Plan for Quality to Improve Patient Safety at the POC

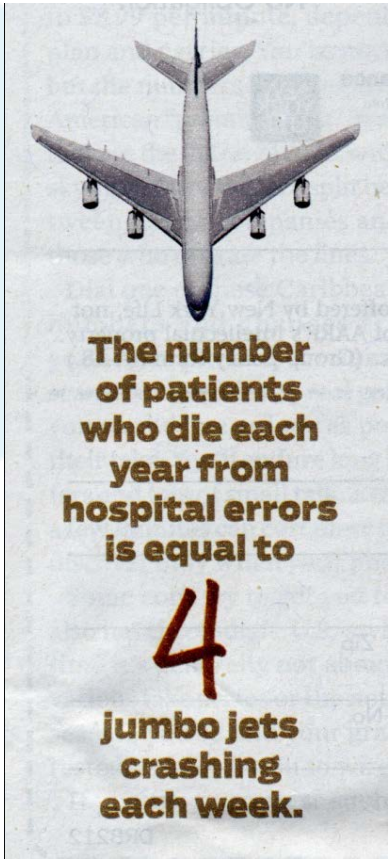
SHARON S. EHRMEYER, PH.D., MT(ASCP)
PROFESSOR, DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE
SCHOOL OF MEDICINE AND PUBLIC HEALTH
MADISON, WI

Q = Quality

Meeting the requirements or needs of the POCT or laboratory's customers
-- doctors and patients –
and satisfying their expectations

“Things” happen

The Worst Place to Be If You're Sick



One study of Medicare patients found that

1 in 7

died or were harmed by their hospital care.

"We" need "Quality" Results and Quality Practices!

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

Quality

And

Patient safety

Quality $\neq$ 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

www.cms.hhs.gov/clia/cowppmp.asp (2003)

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

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

Goldsmith B. *Clin Chem News* 2001; 3:6-8

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?TId=61290154281; Patient safety 2007, Sept. 2007, http://acutecaretesting.org/journalscanner?TId=61290154281

Medical Error Safety ⟷ Quality ⟷ Patient

…*"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*."

Institute of Medicine. *Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press, 2001.*

Patient Safety Culture

Informed and Flexible Organization

Effective Leadership

Patient Safety Training

Feedback

Open Communication

Common goals

Quality Improvement focused on patient outcomes

Faulty system; not faulty staff

Competency Assessment

Patient-centered care

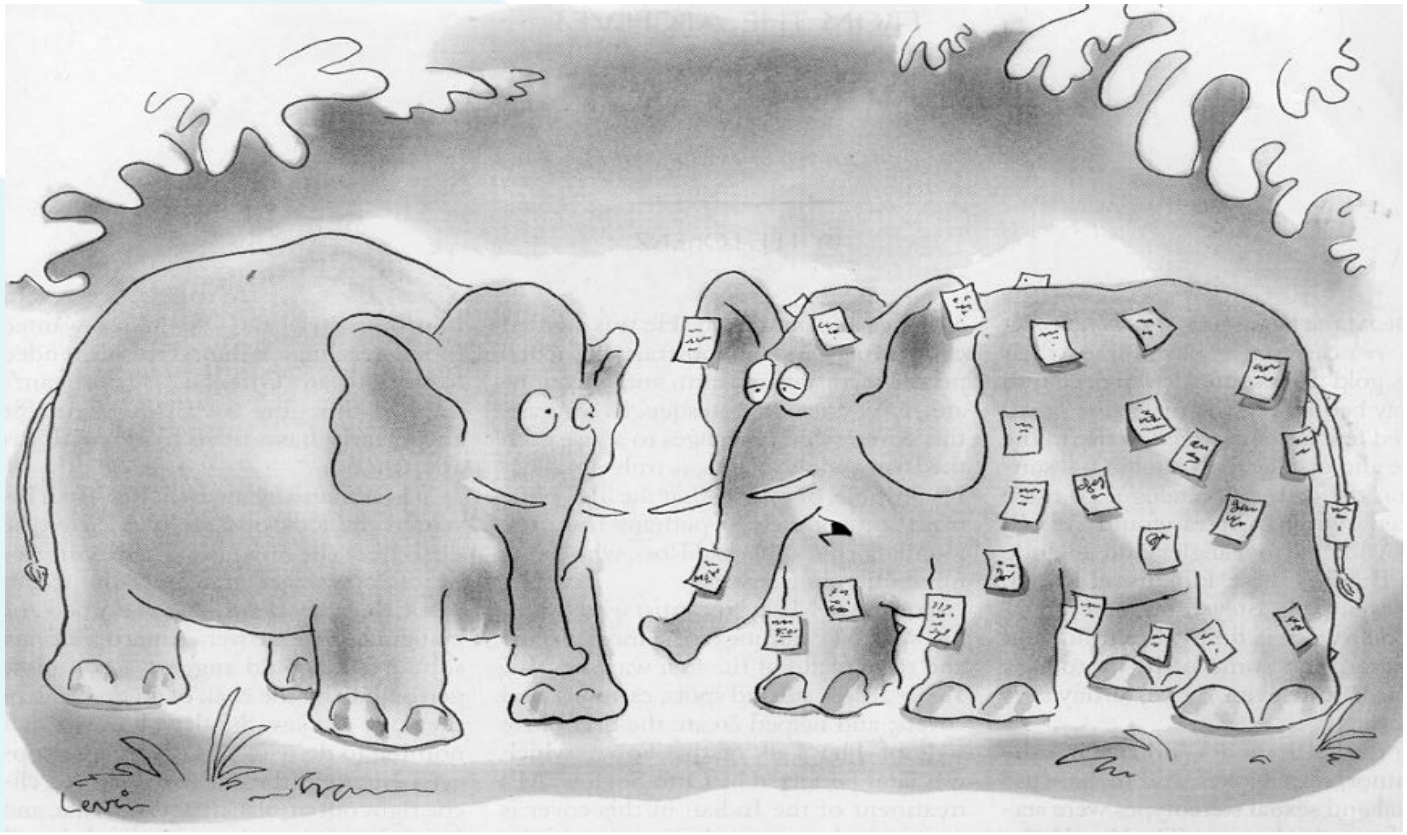
Interventions to Reduce Errors*

- 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/cpoct/poc_forum/Documents/AstionAACC_POCsafetysubm.pdf

Weak Interventions



As I get older,
I find I rely more and more on these sticky notes

Strong Intervention for Quality and Patient Safety

LAB MANAGEMENT

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 that are 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.

Hospital (Mather), a 248-bed community hospital, in Port Jefferson, NY.

Process redesign

Mather's lab, which performs 1.6 million tests per year, has realized dramatic reductions in error potential with a long-term strategy. Based on its experiences, the hospital's laboratory administrators believe that other labs can yield similar benefits as a result of advanced technology, regardless of their size or testing volume.

"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

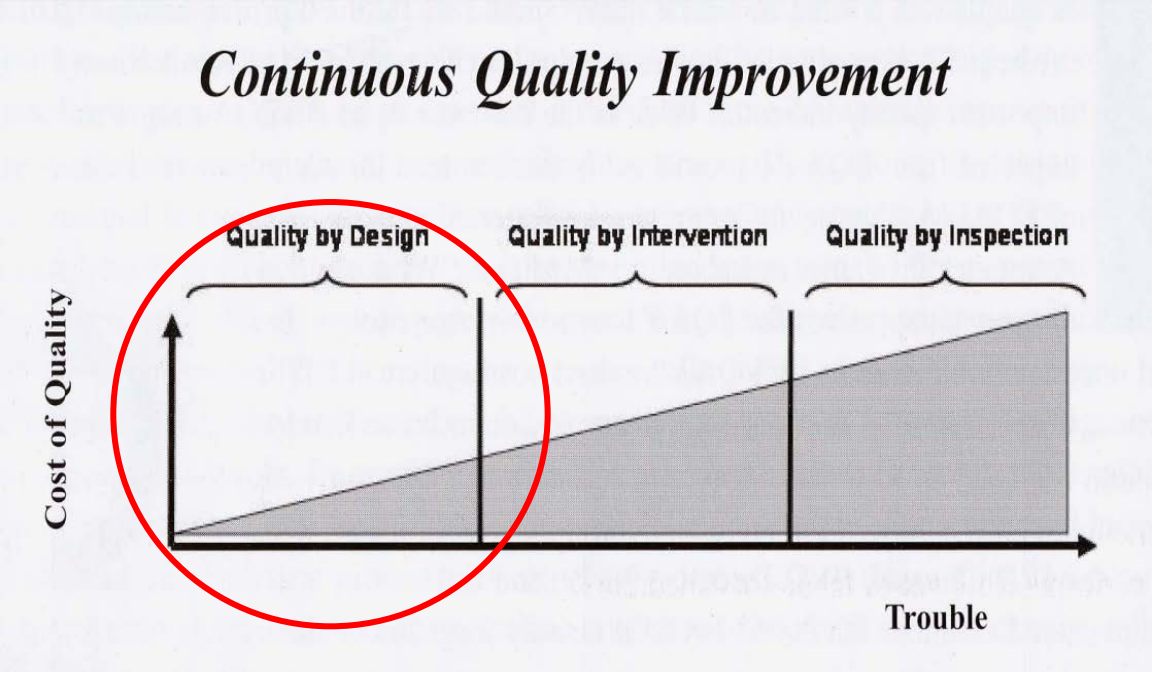
Auto**no**mation – intelligent automation

Meier F, Jones B, *Arch Pathol Lab Med* 2005;129:1262-1267

Ehrmeyer S, Laessig R. *Clin Chem Lab Med* 2007; 45(6):766–773

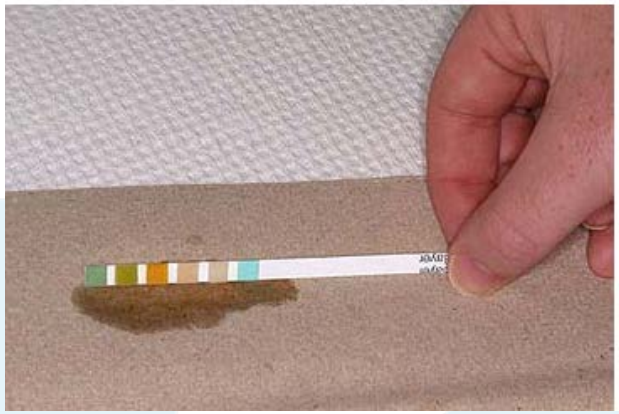
Autonomation, Quality and Patient Safety

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

http://www.chisolutionsinc.com/images/cmsupload/2011_CLIA%20Compliance_Chapter%206%20by%20Chi%20Solutions.pdf

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.

Ford A. Eye the basics, not baubles, for point-of-care testing. Jan. 2010. CAP Today.

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

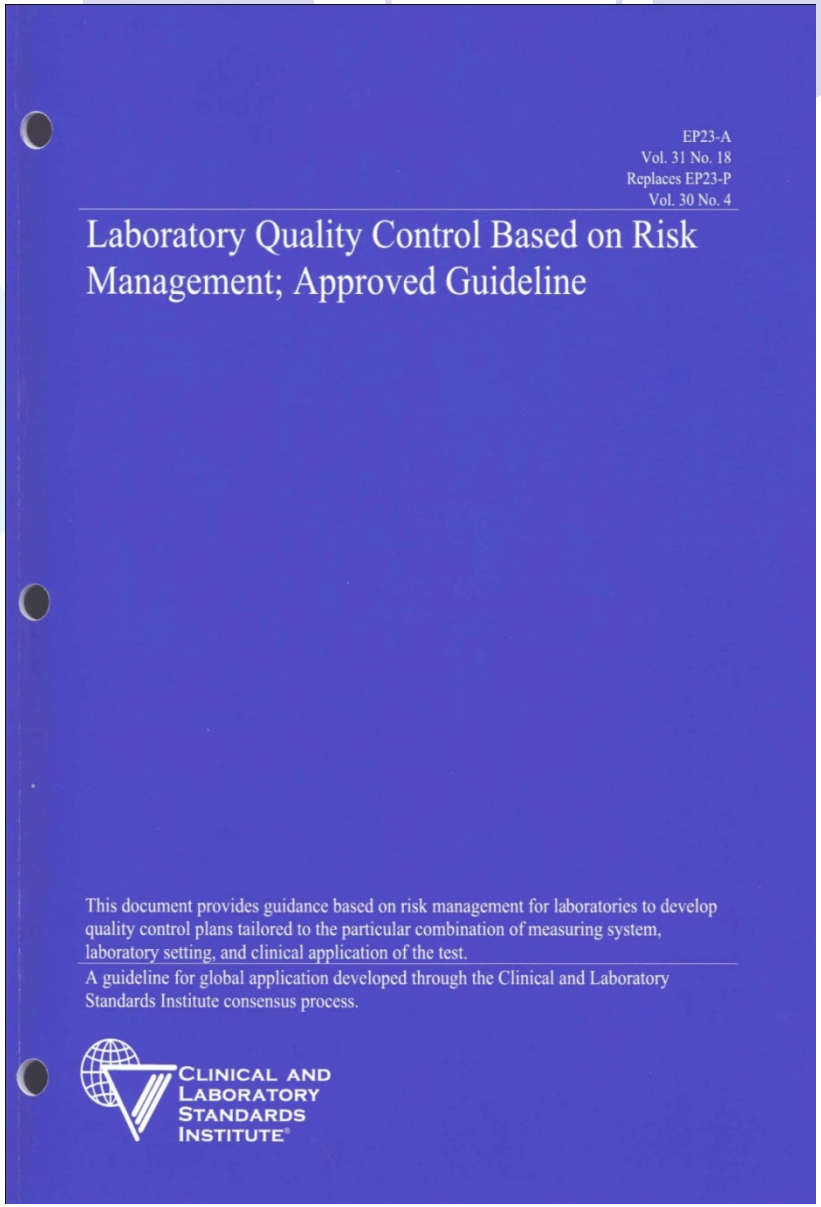
Risk Management

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

CMS

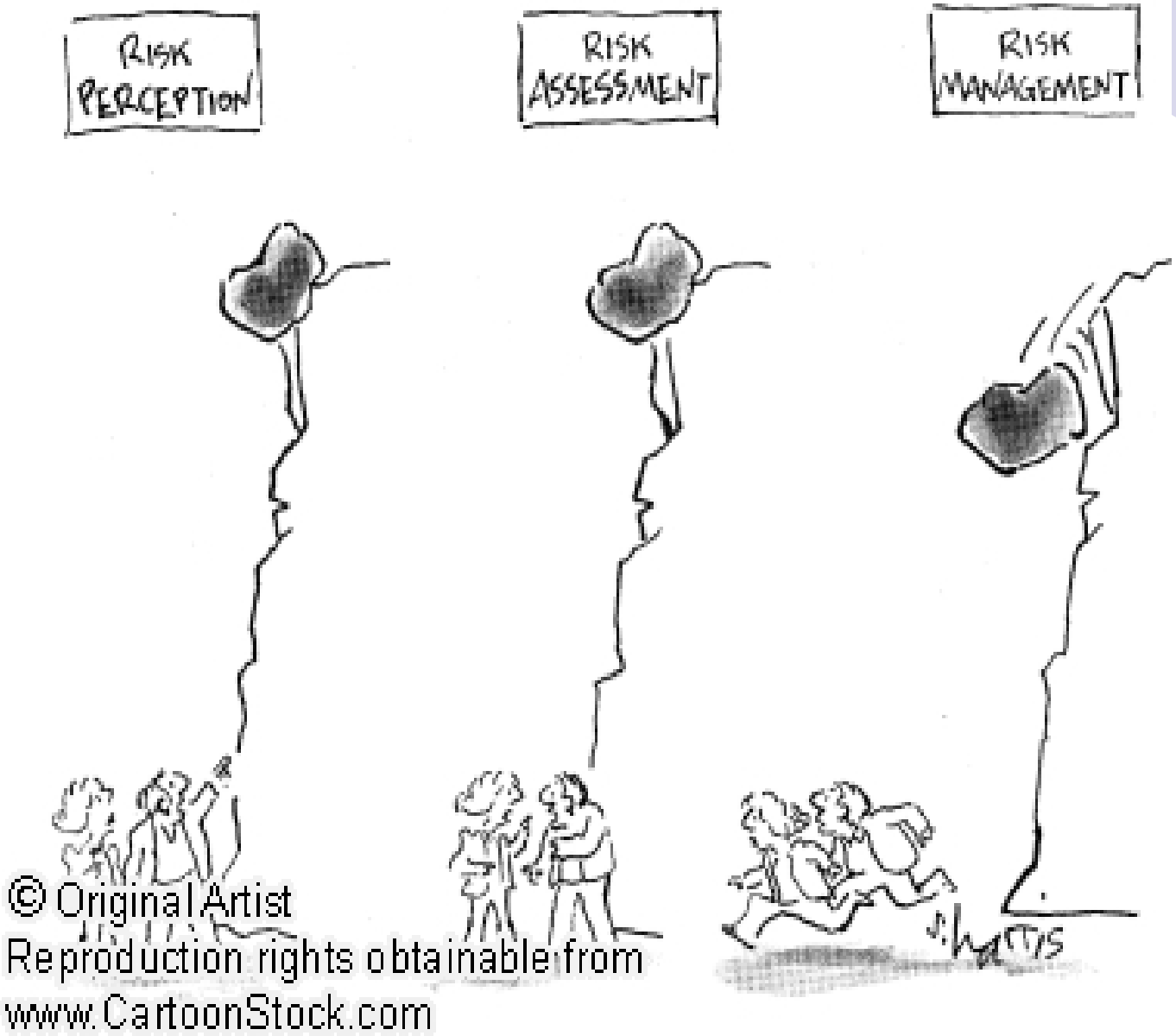
CLSI: GP23-A (October 2011)

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



Clinical and Laboratory Standards Institute
Advancing Quality in Health Care Testing

CLSI formerly known as NCCLS; www.clsi.org

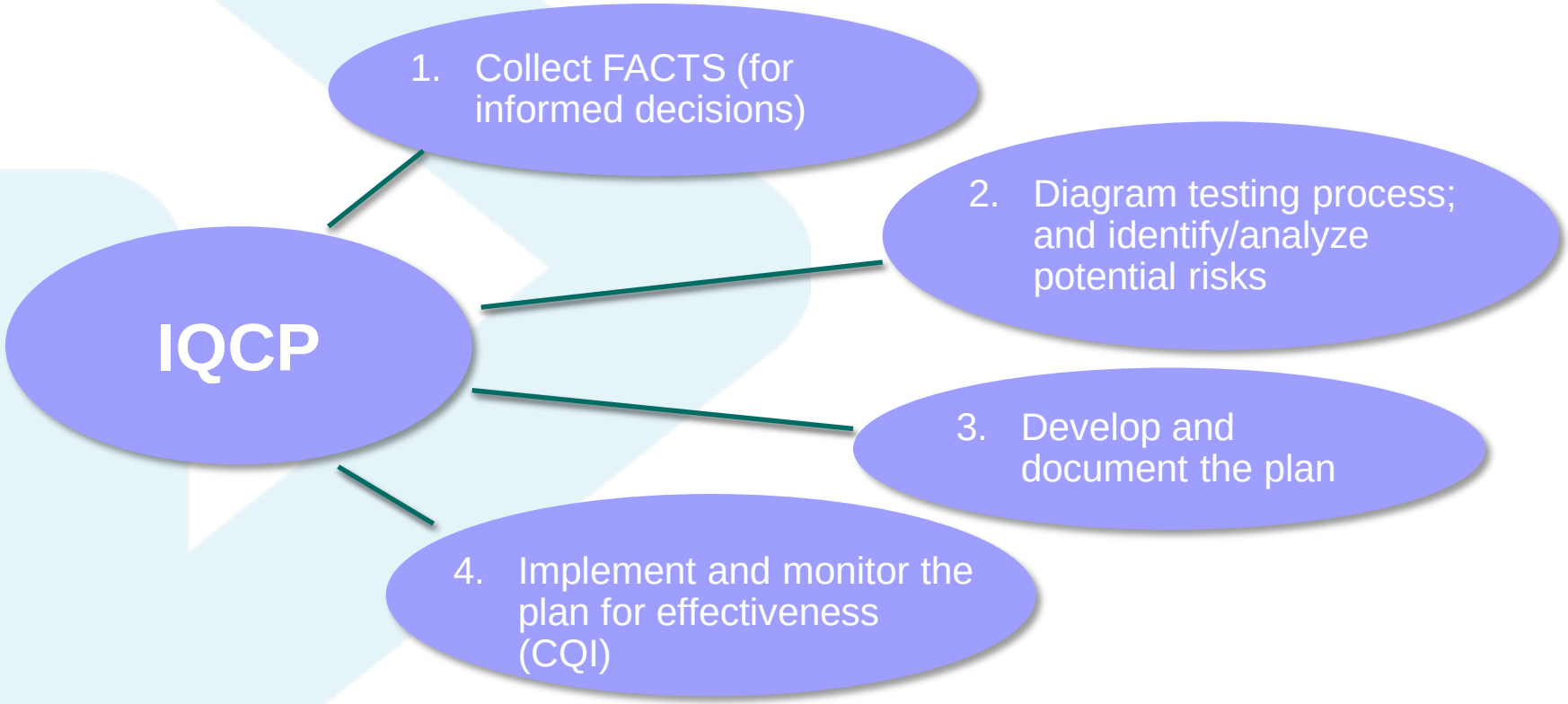

RISK PERCEPTION
RISK ASSESSMENT
RISK MANAGEMENT
© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com

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)

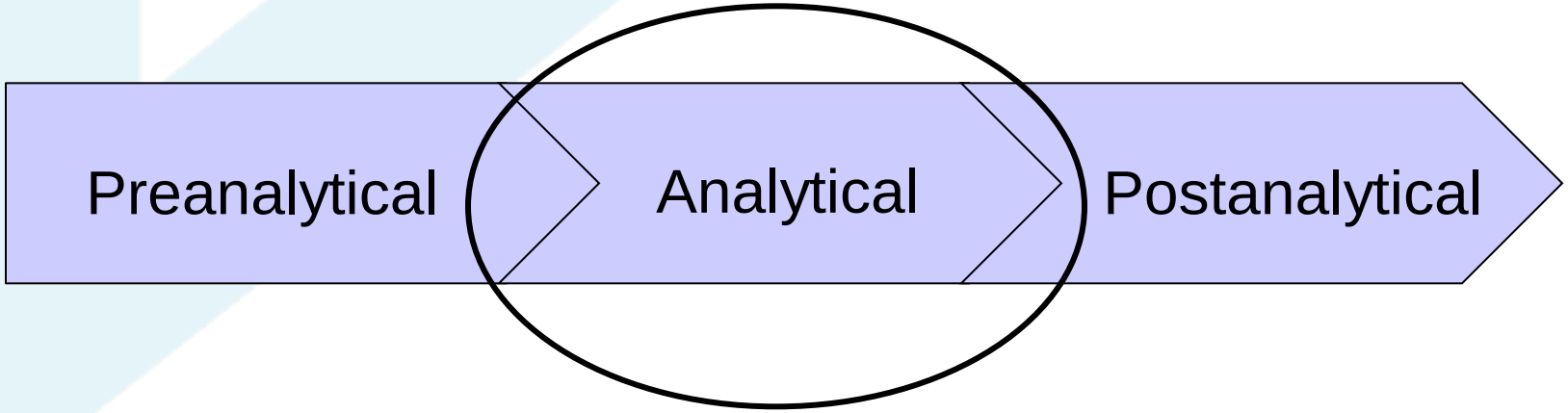
*Clinical and Laboratory Standards Institute (www.CLSI.org); **ISO14971:2007. Medical devices -- Application of risk management to medical devices. (www.iso.org); JO Westgard. Six Sigma Risk Analysis (2011). Westgard QC, Inc. Madison, WI

Steps for IQCP development*



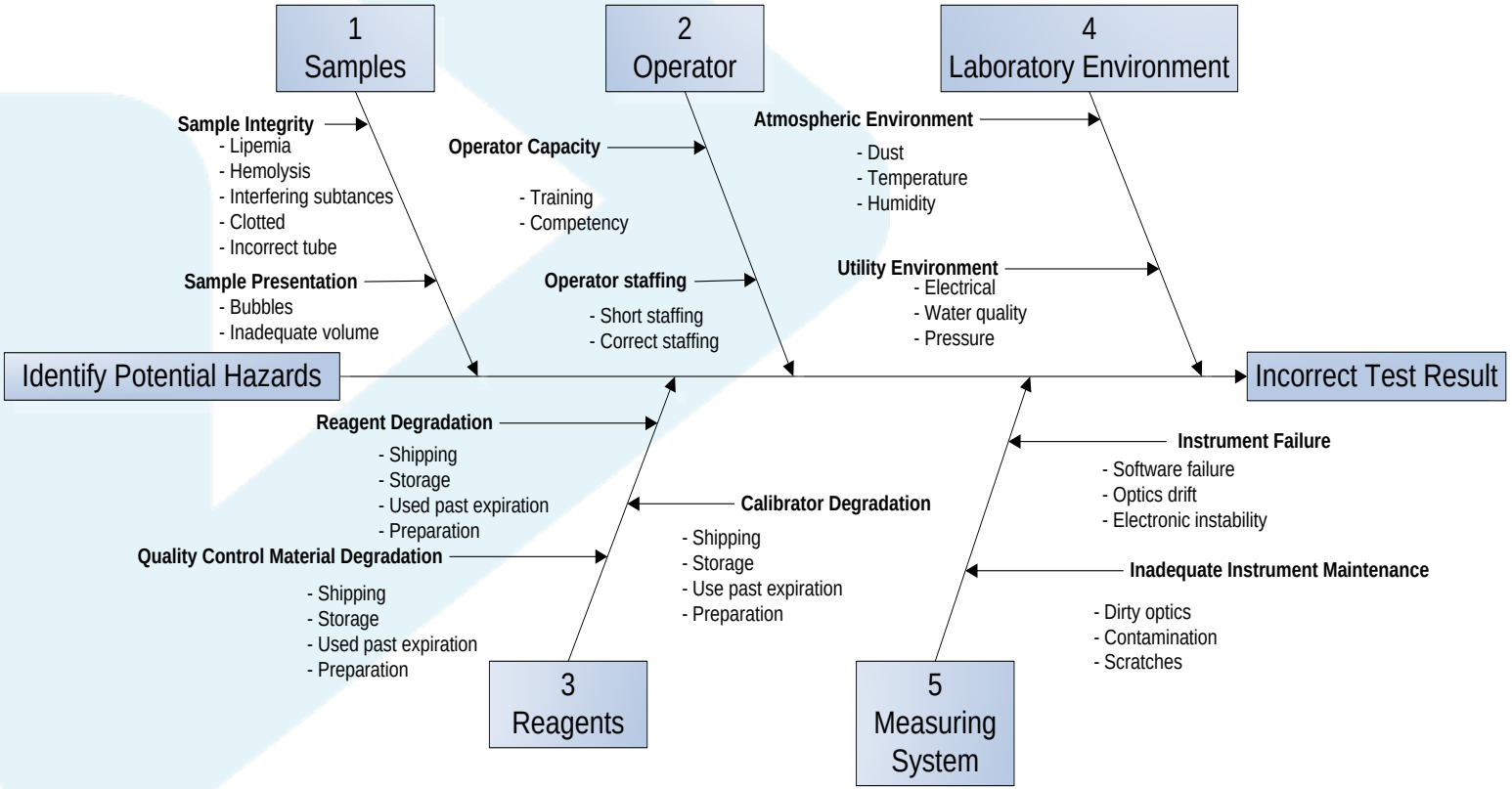
**Adapted from: CLSI EP23-A :Laboratory QC Based on Risk Management. www.CLSI.org; JO Westgard. Six Sigma Risk Analysis (2011). Westgard QC, Inc. Madison, WI; Joint Commission Resources. Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction (3rd ed.). TJC Resources. Oakbrook, IL.*

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*

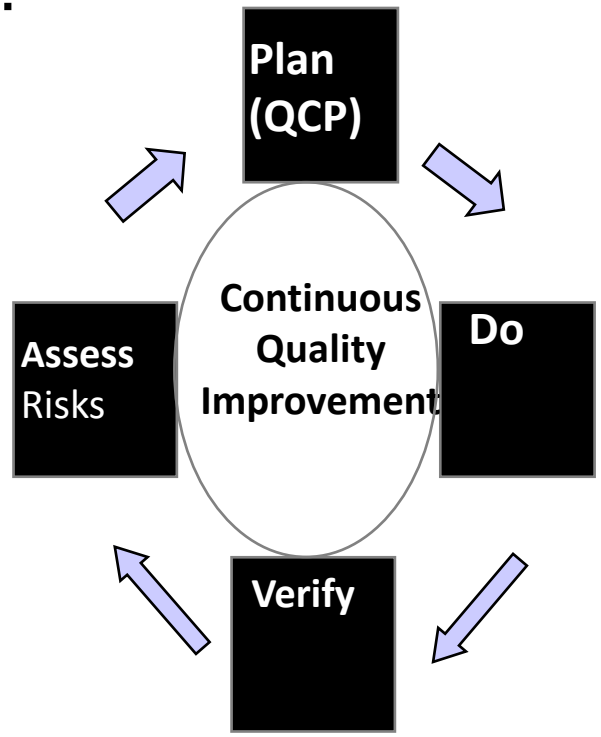


*EP23-A Implementation Workbook: A Practical Guide for laboratory Quality Control Based on Risk Management. www.clsi.org

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

CMS March 2012 Memo. http://cms.hhs.gov/Medicare/Provider-Enrollment-and-Certification/ SurveyCertificationGenInfo/ Downloads/SCLetter12_20-.pdf; CMS presentation at CLSI EP23-A Workshop, May 2012

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!

- 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

We cannot overlook the “RED” criteria

Who is responsible for the "Red Corrects"

Physicians, Clinicians --

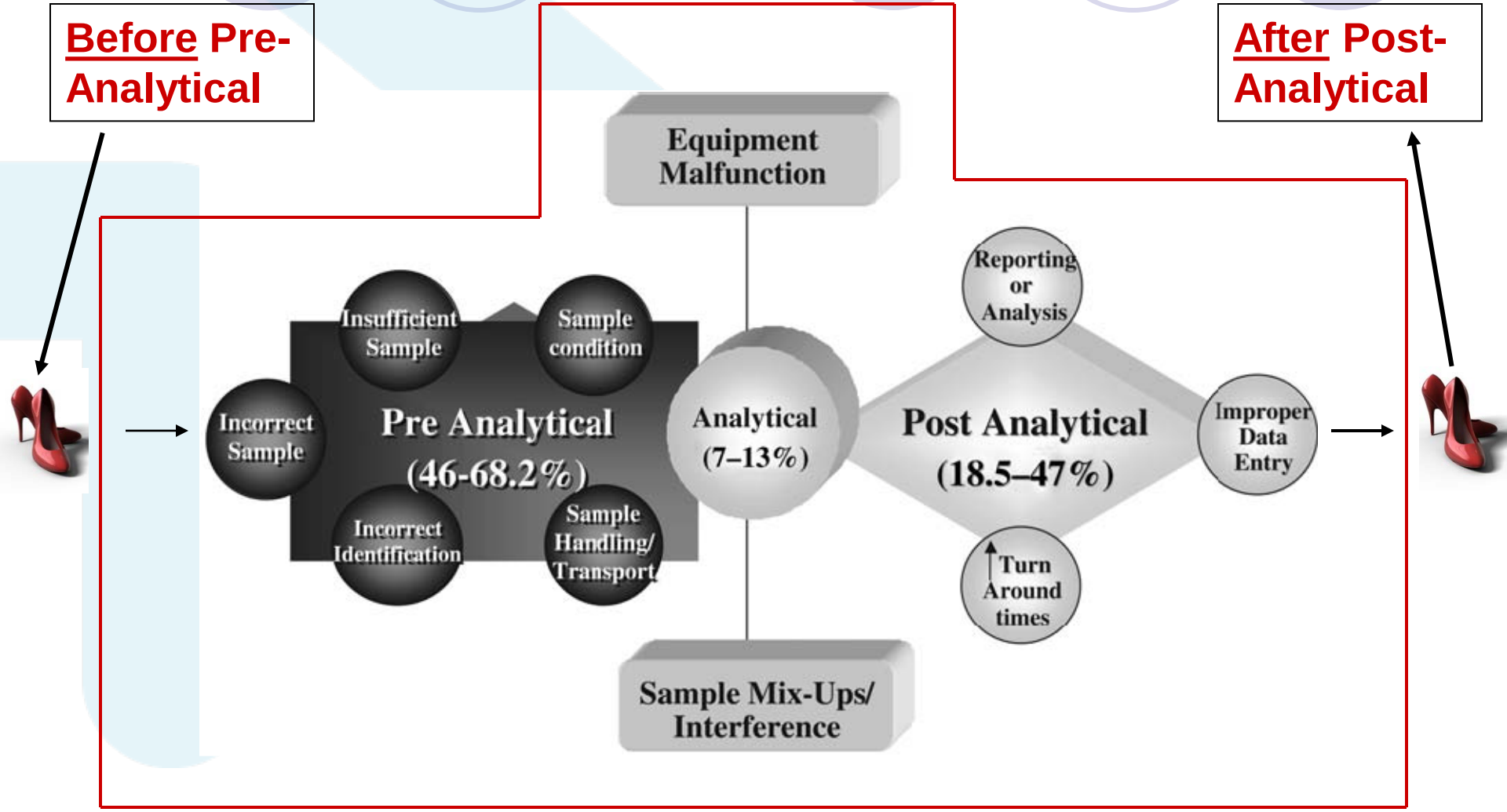
These individuals must be part of the process and concerned with medical errors and patient safety

Ehrmeyer S, Laessig R. *Clin Chem Lab Med* 2007; 45(6):766–773

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

Before Pre-Analytical

After Post-Analytical



Plebani M. *Clin Chem Lab Med* 2006;44(6):750-759

Lippi G, Guidi G, Mattiuzzi C, Plebani M. *Clin Chem and Lab Med* 2006; 44, 358-365

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"**

Ehrmeyer S, Laessig R. *Clin Chem Lab Med* 2007; 45(6):766–773

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

**Plebani M. Partners in error prevention. 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)