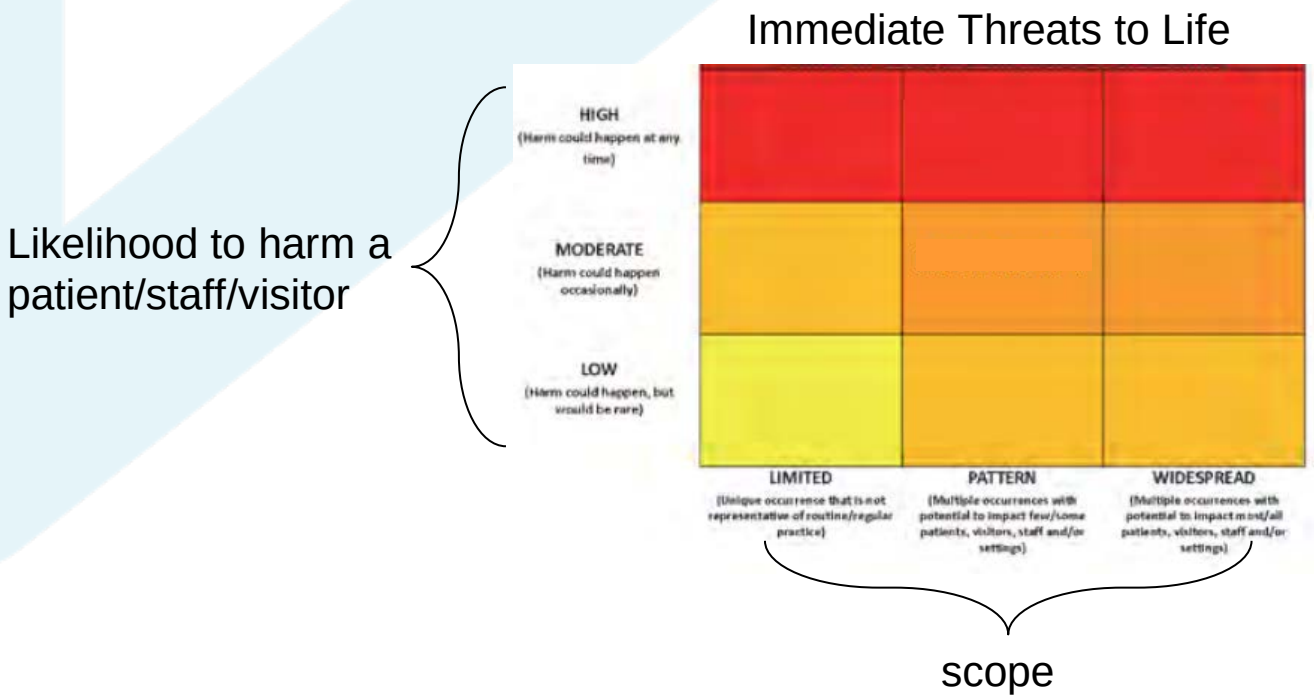
The purpose of the National Patient Safety Goals is to improve patient safety. The goals focus on problems in health care safety and how to solve them.

Identify patients correctly	
NPSG.01.01.01	Use at least two ways to identify patients. For example, use the patient's name *and* date of birth. This is done to make sure that each patient gets the correct medicine and treatment.
Improve staff communication	
NPSG.02.03.01	Get important test results to the right staff person on time.
Prevent infection	
NPSG.07.01.01	Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning. Use the goals to improve hand cleaning.

https://www.jointcommission.org/assets/1/6/2017_NPSG_LAB_ER.pdf

Quality Strategy: Patient Safety Focus

- SAFER (Survey Analysis for Evaluating Risk) Matrix
  - The Joint Commission's New (2017) Scoring Methodology
    - Better identifies and communicates risk levels associated with cited deficiencies; no more EPs or category A & C
    - Helps organizations prioritize and focus on corrective actions



https://www.jointcommission.org/assets/1/6/SAFER_Matrix_NewScoring_Methodology.pdf

Quality Strategy: “Right” POCT Culture

“Quality and Patient Safety *NOT* associated with mismanagement, hostilities, “in-fighting,” incompetence, disorganization”

Anne Belanger, former inspector and Laboratory Accreditation director, The Joint Commission

Effective Quality/Patient Safety Culture

Starts at the top - leadership promotes…makes commitment evident

Vision driven clinical metrics to evaluate performance (compliance with recognized standards) and metrics to evaluate the patient experience

Involves everyone at every level - close gap — where organization is and where it should be

Requires evolution --Not a one-time fix; culture development is a journey

Is consistent - committed leadership; effective/ responsible responsive to adverse events; accountability by all; realize most mistakes due to faulty processes

Transcends leadership – positive, successful culture continues when leadership changes

http://www.beckershospitalreview.com/quality/6-elements-of-a-true-patient-safety-culture.html

“Effective” Thinking
for
Evolving (effective) Cultures

“Right” Culture Requires Shift in Thinking

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

http://www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

“Right” Culture Requires Shift in Thinking

Not Effective Thinking	Effective Thinking
Thinking errors are rare	Realizing errors are everywhere
Great care	Great care in a high-risk environment
Lack of direction; staff make it up as they go along	Principles of fair and just culture, guidelines algorithms, flow charts
Risk of disclosure/confidentiality	Moral duty, risk of non-disclosure
Great staff; poor systems	Great staff; great systems
Deliver care to patients	Partner with team, patients and families

http://www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

Quality Strategy: Meet Requirements

- Established testing requirements/standards represent GLP
  - Know requirements
  - Always do the “right” thing; do more if necessary
- Make sure POCT policies and procedures “line up” with the requirements
  - Pay particular attention to frequent deficiencies, e.g., training/competency

Common 2015 - 2016 deficiencies (2017?)

- Personnel qualifications and associated records
- Competency assessments
- Proficiency testing – enrollment (all regulated analytes) to review of results to corrective actions to maintaining records
- Method comparisons
- Calibration verification
- Equipment maintenance and associated documentation

N. Hess. CLIA and regulatory readiness: How can your lab always be ready http://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201607/html/index.html?page=40 July 2016

Quality Strategy: Proof of Meeting Requirements

https://www.cola.org/insights-newsletters/2016/fall/insights-fall-2016.pdf

Meet POCT's *Many* Challenges

- Stress/chaos
- Many demands
  - Time consuming requirements
  - More testing
- Fewer staff
- Less resources
- You name it --Etc., etc., etc.

Get Help!

Quality Strategy: Buy Smart

Many choices
Choose *right* for YOUR situation & QM

- Know
  - Clinical requirements
  - Patient population
  - Testing environment
  - Methodology/technology performance specifications
    - Accuracy, precision, reportable range
  - Method limitations, interferences
  - Sample type and size; collection requirements/ease of use
  - QC approach and its adequacy
  - Menu
- Assess (meet needs?)
  - Performance capabilities
  - Ease of use
  - Training, competency needs
  - IT capabilities; ease of connection
  - Regulatory compliance capabilities
    - Automatic performance
    - Automatic documentation
    - Ease of retrieval
  - Reagent needs; storage requirements
  - Costs

POCT09-A: Selection Criteria for Point-of-Care Testing Devices; Approved Guideline. 2010 http://www.clsi.org

Quality Strategy: Buy Smart

Many choices
Choose *right* for YOUR testing situation

Quality POCT Strategy??

Quality Strategy: *Not* Same OL', Same OL'

Change, Never Doubt!

Quality Strategy: Be Alert/Aware

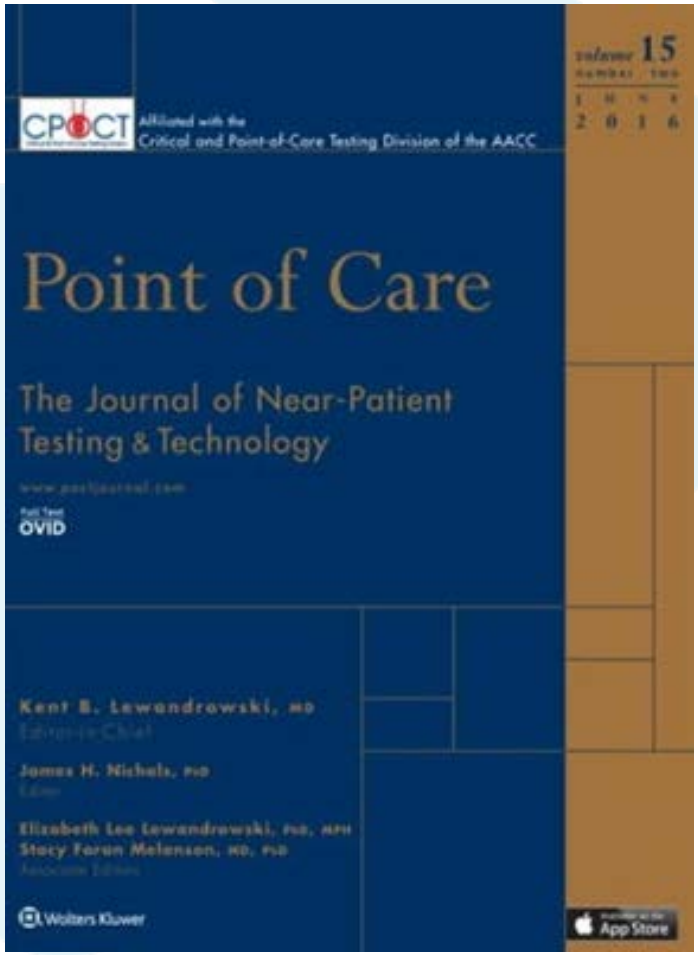
Examples requiring, perhaps, change

- Reimbursement
- Proficiency Testing
- Glucose monitoring
- Laboratory developed tests
- New technologies
- Improved technologies
- Expanding POCT menu
- Changing test requirements
- Revised test requirements
- Government mandates
- Cancer moonshot
- Altered treatment patterns
- Precision medicine
- Cyber threats
- Infectious threats
- New pre-analytical variables
- Medical breakthroughs
- More waived tests
- New drug treatments
- New interferences
- Managed care

Quality Strategy: Be Alert/Aware

- Alertness – “ear to the ground,” know what is happening “outside”
  - Listservs, journals, webinars
  - Professional organizations, POCT and user groups, other sites/organizations, CE activities, etc.
  - Manufacturers’ materials and representatives
  - Government websites
- Preparedness – nothing lasts, so when “true” change happens – Be ready to deal with it!

Quality Strategy: Voice Your Wishes
Turn *your wishes* to Improved POCT



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Kent Lewandrowski, MD, editor-in-chief, asked practitioners for their 3 wishes to improve POCT

http://journals.lww.com/poctjournal/Pages/currenttoc.aspx

What is yours?

- Simplified, reasonable, cost effective, relevant, evidence-based regulatory requirements
- More testing capabilities
- Easier sample collection for better sample
- IT standardization for better technical support
- Design of “small” instruments with easy data entry and network connection (think smart phones)
- More manufacturer support with new installations/upgrades
- Evidence-based regulatory decisions, e.g., glucose (meter) testing

Quality Strategy Summary: Meeting (at least some) of the many POCT challenges

- Manage Risks
- Focus on Patient Safety
- Develop a Patient Safety Culture
- Meet Testing Requirements and More
- Buy Smart
- Be Alert/Aware
- Voice your Wishes

POCT Quality Strategy = Bottomline

Quality results for
quality healthcare and patient safety!

Your Quality Strategy: Start small, but Thing BIG!

Thanks