Plan for Quality to Improve Patient Safety at the POC

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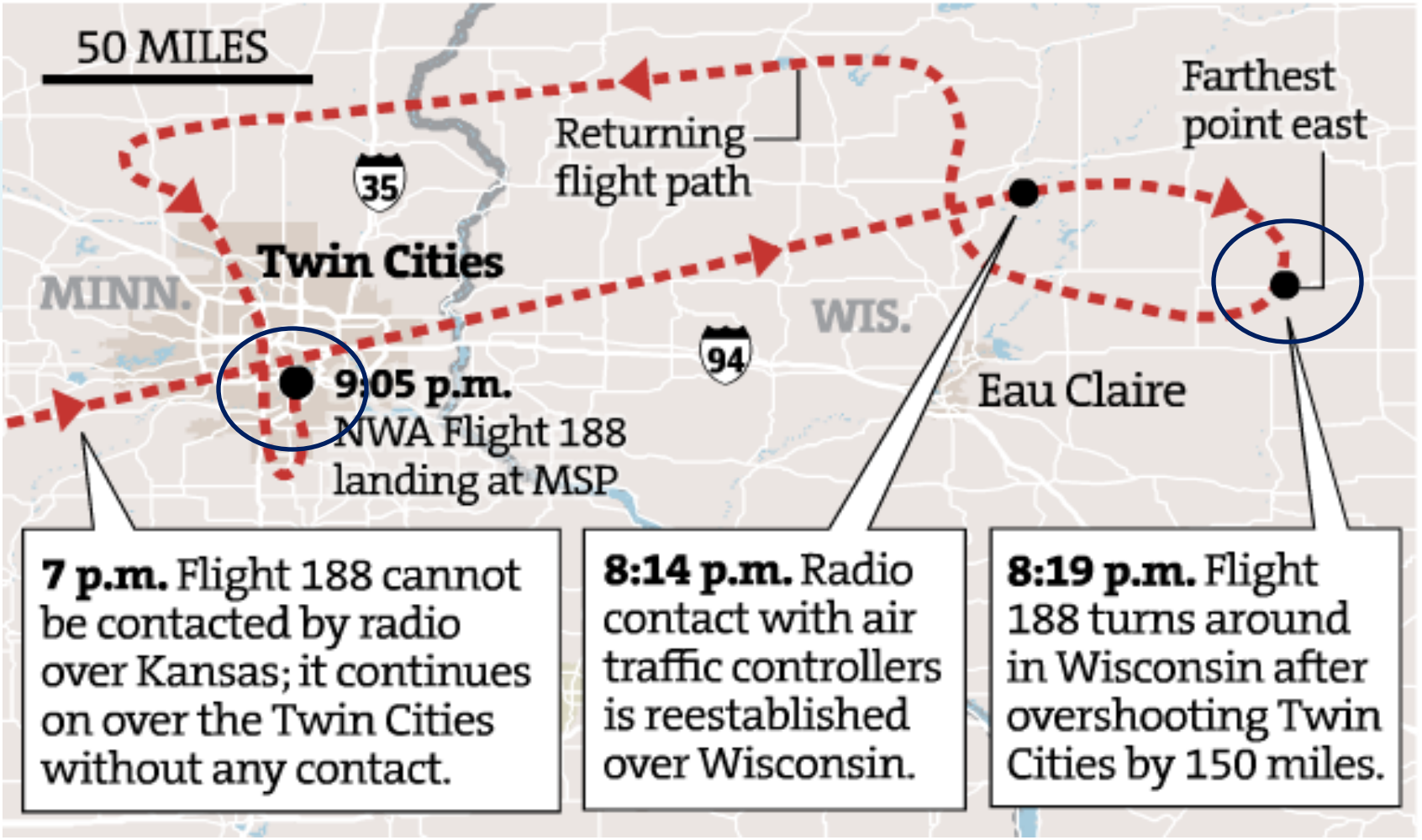
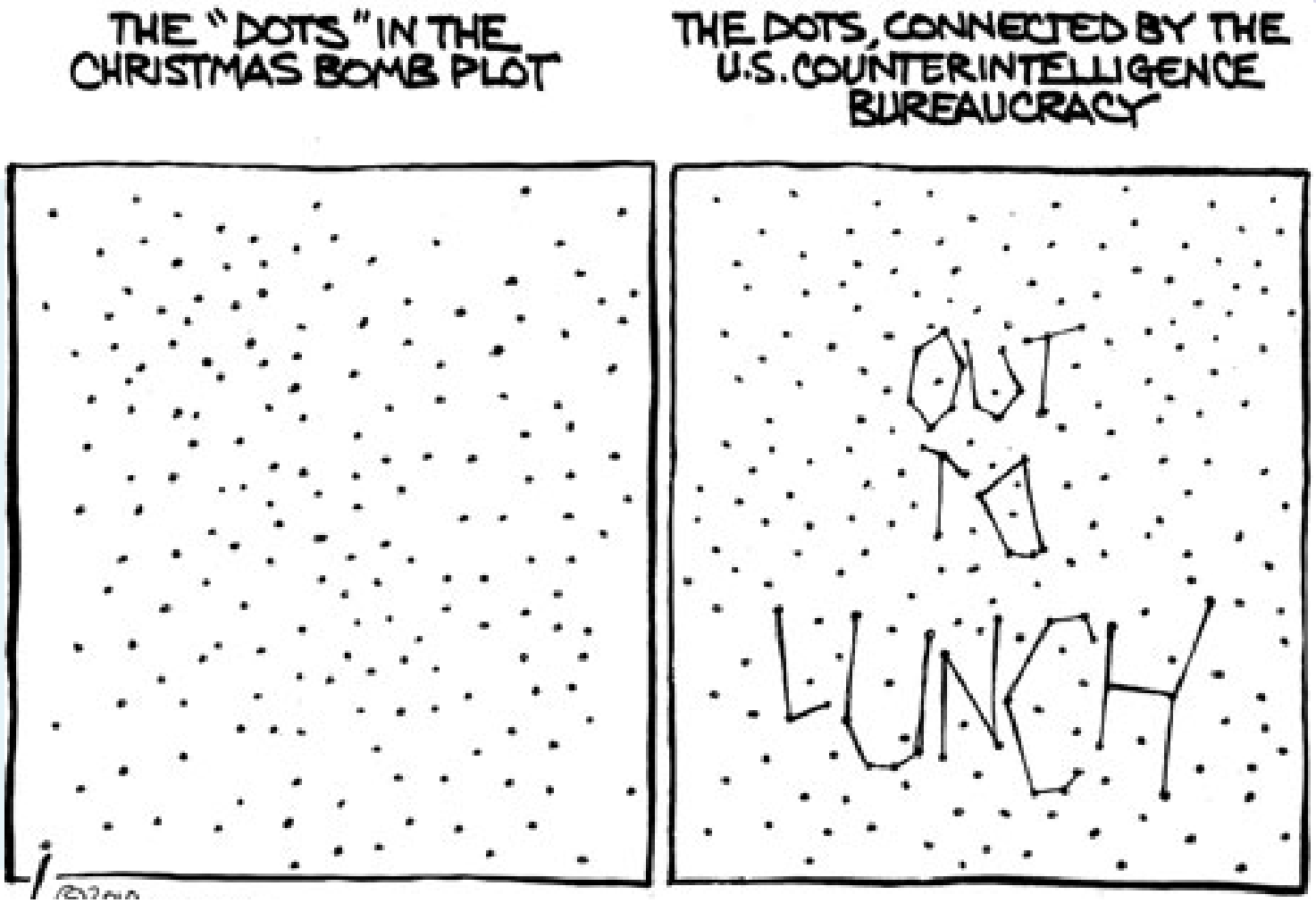
“Things” happen

Things happen! – November 2009
Pilots fly 250 km beyond airport



Things Happen: December 25, 2009 Intelligence Failure



Obama's Comment on Security

Things happen!

- Average non-laboratorian POCT analyst finds ways for tests to fail regardless of design and fail-safe engineering
  - Fecal occult blood – wrong developer; wrong timing
  - Urine pregnancy – original negative test reported was reread as positive
  - Rapid group A Strep antigen test requires equal volumes of reagent A & B, yet:
    - Only a new vial of one of the reagents is requested
    - Reagent vials refilled with water (original reagent looks like water)
    - Interchange of reagents from different kits and lots
  - Fingerstick glucose
    - Supervisor tests self to show meter is working

Ng VL. QC for the future: Laboratory Issues – POCT and POL Concerns. *Lab med*. Oct. 2005; 36:621-625.

In 2010, 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

Patient Safety and Quality Testing in 2010 has 8 criteria:

- 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

2010: Managing Quality Testing for Patient Safety

- Ensuring quality of ALL processes impacting test results
- Detecting and reducing errors
- Improving quality continuously (CQI)

The Central Laboratory and POCT are like…….

Fred Astair

and

Ginger Rodgers

Circa 1938…Fred and Ginger

In 2010……

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) “I do everything Fred Astaire does except [I do it] backwards and in [red] high heels”*

* 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 – Continually increasing!

- Alternate testing continues to increase
  - 377 pharmacies in 1997; 3442 in 2008
- Technology is dynamic & robust?
  - 8 waived tests in 1992; >100 analytes in 2010 with more than 1000 methodolgies
- 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

The ten most cited POCT deficiencies

Failure to:

- Perform **quality control**
- Document **QC**
- Follow **manufacturers' instructions**
- Document **personnel training and competency**
- Document and **take appropriate corrective action** for QC outliers
- Follow a **procedure manual**
- Perform and document **calibration / calibration verification**
- Verify **accuracy** for all analytes
- Provide **continuing education** for testing personnel
- Document **POCT results in patient record**

Plebani M. www.bloodgas.org Jan 2009

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

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/acceptence of deviant behavior
- Multi-tasking / fatigue combination
- Disconnect between “lab” work and care providers
- Favoring weak interventions because they are easier
  - More directives versus more automation

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

POCT: Error Monitors and Implementing Safety Strategies

Error monitors

- Order documentation
- Patient and analyst identification
- Specimen acceptability
- Result accuracy
- Result report accuracy
- Documentation in patient record

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

POCT: Error Monitors and Implementing Safety Strategies

Error monitors

- Order documentation
- Patient and analyst identification
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- Result accuracy
- Result report accuracy
- Documentation in patient record

Safety strategies

- Quality control assessments
- Checklists for performance; competency assessment
- External quality assessments / accuracy evaluations
- Autonomation (instrument performs/assesses functions)

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

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

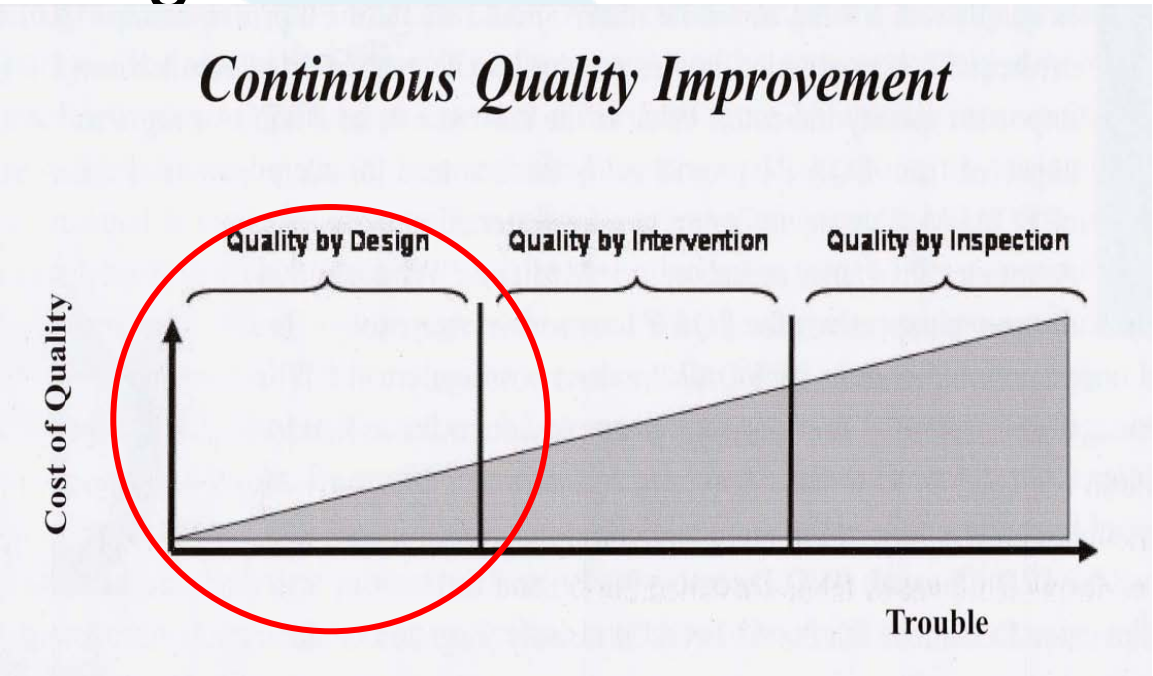
Auto**no**mation – intelligent automation

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

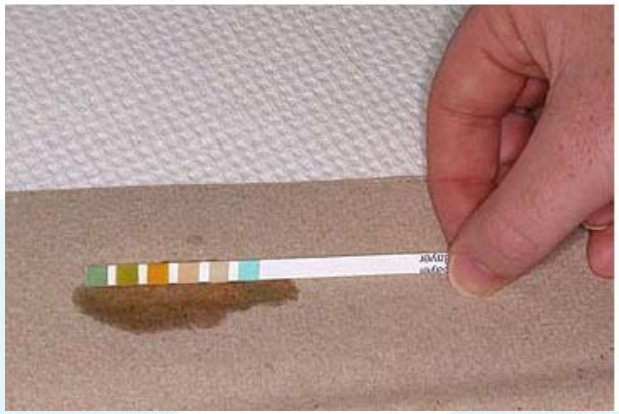
Autonomation, Quality and Patient Safety

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

In 2010 Quality and Patient Safety Require Quality ("Risk) Management

CLIA

JC, CAP, COLA

CLSI (NCCLS)

Risk Management EP - 18, 22, & 23

Quality and Patient Safety - Just don’t happen!

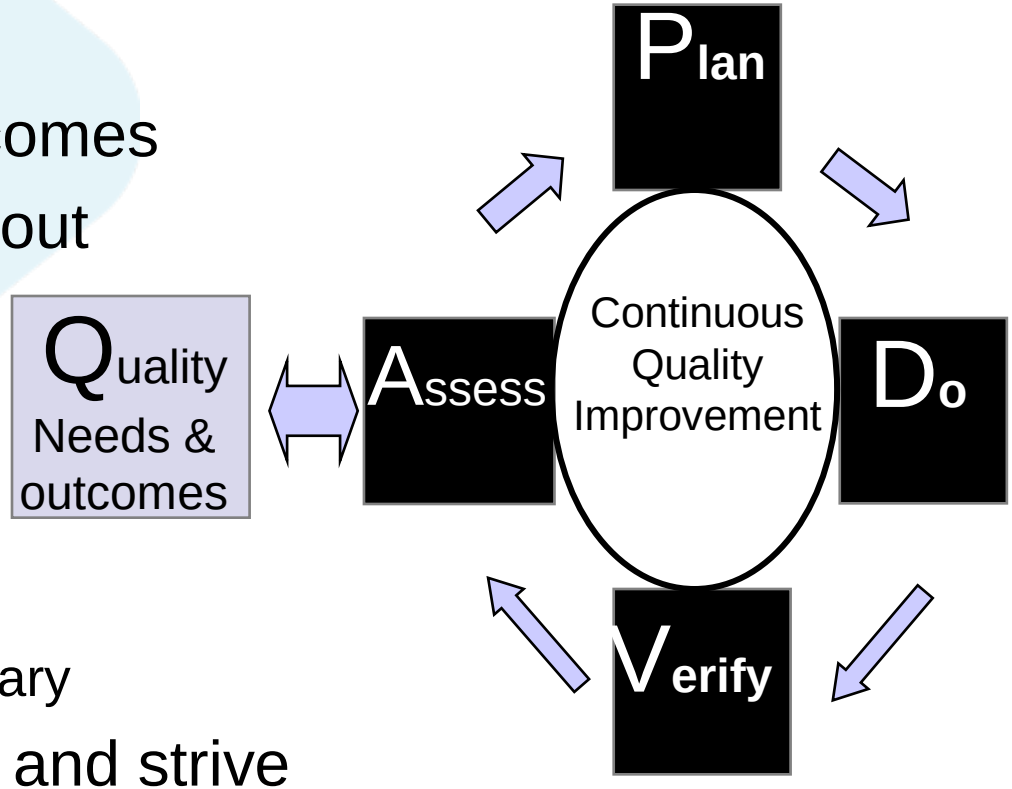
Plan

Plan

Plan

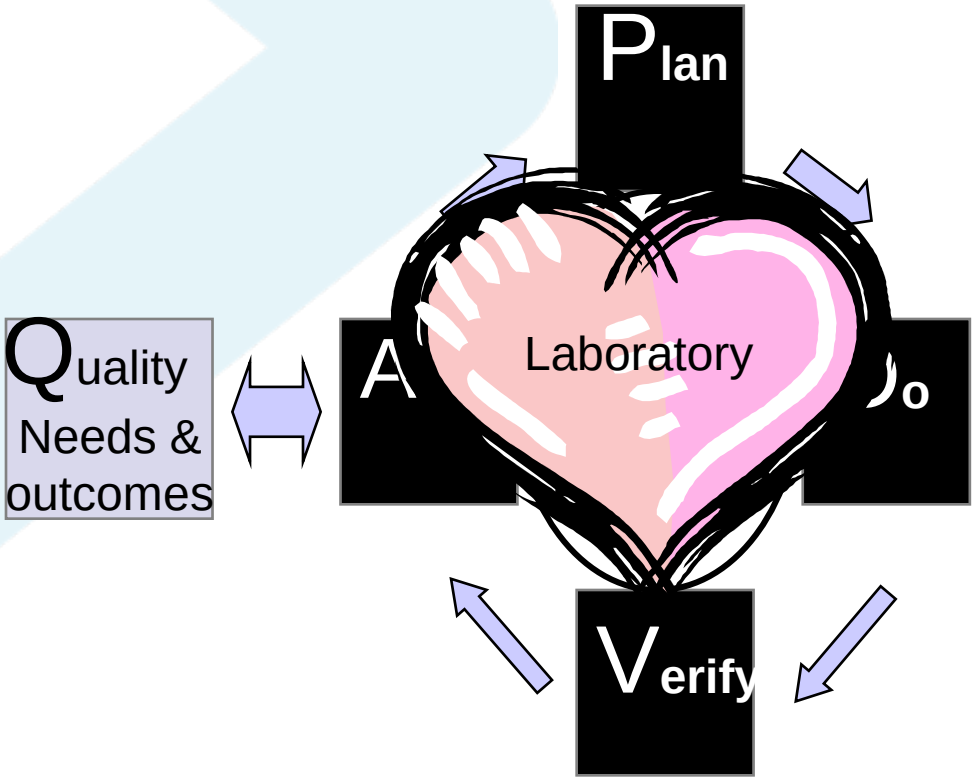
Quality (Risk) Management

- Prevent testing errors and ensure patient safety!
  - Assess needs and outcomes
  - Plan for quality throughout
  - Develop policies; implement procedures
  - Continually verify effectiveness
    - make changes if necessary
  - Re-assess for changes and strive for continuous quality improvement



Quality (Risk) Management

Qualified Laboratory Professionals are at the center!



Quality and Patient Safety Require Team Work!

- 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

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 for Quality and Patient Safety*

- Start with a plan
- Establish a framework, e.g., 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

10 Top Planning Tips for Managing POCT

- Standardize instruments /methods across system
  - Simplifies
- Communicate
  - Clear, concise and consistent
- Establish a goal-oriented team
  - Clear objectives
- Seek improvement
  - CQI, nothing stays the same
- Establish networks for help
  - Web, manufacturers, POCT groups, etc.

10 Top Planning Tips for Managing POCT

- Conduct research to determine value of POCT
  - Another part of improvement
- Implement connectivity
  - Eliminates many problems
- Integrate POCT with central laboratory
  - POCT is part of overall patient care pathway
- Self-manage
  - While POCT is a partnership, site must take charge
- Be positive
  - Positive attitude is necessary for changing practices

8 Criteria for Patient Safety and Quality Testing

- 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)
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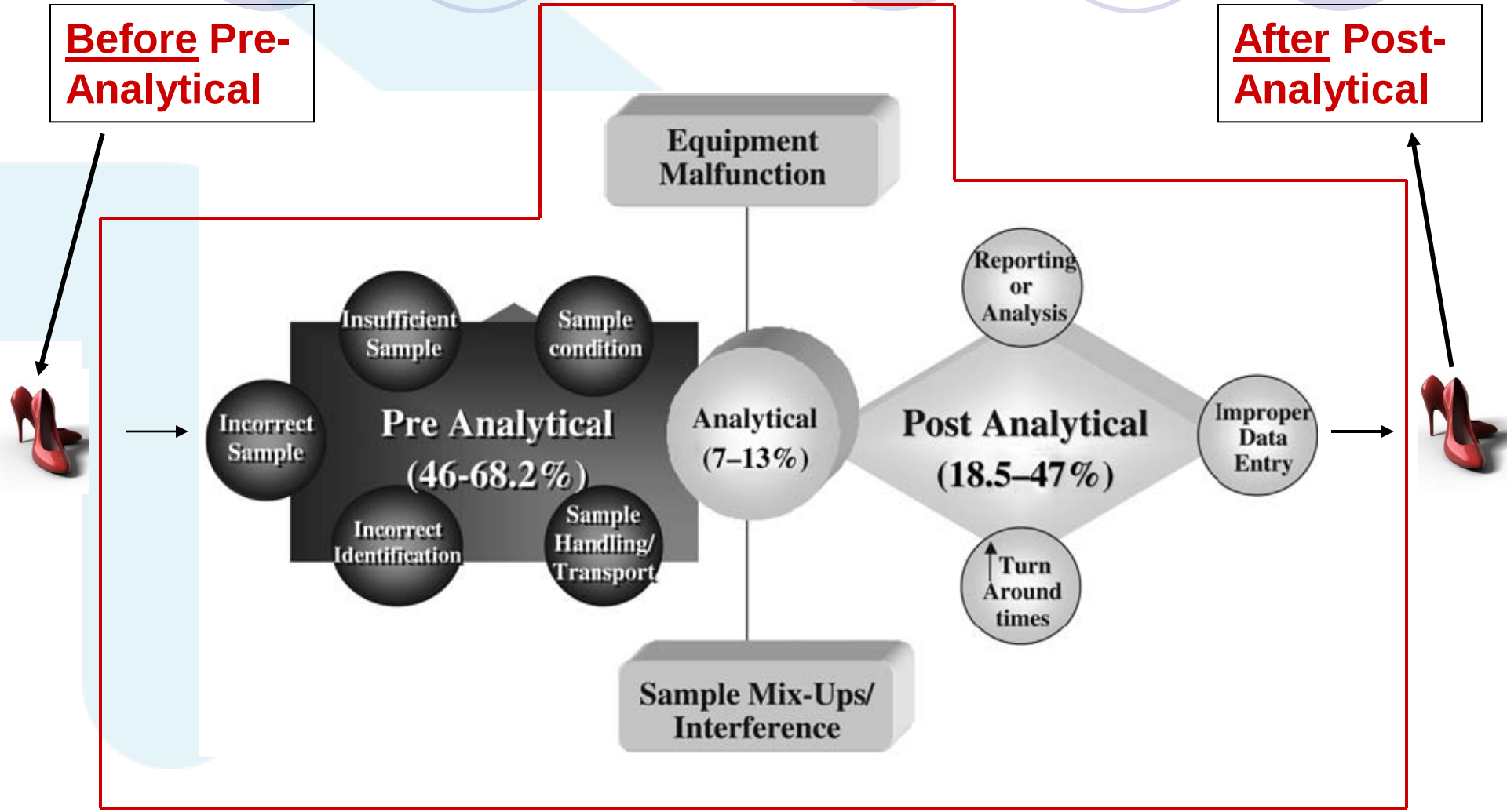
Who is responsible for the "Red Corrects"

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*



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?

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?

New Physician Paradigm and New Generation of Physicians

Paper

PDA/cell phone

New Physician Paradigm

- Evidence based medicine
  - Using the best evidence from test ordering to decision-making to treatment
- Using Technology for Effective Communication Among Caregivers
  - Patient safety is literally “on the line” every time communication about a patient takes place
  - Miscommunication due to:
    - Multiple handoffs between care providers
    - Demands on staff and physician time
    - Speed with test orders and test result generation

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

(POCT) “I do everything Fred Astaire does except [I do it] backwards and in [red] high heels”*

And, much more!!

* Ginger Rogers

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)


MOO-CHAS GRACIAS!
THANK YOU DAIRY MUCH!
I'M UDDERLY GRATEFUL!
THANKS HEIFER SO MUCH!