

Developing a Patient Safety Culture in the Clinical Laboratory

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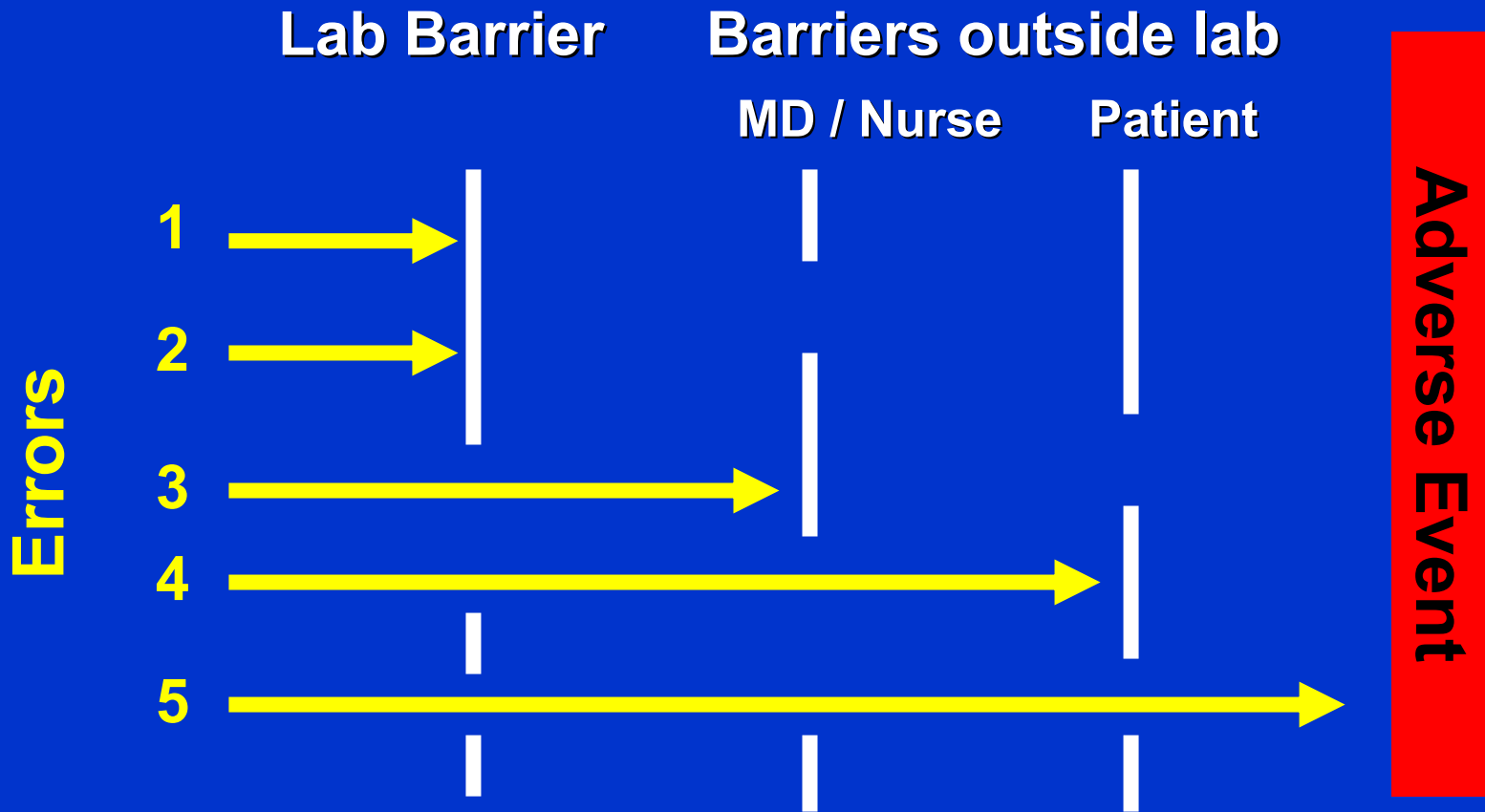
Overview

- **Definitions and scope of patient safety problem**
- **Obstacles to a patient safety culture**
- **Ideas for overcoming the obstacles through:**
 - **Training**
 - **QI projects focused on outcomes**
 - **Interactions with staff and management**

Definitions:

- An adverse event is an injury related to the patient's medical care and not due to the patient's underlying condition
 - Example: Post analytic data entry error leads to false positive troponin, incorrect Dx of MI , unnecessary Rx and hospital admission
- Potential adverse events are “near” hits
 - Example: Transport problem delays stat Amylase; patient is unaffected

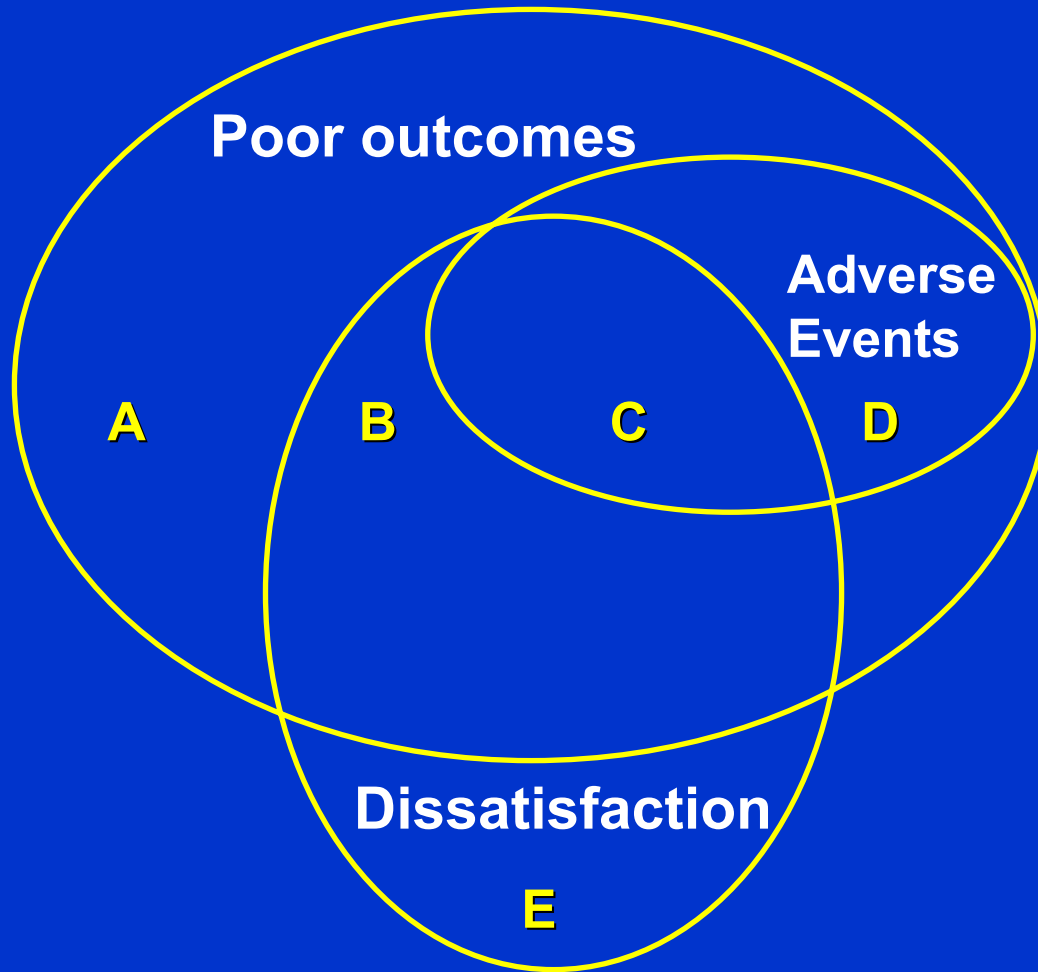
Errors rarely become adverse events



1 – 4 = potential adverse events

5 = actual adverse event

Relationship between poor patient outcomes, adverse events and patient dissatisfaction



The Seattle Times

Nation & World: Tuesday, November 30, 1999

Study: 98,000 deaths each year are linked to medical mistakes

by Rick Weiss

The Washington Post

WASHINGTON - About 98,000 Americans die unnecessarily every year from medical mistakes made by physicians, pharmacists and other health-care professionals, according to an independent report that calls for a major overhaul of how the nation addresses medical errors.

More Americans die from medical mistakes than from breast cancer, highway accidents or AIDS, according to the report released yesterday by the **Institute of Medicine**, an arm of the National Academy of Sciences. That costs the nation almost \$9 billion a year, the congressionally chartered research group concluded.

What if 1% of tests were erroneous, and 6% of the erroneous tests led to inappropriate care?

4,000,000 lab tests per year



1% are erroneous

40,000 erroneous lab results per year



6% inappropriate care

2400 cases of lab-related care problems per year (> 6 cases per day).

Labs lack an optimal “patient safety culture”

- Poor (or no) methods for detecting adverse events
- Isolated from the patient
- Misplaced emphasis on:
 - errors not adverse events
 - error rate not # of errors



Obstacles to a patient safety culture

- A “blame the person first” mentality
- Risk management / Human Subject concerns slows or stops communication of patient safety results and best practices.
- QI unfocused on patient outcomes
- Staff are anxious about openly discussing errors.
 - Who is going to be first to participate in the new blame-free culture of openness?

Blaming people vs. blaming the system

- **Natural tendency is toward looking at active error (sharp end), not latent error (blunt end).**
- **One latent error can produce many active errors**

1 latent error produces many active errors

- Computers: A lack of 1 instrument interface is responsible for many active data entry errors.
- Staffing: 1 latent error regarding suboptimal staffing leads to multiple active errors by staff who are forced to multitask.
- Policy and Procedure: A bad strategy for handling phone calls can lead to multiple errors
- Force yourself to look at the latent error first.

When is blaming a person appropriate?

- Impairment
- Purposeful disregard of rules
- Mismatch of skills with job duties
 - Staff with error rates and impact > than peers.
 - Some people can't process specimens.
 - Some can't perform microscope tasks.

Risk Management: The goal

“Within healthcare organizations, the implementation of an effective risk-management system leads to improvement in the quality of care delivered, staff morale and relationships, and the efficiency of the organization, which in turn results in cost savings.”

**Institute of Healthcare Management, UK:
www.atalink.co.uk/ihtm/html/p159.htm**

Risk management (RM): the reality

- RM will not allow, or is not supportive of sharing of patient safety QI data, even if approved by Human Subjects board (IRB)
- RM is concerned that data publication will eliminate legal QI protections.
- RM is focused on economic loss.
- RM obstacles reduced by informing RM early and often of all patient safety QI projects and data.

Would a medical center lose or gain financially if it was more forthright about reporting adverse events?

Obstacles to a patient safety culture

- A “blame the person first” mentality
- Risk management / Human Subjects concerns
- **QI unfocused on patient outcomes**
- Staff anxiety

Why are patient outcomes important?

- **Sets the priority order for interventions.**
- **Connects lab staff to patients**
- **Creates urgency in your organization.**
- **Gives powerful data to support resource requests**

Obstacles to obtaining patient outcomes?

- **Who should collect them?**
 - **Contract pathologists?**
 - **Technologists?**
 - **Why would a for-profit lab collect this data from its clients?**
- **Health care workers underestimate impact to patients.**
 - **Usually self-deception**

How to obtain accurate patient outcomes (1):

“I have terrible anger that has ruined every relationship in my life and I need to talk to you about your anger.”

vs.

“I am an easy-going, cool-headed, California dude, and I need to talk to you about your terrible anger problem.”

Obtaining accurate outcomes (2): Use records to create specific questions

- **Lab records reveal key facts including timing of events.**
- **Medical records under-report injury but can still be useful**

ANIQ report

Date: 7/20/03

Test: Ionized Calcium

Patient: John Doe

(U23192876)

<u>Activity</u>	<u>Time</u>
Order Entered	16:30
Results Entered	17:10
Results Modified	20:10

Obstacles to a patient safety culture

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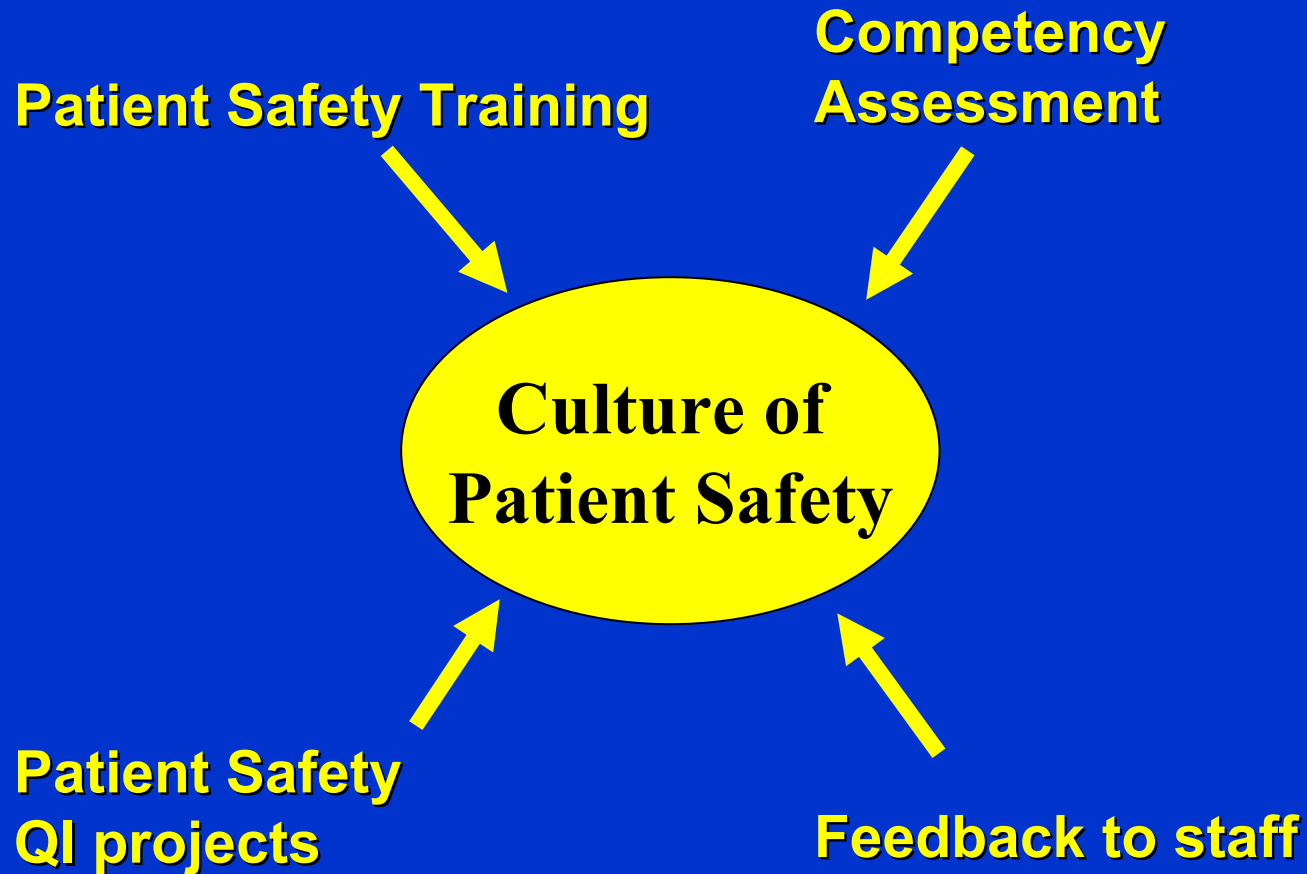
Techniques for communicating with staff

- Frequent communication
- Emphasize:
 - Inevitability of human error
 - The problems were here before we started talking about them openly.
 - Latent and active errors, not just active errors

Frequent communication of patient safety issues at UW Department of Lab Medicine

- Twice annually: In-services for divisions with active patient safety QI projects
- Weekly: Email reply to staff on all submitted cases
- Weekly: Resident's report
- 2-3 times per year: Present safety data at faculty QA meetings
- Annually: Medical Center QI committee
- Other: Grand Rounds, Research conference

4 contributors to a patient safety culture



Patient Safety Training: Pathologists

- **The Univ. of Washington now requires patient safety training for pathology residents**
- **The training consists of:**
 - **A 3-hour workshop**
 - **Annual workup of about 10 cases of actual or potential adverse events**
 - **Special projects for interested residents**

Patient safety training related to the clinical lab (free resources)

- **LabVoice online magazine**
 - **www.labvoice.org**
 - **3 articles on the lab and patient safety**
 - **2 teaching cases of lab related adverse events**

MTS LAB TRAINING LIBRARY UW University of Washington DEPARTMENT OF LAB MEDICINE

Lab Voice

Training and Competency in the

HOME TRAINING COMPETENCY

SPOTLIGHT: LAB ERRORS

“LAB MANAGEMENT BLUNDER: INTERVENTIONS THAT DON'T WORK.”

By Michael Aston, MD, PhD

READ

LAB TRAINING COURSE

Orientation to Patient Safety - Part III

The final segment of patient safety training features case studies and test questions. [Apply](#) for 2 hours of PACE credit upon completion.

START

PATIENT IDENTIFICATION

LabVoice, Issue 3, Dec 2003

Patient safety training and the clinical lab (more free resources)

- **Bonini P, et al. Errors in laboratory medicine. 2002. *Clin Chem.* 2002. 48:691-698.**
- **Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clin Chem.* 1997. 43:1348-1351.**
- **Astion ML, et al. Classifying laboratory incident reports to identify problems that jeopardize patient safety. *AJCP.* 2003. 120:18-26.**
- **These articles -and the references they contain- are useful for continuing education.**

Patient Safety Training (subscription-based)

- UW online patient safety tutorial (www.medtraining.org)
- Laboratory Errors and Patient Safety (newsletter), an industry – academic collaboration



Lab Errors & Patient Safety
Preventing Adverse Events Caused by Laboratory Errors

[Home](#) [Sample Issue](#) [Subscribe](#) [Contributors](#) [Case Submission](#)

Welcome to *Lab Errors & Patient Safety*, a publication dedicated to the clinical laboratory's impact on patient outcomes.

The increasing awareness of issues involving medical errors with healthcare and in the popular press has cast a spotlight on the factors that contribute to the resulting adverse events and has made the laboratory the subject of scrutiny. The need to look beyond the lab to grasp the impact that lab errors have on patient care, as well as the need for effective interventions, requires a concentrated effort from the laboratory community to share concrete experiences and collective wisdom.

Lab Errors & Patient Safety provides a forum for this dialogue. The publication includes articles from thought leaders, and case studies that document errors and adverse events along with expert commentary, interventions, and analysis of potential liability. Checklists and other useful resources will also appear, in addition to interviews and Q & A. Readers can submit questions, comments and cases to the editors through this site.

Every lab has much to learn and share. We invite you to participate in this growing community of stakeholders to improve patient care.

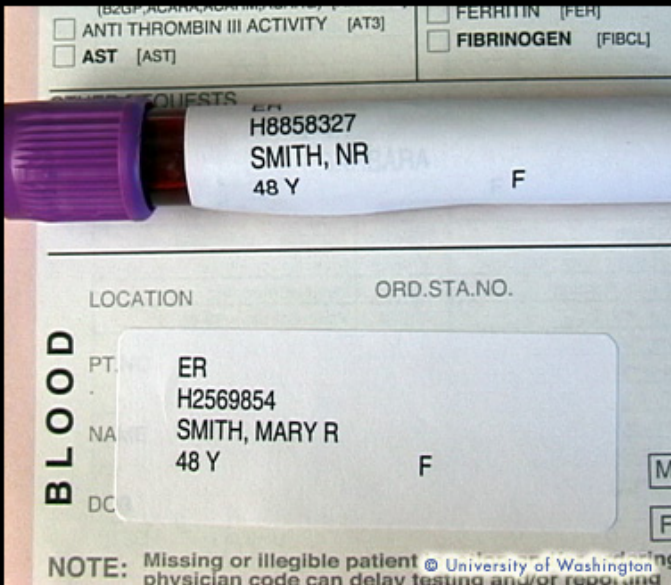
Sincerely,
Richard Astor

www.laberrors.org

UW Competency Assessment in Patient Safety

- www.medtraining.org ; 2 patient safety exams per year
- 117 labs participated in 1st exam (Jan 2004), and expect growth each year.

MTS Patient Safety



QUESTION 5

Investigation of an adverse event revealed that a nurse submitted a specimen in which the tube label and requisition label did not match. The lab failed to detect the nursing error and analyzed the specimen. To what group should an intervention be directed?

- Nursing staff only
- Laboratory staff only
- Both nursing and laboratory staff

The correct answer is shown in green.

Explanation

There are two errors in the case. The nursing error, which is the driving force behind the case, is a labeling error. The laboratory error was failure to detect the labeling error. Both errors are preventable and should be addressed.

A sample question from a patient safety exam

Estimates of National Competency:

Ave scores on 9 online exams from Semester 1, 2004.

Topic	# Users	# Labs	<u>Score</u>	SD
Safety	3101	142	94	8
Spec Proc	2499	138	89	10
Phlebotomy	2312	135	90	9
Patient Safety	2099	117	84	14
Urinalysis	1906	139	93	11
Hematology	1765	139	89	13
Spec Transport	1367	107	84	14
Coagulation	1361	122	85	15

Patient Safety Training

**Patient Safety
Competency Assessment**

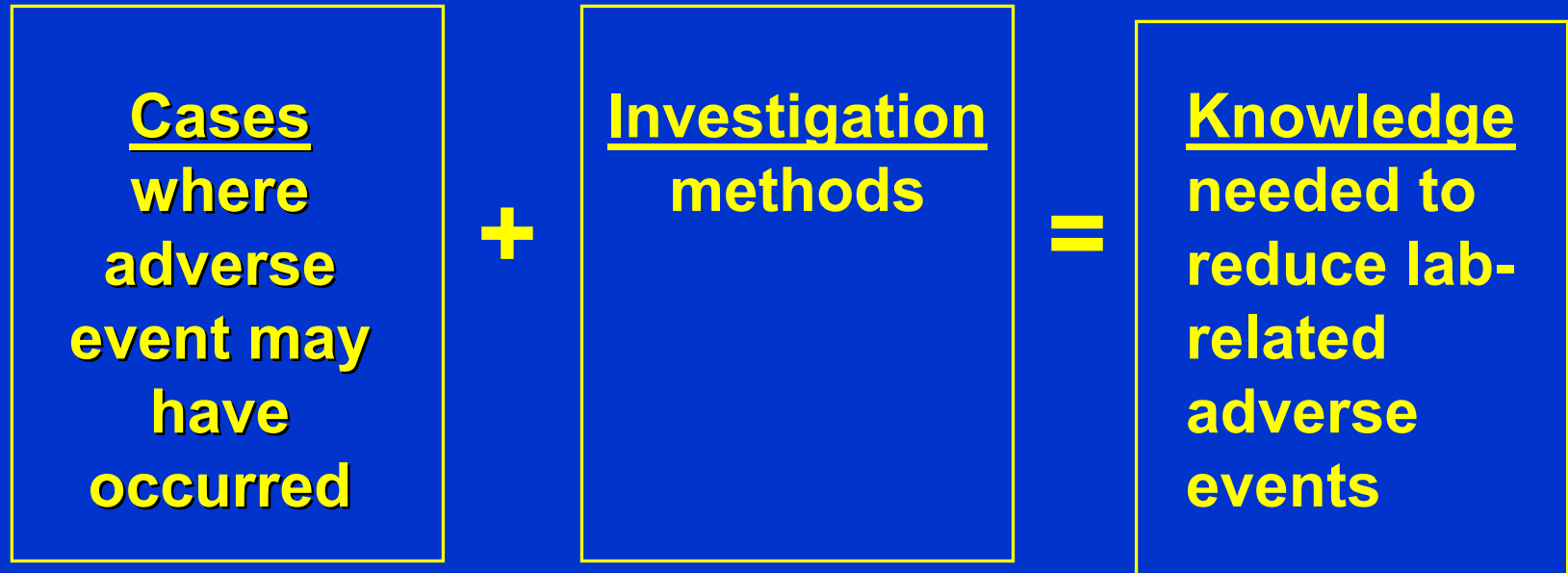


**Patient Safety
QI projects**

Feedback to staff

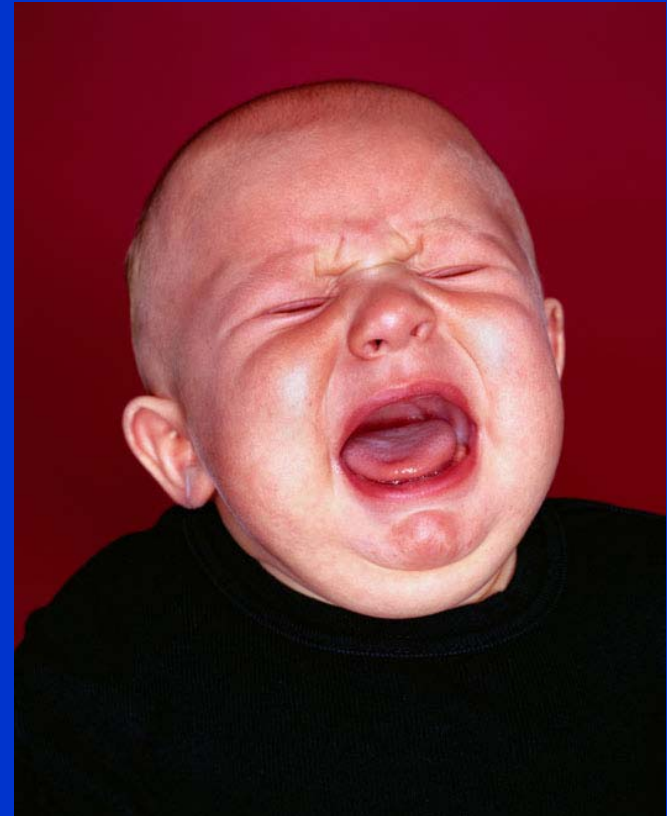


QI projects in patient safety



Cases + Investigation = Knowledge

- Sources of cases:
 - Complaints, collaboration
 - Incident reports
 - Usually not timely
 - Management reports
 - Corrected reports
 - TAT reports
- No single source is sufficient to find all cases, but any source can be useful for a QI project.



Cases + Investigation = Knowledge

Each case is classified for...

1. Patient outcomes
2. Responsibility for problem
3. Testing phase (general and specific)
4. Preventability and error type

Possible patient outcomes (check all that apply)

- Outpatient requires admission or ER visit
- Inpatient stay prolonged / incr level of care
- Rx delay or not received
- Unnecessary Rx
- Unnecessary invasive test
- Morbidity – transient
- Morbidity > 1 week
- Death

Multi-institutional “Stat” chemistry project

- Jan 2003 – Feb 2004
 - Source of Cases = incident reports
-

N ~ 580 incident reports



Screen 1: Were tests stat?

N₁ = 277 involving stat tests



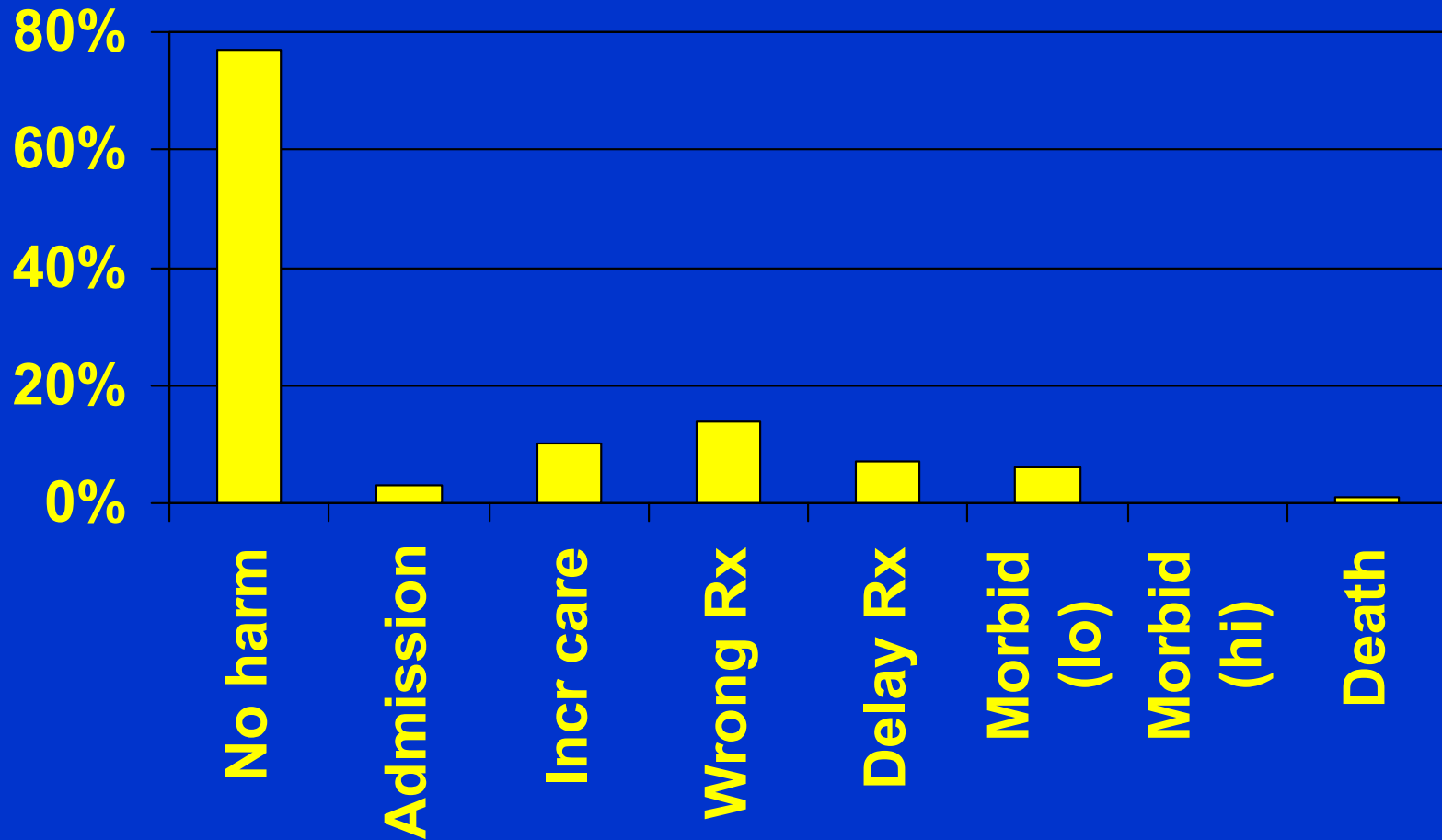
Screen 2: Medical record review

**N₂ = 70 Adverse event cannot be ruled out.
Case investigated.**

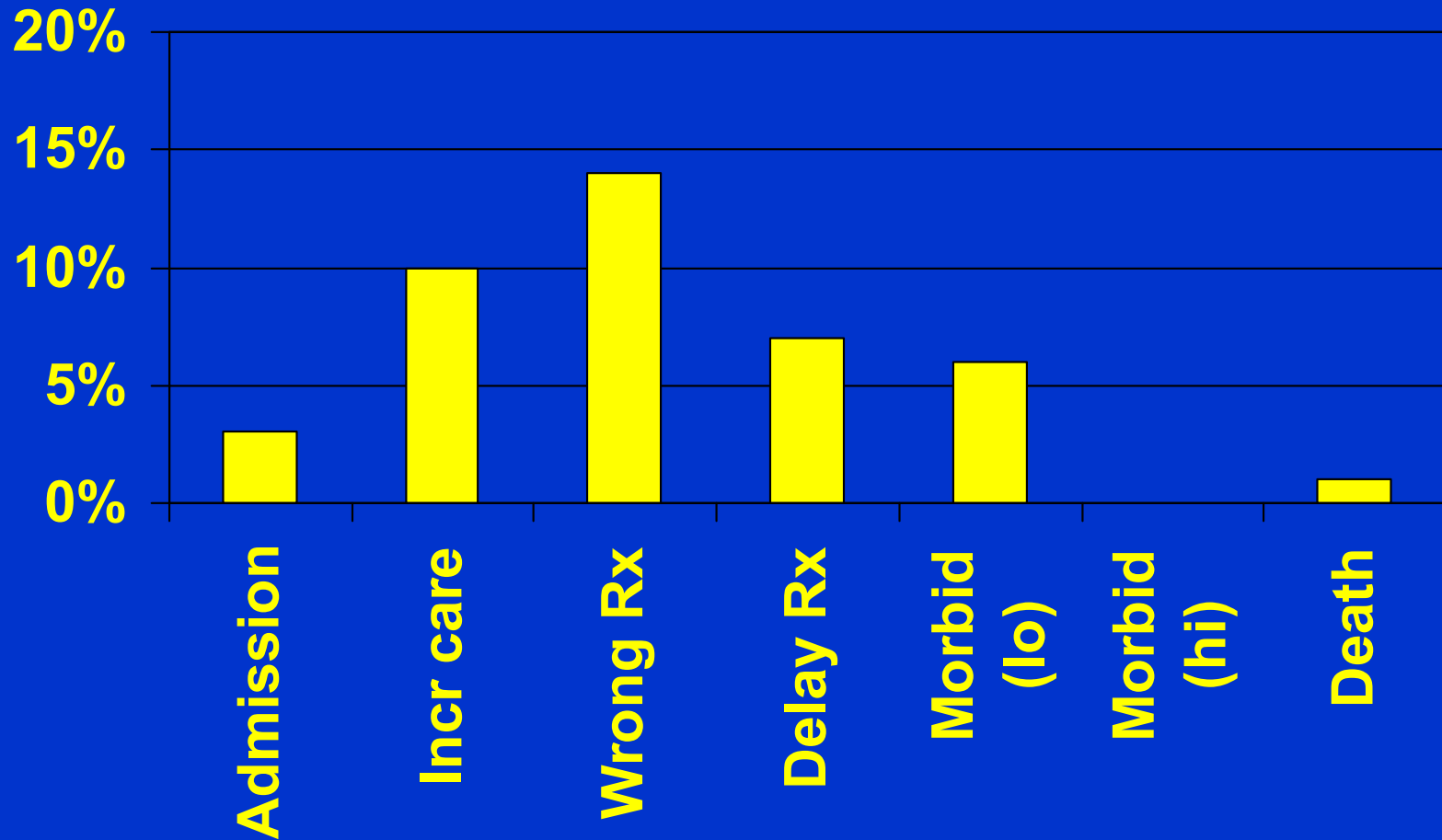
Multi-institutional Stat chemistry project: Of 70 cases that were investigated...

- **77% had no patient impact**
- **23% (16 cases) had undesirable patient impact**
 - **6% of “stat test” incident reports**
- **Adverse events rarely mentioned in medical record.**

Patient Outcomes associated with 70 incident reports that screened positive for full investigation. Each report was scored for 1 or more categories.



Patient Outcomes associated with 70 cases that were investigated



Sample cases from chemistry project

- **Miscommunication of test result leads to improper radiology tests and medications**
 - Increased care, wrong Rx, morbidity (low)
- **Line contamination in ICU and poor communication in lab lead to unnecessary medication**
- **Analytic interference leads to false positive Dx of MI, unnecessary admission to hospital.**
- **Math error leads to falsely low test result and Rx delay**

Multi-institutional microbiology project

- July 03 – Feb 04 (~ 76,000 specimens)
 - Source of Cases = corrected reports
-

N = 458 Corrected reports (0.6 % of specimens)



Screen 1: M.D. expert review

N₁ = 172 potentially clinically significant



Screen 2: Medical record review

N₂ = 148 Adverse event not ruled out.
Case investigated.

Multi-institutional microbiology project: Of the 148 cases that were investigated...

- **81% no patient impact**
- **19 % undesirable patient impact**
 - **6% of all corrected reports**
- **Adverse events rarely documented in medical records.**

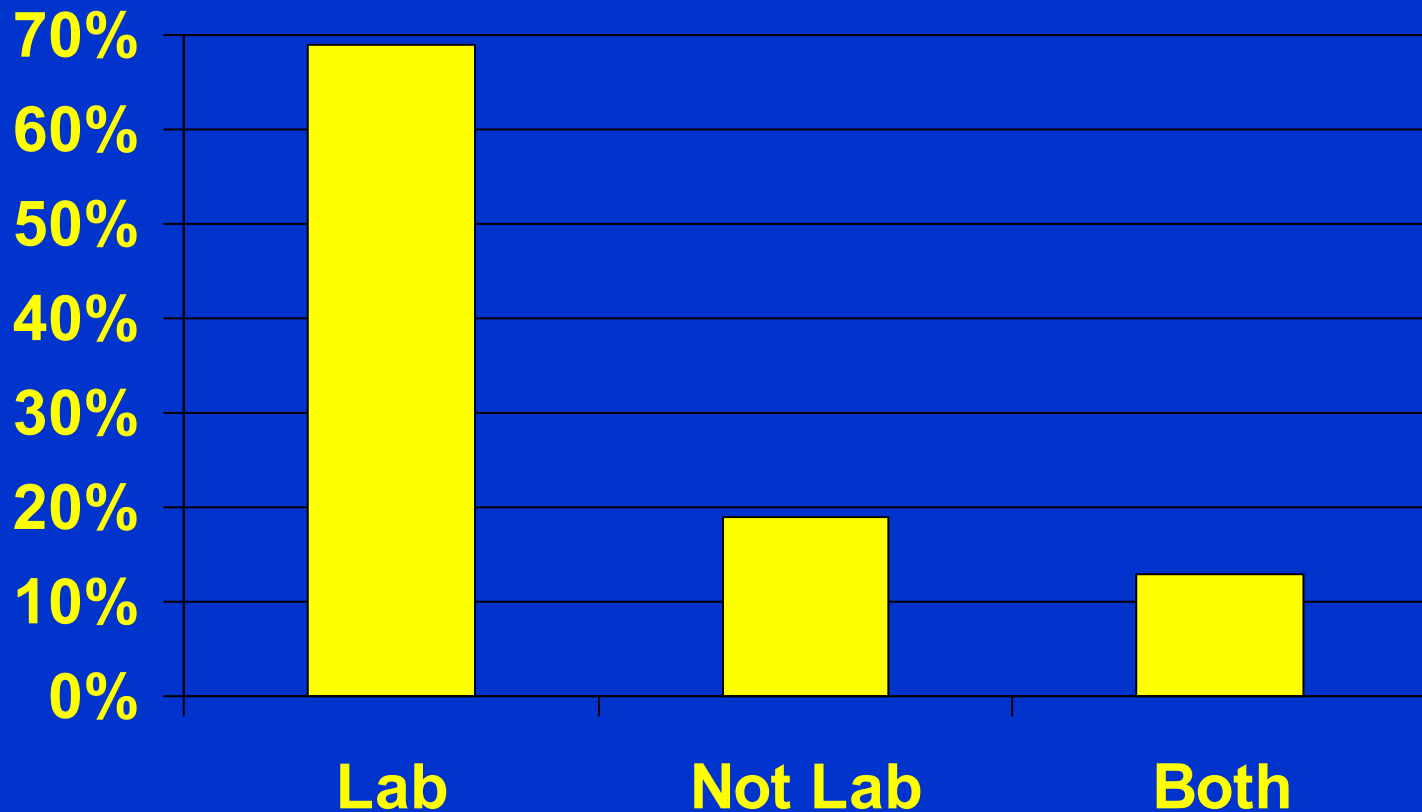
Multi-institutional microbiology project: Outcomes of the 28 cases with undesirable patient impacts

<u>Outcome</u>	<u>#</u>	<u>Comments</u>
Delayed Rx	17	0.5- 4 days; Ave =1.6 days
Unnecessary Rx	7	1- 5 days; Ave = 2.6 days
Inappropriate Rx	5	1- 6 days; Ave = 3.3 days
Inc. Level of Care	3	ID consult, surgery
Transient Morbidity	??	Hard to estimate (Fever, dyspnea, sepsis)
Invasive Procedure	1	Surgery

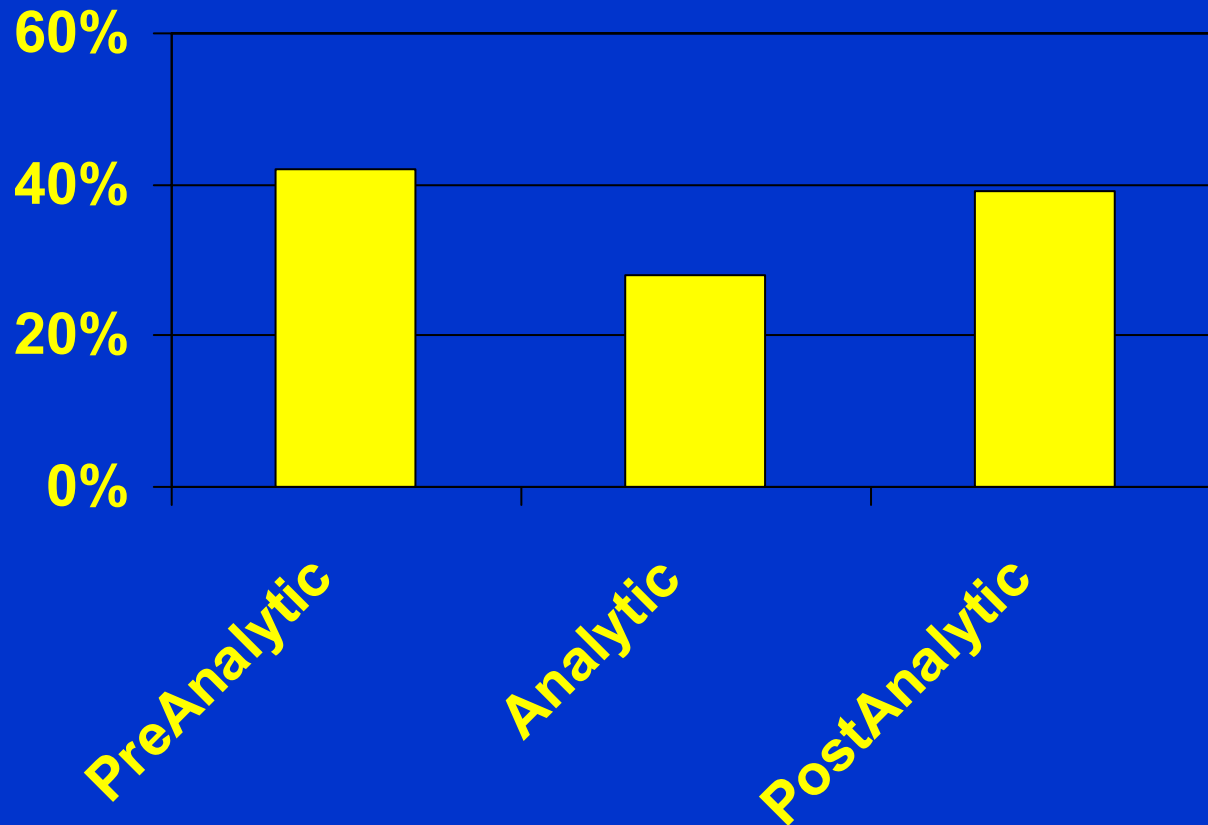
Methods used to investigate cases: Each case is classified regarding...

1. Patient outcomes
2. Responsibility for problem
3. Testing phase
4. Preventability and error type

Responsibility for the problems in 70 “stat-chemistry” incident reports that were investigated



“Stat chemistry” project: Phase of testing involved in the 70 “stat chemistry” cases that were investigated



Preanalytic errors in the the lab testing process

- **Requisition incorrect**
- Specimen unlabeled or mislabeled
 - Not unusual to see a rate of ~ 0.2%)
- **Failure to collect a specimen**
- Specimen suboptimal or ruined
 - Not unusual to see hospital rate of ~ 0.4%
- **Specimen lost or delayed in hospital unit, in transport, or in lab**
- **Failure to order test in lab information system**
- **Data entry error during accessioning**
- **Specimen processing error**
- **Other**

Methods used to investigate cases: Each case is classified regarding...

1. Patient outcomes
2. Responsibility for problem
3. Testing phase
4. **Preventability and error type:**
 - **only preventable errors have interventions**
 - **error type determines interventions**

A preventable problem is an error that is reasonably avoidable. Preventability is scored as:

Not preventable

Preventable

- **More than 85% of errors in QI projects to date have been preventable**

Preventable problems can be further analyzed as to error type:

- ❑ Cognitive errors are due to lack of knowledge or poor judgment
 - confusing yeasts for host cells on Gram stain; mistakes in interpreting flags

- ❑ Noncognitive errors are due to interruptions in a relatively automatic task
 - mislabels, data entry errors, math errors

Error types determine interventions

Cognitive errors are reduced by increasing supervision or training.



A supervisor (left) helps a technologist (right) with a problem specimen

Error types determine interventions: To reduce noncognitive errors use...

- **Checklists**
- **Automation (e.g. instrument interfaces, delta checking)**
- **Other strategies for avoiding interruptions and lapses in concentration**
 - **remove phones**
 - **simplify procedures**

Preventable errors in the laboratory: Comparison between 3 QI projects

	Micro: Corrected reports	Chem: Stat Incident Reports	Ambulatory Lab: Incident Reports
Cognitive only	82%	5%	16%
Noncog only	18%	70%	71%
Both	0%	12%	13%
Unable	0%	13%	0%

QI projects: Interventions to date

- **Cognitive:**
 - CNE regarding decreasing line-contamination
 - Supervisor review of unusual test results
 - Calling of critical values before test is repeated (in response to delta check failure)
- **Noncognitive**
 - Double check manually- entered chem results
 - Alter requisition to decrease “missed” tests
 - Change in preanalytic handling of specimens collected in OR setting

Patient Safety Training

**Patient Safety
Competency Assessment**



**Patient Safety
QI projects**

Feedback to staff



Acknowledgements

- All 75 staff and faculty who have contributed to the web site
- James Fine, MD
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- Ajit Limaye, MD
- Pete Rainey, MD, PhD
- UWLM Residents
- UWLM Clinical Laboratory Directors
- UWLM staff

Conclusions

- **Lab testing problems cause adverse events.**
- **A patient safety culture will reduce adverse events.**
- **Create this culture through:**
 - **Training, competency assessment**
 - **QI projects with patient outcomes**
 - **Feedback to staff, faculty**