



EXPERIENCES FROM THE LABORATORY

Introduction

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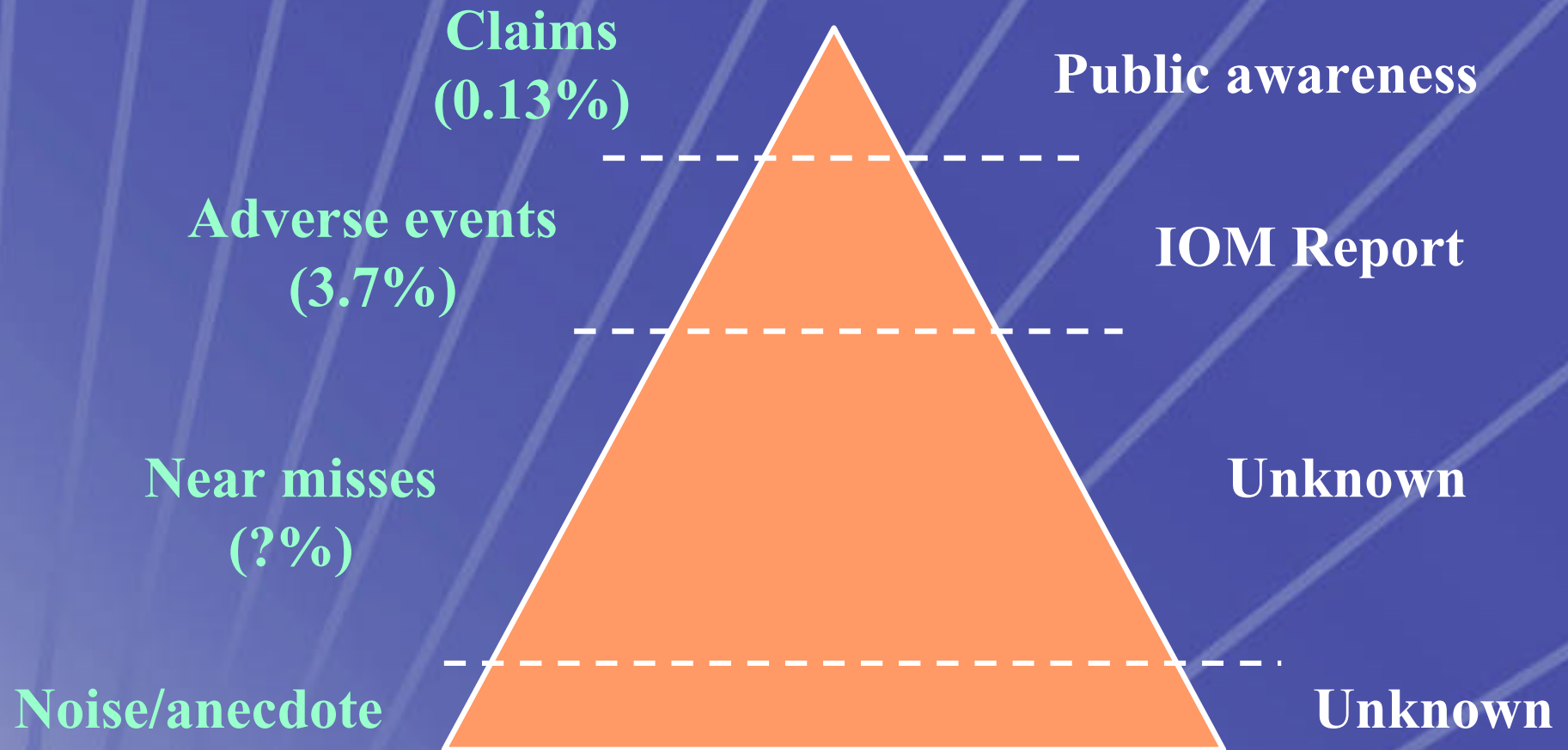
The Laboratory Is a Key Partner in Patient Safety

Objectives:

- Highlight US patient safety initiatives
- Present some perspectives on laboratory testing mistakes and their impact on patient care
- Describe initiatives that were undertaken by the laboratory community in order to improve the quality of laboratory services and enhance patient safety



Medical Errors

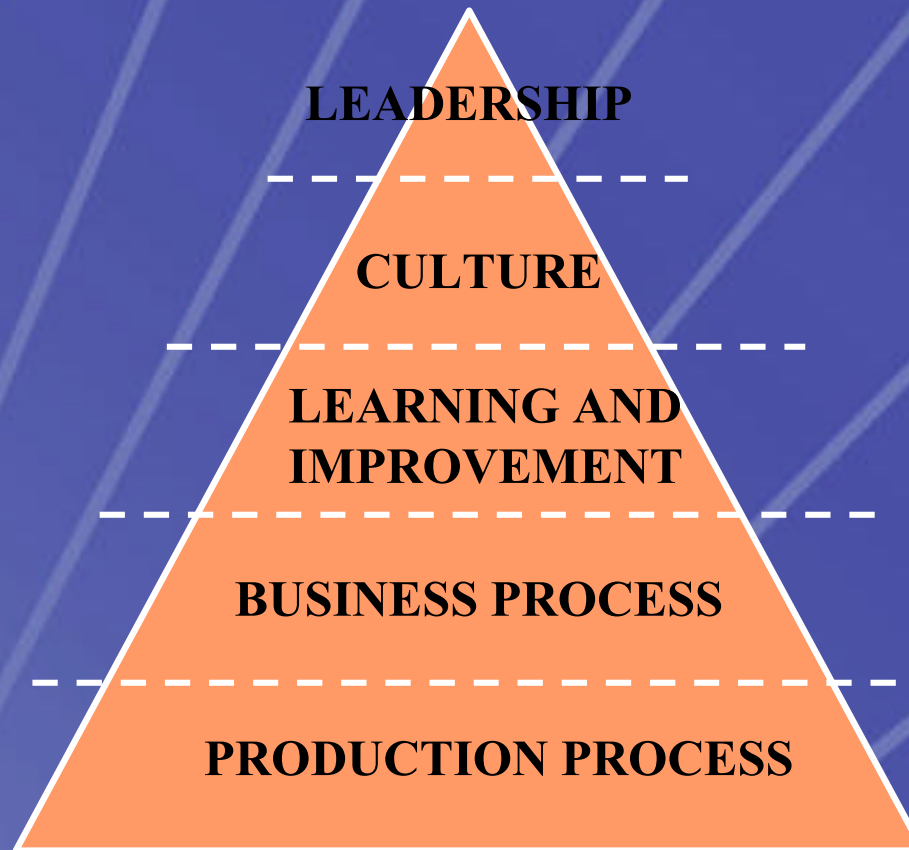


A Few Responses to IOM Reports

- National Health Care Quality Report -2003
 - ◆ Measures to follow Healthy People 2010 Framework
- Medical Specialties
 - ◆ Pharmacy – Links between Pharmacy, Laboratory, and Care Providers
- Professional Organizations
 - ◆ NCCLS – Closing the Gap: Error Proofing the System 2002
- Laboratories
 - ◆ Quest - Become a Six Sigma Company by 2004
- Congress
 - ◆ H.R. 4889 - Patient Safety Improvement Act of 2002



How To Improve Patient Safety

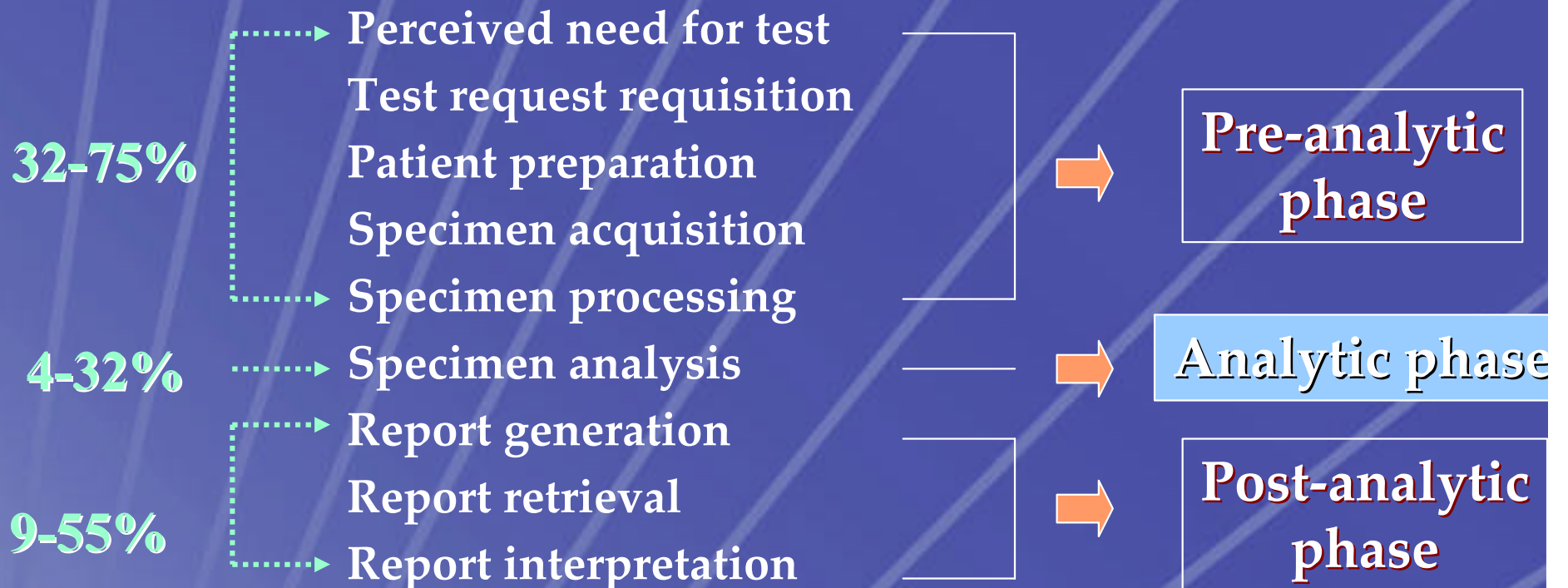


Laboratory Testing Errors

- Understand where laboratory testing errors occur
- Evaluate the impact of laboratory testing errors on patient care
- Describe common study findings and their limitations
- Laboratory initiatives that improve patient care
- Experiences from other industries that can be applied to the laboratory in order to further improve patient safety



The Total Testing Process: Laboratory Testing Errors



Howanitz and Howanitz, Clin. Lab. Med, 3:541-551, 1983
Bonini et al. Clinical Chemistry 48:5, 691-698, 2002



Laboratory Testing Errors: Examples (1)

1987 – Private hospital reviewed 336 medical records of patients involved in 304 incidents where hospital QA practices were violated (*Ross JW and Boone DJ. 1989 Institute on Critical Issues in Health Laboratory Practice. DuPont Press p 173, 1989*)

- ◆ 70% not affected
- ◆ 24% not harmed, but subjected to unnecessary procedure
- ◆ 6% not harmed, but placed at increased risk of harm
- ◆ Pre-analytical 46%; Analytical 7%, Post-Analytical 47%
- ◆ Non-laboratory personnel involved in 29% of incidents
- ◆ 37.5/100,000 patients placed at risk because of mistakes in testing process



Laboratory Testing Errors: Examples (2)

1991 – 5470 participants were surveyed in CAP Blood Bank PT Program about monitoring of 24 steps in the transfusion process (*Boone DJ et al., Transfusion medicine monitoring practices. Arch Pathol Lab Med, 119:999-1006, 1995*)

- ◆ 25% response rate (>30% nation's blood supply)
- ◆ 7% of institutions monitored all 24 steps
- ◆ 8% of institutions did not monitor any of the steps
- ◆ Defects found: pre-analytical 41%; analytical 4%, Post-Analytical 55%
- ◆ Monitoring could not be linked to prevention of complications
- ◆ 1% of defects in ABO or Rh testing



Laboratory Testing Errors: Examples (3)

1993 – Survey of 124 primary care clinicians in 49 practices, who reported all laboratory testing problems detected during a 6 month period (*Nutting PA et al. Problems in laboratory testing in primary care. JAMA; 275:635-639, 1996*)

- ◆ 180 problems reported (110 per 100,000 patient visits)
- ◆ Problems found: pre-analytical 56%; analytical 13% , post-analytical 39%
- ◆ 27% of problems had an impact on patient care
- ◆ 34 per 100,000 patient visits incur mistakes that impact care



Laboratory Testing Problems In Primary Care

| TEST | TYPE OF PROBLEM | SITE | OUTCOME |
|-----------------|-----------------|---------------------|----------------------|
| HIV | FN error | Referral Laboratory | Delayed Diagnosis |
| Urine Pregnancy | FP error | Referral Laboratory | Ultrasound Performed |
| Potassium | Delayed Report | Referral Laboratory | Hospitalize Patient |
| Urine Culture | FN error | Office Laboratory | Treatment Delayed |

Nutting PA et al. Problems in laboratory testing in primary care. JAMA 1996; 275:635-639.



Accuracy of Laboratory Tests Based On Q-Probe Studies

- Ordering the right test – 53%
- Transmission of orders – 97.1%
- Patient preparation – 79% digoxin testing after dosing
- Patient ID – 97.3% wristbands
- Procurement of specimen – 93% collected
- Specimen acceptable – 99.6%
- Results charted – 96.6%
- Physician response to elevated Ca^{++} – 53% no response

Accurate testing for 163/1000 patients



Dr. Peter Howanitz, 1994

JCAHO: Sentinel Events Studies

1. Inpatient Suicides – 17.1%
2. Operative/post operative complications – 12.2%
3. Medication error – 11.5%
4. Delay in treatment – 5.3%
5. Transfusion error – 2.6% (ABO incompatibility)

n = 1000 events

Event = Unexpected death, injury, or risk

Joanne Born, 2002



JCAHO: Root Causes of Sentinel Events

1. Communication – 63%
2. Orientation/Training – 58%
3. Lack of Information – 20%
4. Staffing Levels – 18%
5. Competency – 12%
6. Compliance with procedures – 12%

Note: 75% of transfusion events were linked to orientation/training and 25% to staffing

Joanne Born, 2002



Perspective: Risk of Viral Infection Per Unit of Blood Products (1980-2003)

| | 1980s | 1990s | 2000s |
|-------------|--------|-----------|-------------|
| HBV: | 1:2100 | 1:63,000 | 1:220,000 |
| HCV: | 1:200 | 1:103,000 | 1:600,000 |
| HIV: | 1:100 | 1:493,000 | 1:1,800,000 |

Compare with:

| | |
|---|-------------|
| Risk of acute hemolytic reaction | 1:25,000 |
| Risk of dying while in hospital from something else than trans.Tx | 1:6,000 |
| Risk of dying in a plane crash | 1:7,000,000 |



Errors in Laboratory Medicine: Limitation of Studies

- Focus mostly on analytical errors
- Inappropriate test ordering and interpretation is difficult to capture
- Errors are often difficult to detect
 - ◆ Goldschmidt and Lent found that 75% of test errors still fall within the reference interval
 - ◆ 12.5% absurd and 12.5% effect on patient health
- New tests may not have a gold standard
- Complaints vs. testing process review

Bonini et al. Clinical Chemistry 48:5, 691-698, 2002



Errors in Laboratory Medicine: Common Elements of Studies

- No common nomenclature – blunder, mistake, problem, defect, error
- Similar distribution of errors in total testing process
- Method of data collection influences results:
 # Complaints < # Testing Process Review
- No definition of allowable error rate

Bonini et al. Clinical Chemistry 2002; 48:5, 691-698



Errors In Laboratory Medicine: Needs For The Future

- Definitions - errors and their causes
- Defined relationships between error and actual or potential patient outcome
- Standardization of methods – risks stated in common terminology
- Adopt techniques of other industries – focused error prevention/reduction
- Measures for critical errors - rare
- Cultural change – human and system risks

Bonini et al. Clinical Chemistry 2002; 48:5, 691-698



Errors In Laboratory Medicine: More Studies Are Needed!

Barriers:

- ◆ Public awareness – legal issues
- ◆ IRB issues
- ◆ Funding
- ◆ Lack of shared information



Lessons Learned From the Laboratory

- Expertise on the accuracy of diagnostic testing
- QA/QC, proficiency testing
- Standard setting organizations
- Accreditation programs
- Licensing, certification and training programs
- Regulatory oversight: CLIA'88
- Voluntary reporting of adverse events: transfusion medicine (MERS-TM)



Lessons For The Laboratory

- Lessons from other industries:
 - ◆ Aviation industry
 - ◆ Car manufacturing industry
- Lessons from a medical specialty:
 - ◆ Anesthesia Patient Safety Foundation
- Lessons from a large healthcare organization:
 - ◆ Creating a culture of safety in the VA





Flowchart of Problem Resolution

CDC Sponsored Institutes On Critical Issues In Clinical Laboratory Practice

- **1984** – “The Impact of Alternative Reimbursement Methods on Laboratory Practice” - **where, what, how, whom, how well**
- **1986** – “Managing the Quality of Laboratory Test Results in a Changing Health Care Environment” - **quality in total testing process**
- **1989** – “Improving the Quality of Health Management Through Clinician and Laboratorian Teamwork” - **partnership**
- **1995** – “Frontiers in Laboratory Practice Research” - **beyond CLIA**
- **2003** – Quality Institute – **Making the Laboratory a Key Partner in Patient Safety**



Why a QI Conference?

- Healthcare system changes affect clinical laboratory services:
 - ◆ Access,
 - ◆ Cost,
 - ◆ Quality, and
 - ◆ Patient safety
- Significant role of clinical laboratory services in the healthcare system
- Improvement in clinical laboratory service depends on better collaboration and coordination within the healthcare system





QI Conference: Experiences Section

- Present examples of organizational activities within the clinical laboratory setting that have enhanced patient safety:
 - ◆ Primary care
 - ◆ Independent laboratories
 - ◆ University hospital laboratories
 - ◆ Professional/accrediting organizations



Laboratory Safety and Quality in Primary Care: Evidence and Evolution

Robert Phillips MD MSPH

The Robert Graham Center:
Policy Studies in Family Practice and Primary
Care





The Power of Six Sigma Quality

Kenneth Freeman
Chairman and CEO
Quest Diagnostics, INC



SAFER • HEALTHIER • PEOPLE™

CAP Q-Probes and Q-Tracks: 15 Years of Laboratory Quality Indicator Development



Richard J. Zarbo, MD, DMD



SAFER • HEALTHIER • PEOPLE™

**Reducing Medical Errors by Providing
Expert Advice in the Selection and
Interpretation of Laboratory Tests**

Michael Laposata, M.D., Ph.D.

**Director of Clinical Laboratories
Massachusetts General Hospital
Professor, Harvard Medical School**

