



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Beyond the

Quality  
Institute  
Conference  
2003

*Making the Laboratory a  
Key Partner in Patient Safety*

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# Is it Safe to have a Laboratory Test?

7 billion tests/year  
70% of medical decision-making

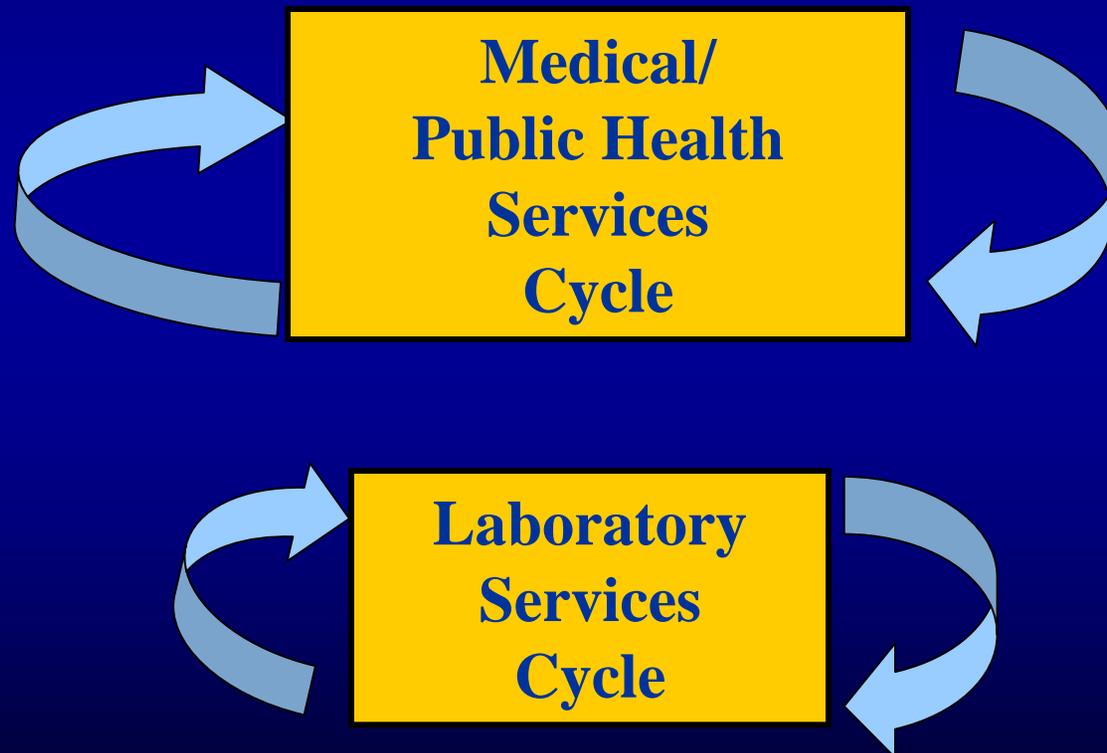


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# CDC Sponsored Institutes “Critical Issues In Health Laboratory Practice”

- 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 Conference – Making the Laboratory a Key Partner in Patient Safety”

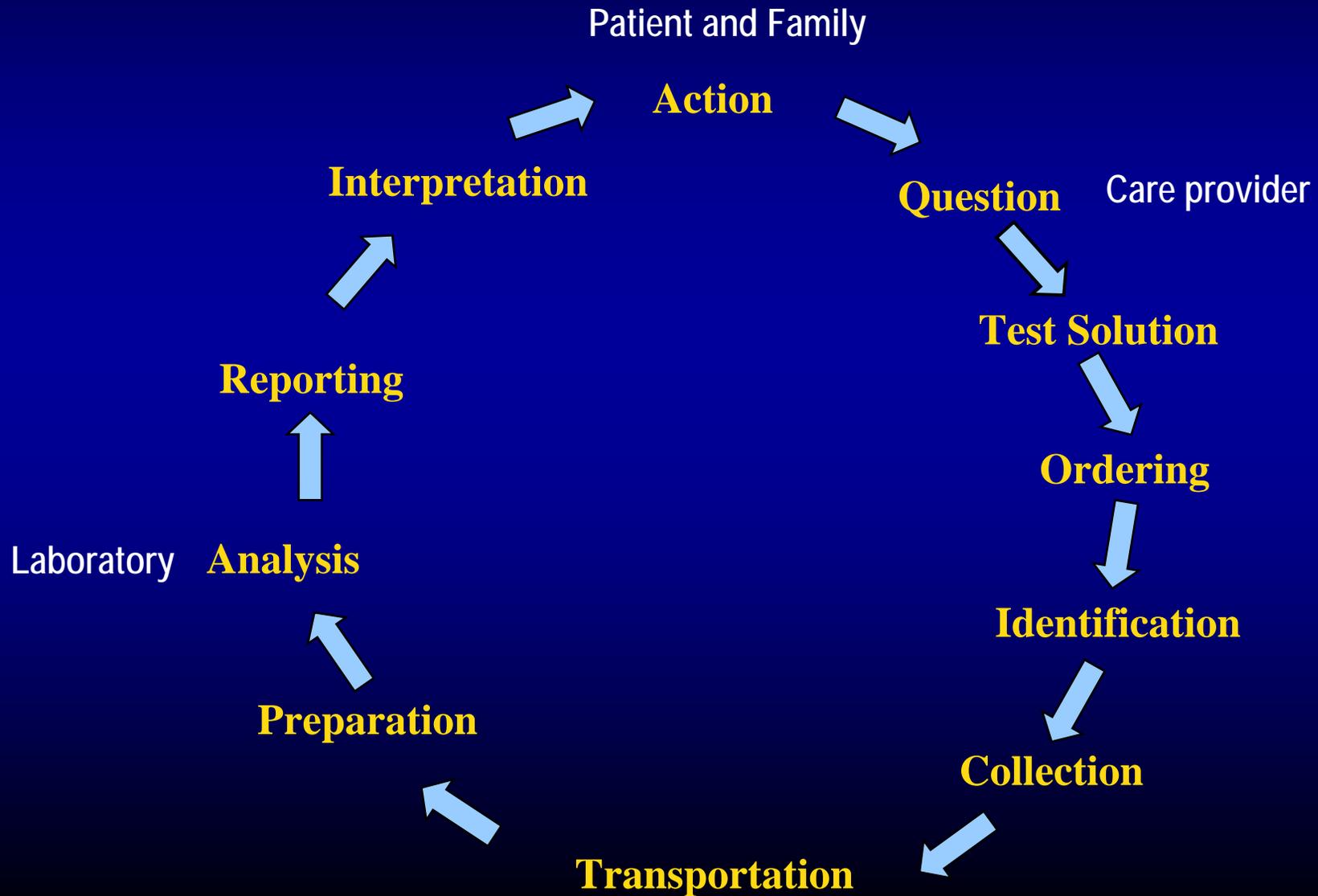
# Current Testing Process



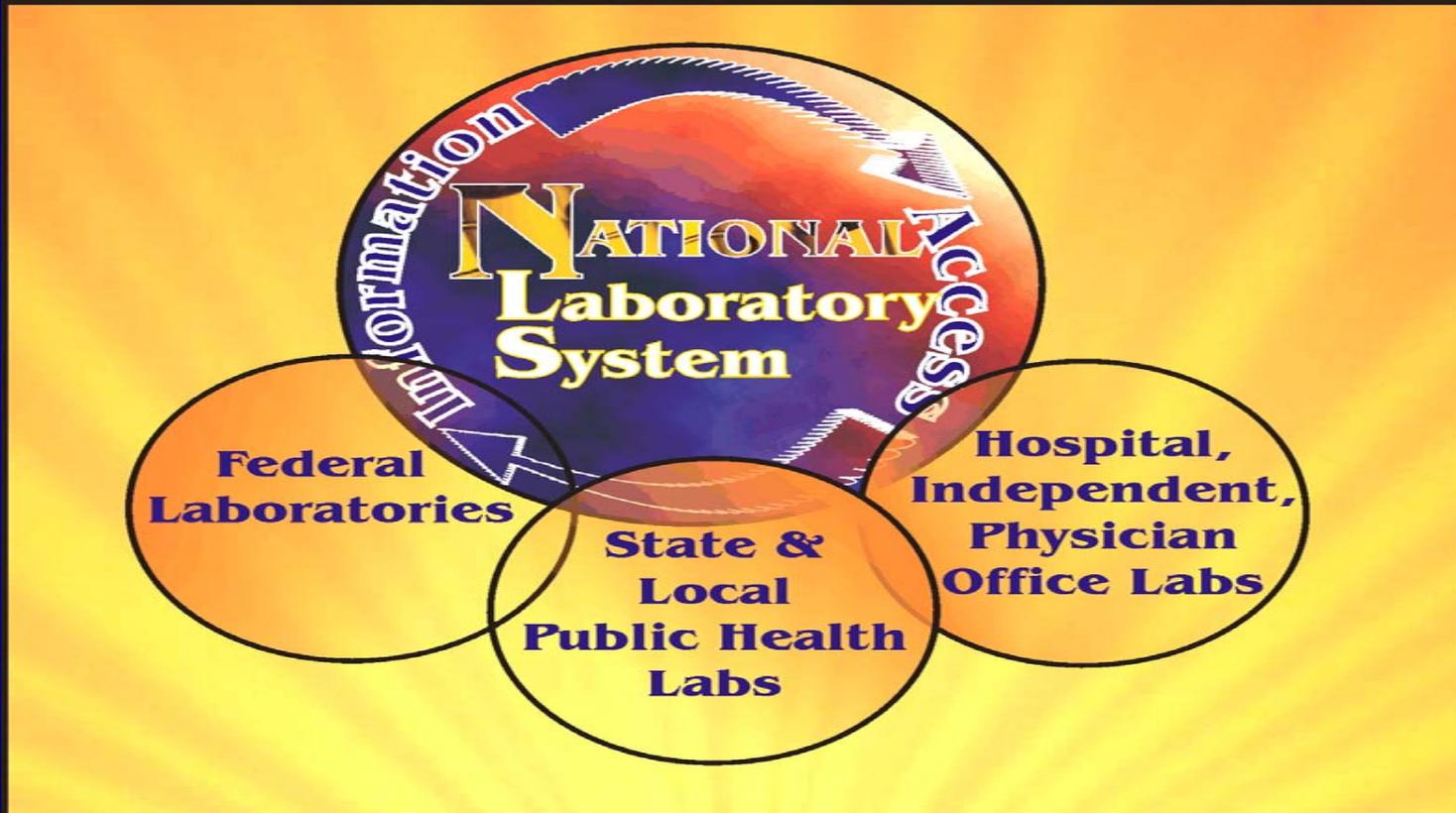
# Ideal Testing Process



# Total Testing Process



# National Laboratory System



The US needs a national laboratory system  
J. Hughes, J. McDade 1999, US Medicine

# Reasons for the Disconnect

- Communications
- Poor Integration of Services
- Lack of Accountability/Responsibility at Interfaces
- Reimbursement Dances
- Fragmented IT
- Lack of Performance Measures

# Institute of Medicine Reports

## To Err is Human – 2000

- Medical errors 8<sup>th</sup> leading cause of death
- Cost - \$17 billion to economy from preventable errors
- Health care is highly variable

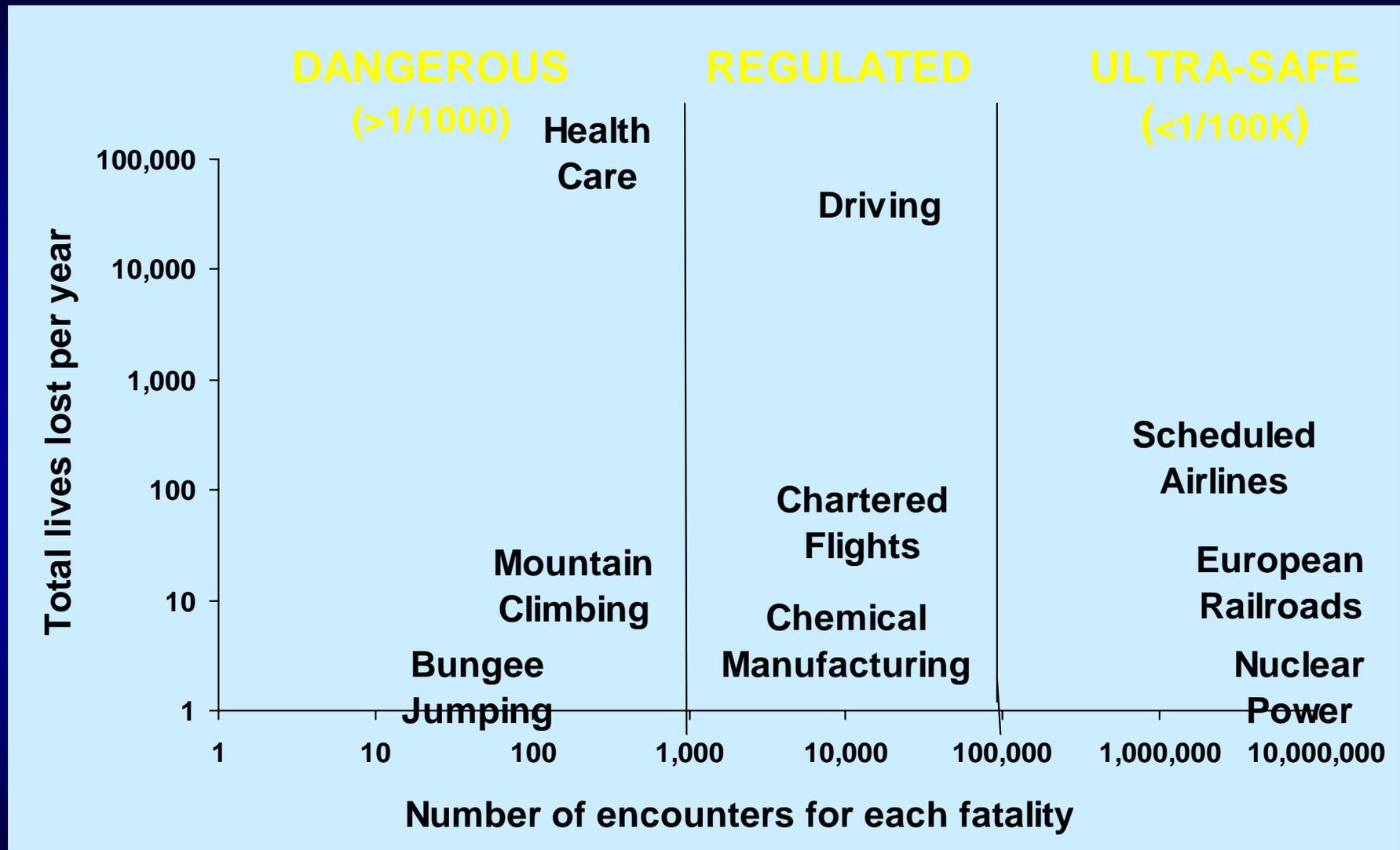
## Crossing the Quality Chasm – 2001

- Safe, Effective, Patient-centered, Timely, Efficient

## Envisioning the National Health Care Quality Report – 2001

**50/50 chance of proper health care. Elizabeth A. McGlynn, Ph.D., et al. The Quality of Health Care Delivered to Adults in the United States. NEJM, June 26, 2003**

# How Hazardous Is Health Care?



From Lucian Leape – QI Conference Keynote

# Laboratory Testing Errors Impact Patient Safety

- About 12.5% of laboratory errors have some effect on patient health (*Bonini et al. Clinical Chemistry 48:5, 691-698, 2002*)
- 37.5/100,000 patients placed at risk because of mistakes in testing process in a private hospital ( *Ross JW and Boone DJ. 1989 Institute on Critical Issues in Health Laboratory Practice. DuPont Press p 173, 1989*).
- 34 per 100,000 patient visits to primary care physicians incur mistakes that impact care (*Nutting PA et al. Problems in laboratory testing in primary care. JAMA; 275:635-639, 1996*).

# Six Sigma Quality Defined

Sigma	% Accuracy	DPMO	Cost of Poor Quality
6	99.9997%	3.4	< 1% of Revenue
5	99.98%	233	5 – 15% of Revenue
4	99.4%	6,210	15 – 25% of Revenue
3	93.3%	66,807	25 – 40% of Revenue
2	69.1%	308,537	Not Competitive

**“Good” Enterprises** {

Source: *Six Sigma* by Mikel Harry, Ph.D. and Richard Schroeder, [www.6-sigma.com](http://www.6-sigma.com)

# How Errors are Detected Greatly Impacts the Frequency

## Frequency of transfusion errors:

### Active

1: 24 transfusions - systematic analysis at the bedside

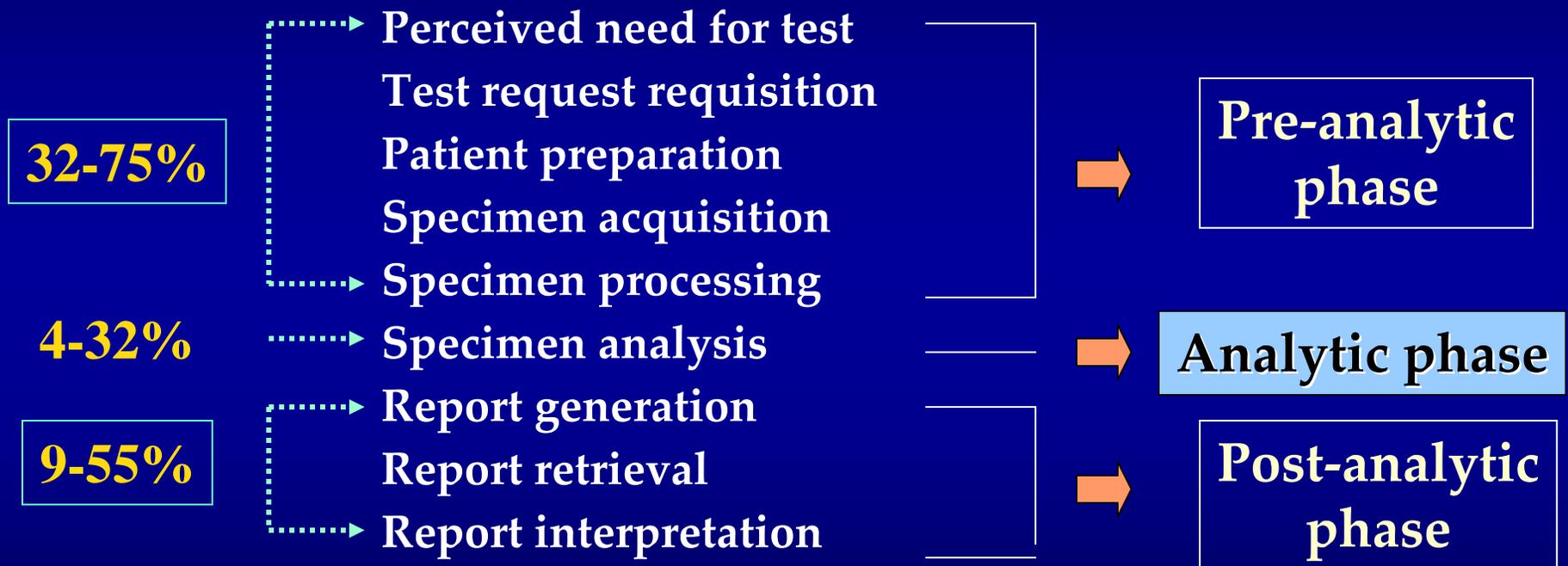
*(Beale et al, Vox Sang 66:117-21, 1994)*

### Passive

1:6,000 -29,000 – complaints or fortuitous detection

*(McClelland and Phillips, 1994; Shulman et al., 1994;  
Williamson et al.,1999)*

# Most Laboratory Testing Errors Occur Outside the Analytic Phase



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

# QI Conference: Goals

- Develop the framework for a National Report on the Quality of Laboratory Services
- Develop criteria for quality indicators of laboratory services
- Develop a process for ongoing collection and analysis of data related to the quality of the US laboratory services – Quality Institute

Identify Issues and Best Practices



National Report

Quality Institute

Continuously Reported in



Quality Indicators

Develops indicators and monitors progress



# Our Partners

- Agency for Healthcare Research and Quality
- American Academy of Family Physicians
- American Association for Clinical Chemistry
- American Association for Respiratory Care
- American Association of Bioanalysts
- American Association of Blood Banks
- American Association of Health Plans
- American Association of Physician Office Laboratories
- American Clinical Laboratory Association
- American College of Medical Quality
- American College of Physicians
- American Society of Internal Medicine
- American Medical Association
- American Medical Technologists
- American Osteopathic Association
- American Society for Clinical Laboratory Science
- American Society for Clinical Pathology
- American Society for Healthcare Risk Management
- American Society for Histocompatibility and Immunogenetics
- American Society for Microbiology
- American Society for Quality
- American Society of Hematology
- Association of Public Health Laboratories
- Beckman Coulter
- Becton Dickinson and Company
- Blue Cross and Blue Shield Association
- Center for Medicare and Medicaid Services
- Clinical Laboratory Management Association
- College of American Pathologists
- Commission on Office Laboratory Accreditation
- Federation of American Hospitals
- Food and Drug Administration
- Joint Commission on Accreditation of Healthcare Organizations
- March of Dimes
- National Academy of Clinical Biochemistry
- National Committee for Quality Assurance
- National Quality Forum
- NCCLS
- Quest Diagnostics Incorporated
- Society of General Internal Medicine

# National Report: Issues

- Users:

Laboratorians, Care providers, Public, Government agencies, Insurers & payers, Policy makers, Accreditors & standard setting organizations, Administrators

- Content

Sources of error in the testing cycle

Workforce

Tests for specific conditions

Point of care testing

Communication of information

# National Report

## Benefits

- ID ways to improve the quality and safety of laboratory services
- Increased appreciation of laboratory services/ scientists
- Better cooperation between care providers and laboratorians

## Challenges

- Cost of participating
- Legal/regulatory implications of report
- Reluctance to report adverse outcomes

# Quality Indicators (QIs)

- Indicators for the quality of health care:  
Access, Timeliness, Appropriateness
- Preference for national vs state reporting
- Useful for different stakeholders
- Who should have access to original data
- Most favor open access to analyzed data
- Voluntary vs Mandatory reporting

# Quality Institute

- Characteristics - ongoing, independent, not-for profit, with a broad mission
- Need - exists; laboratory community has not been involved so far in the patient safety initiative
- Organization - several possibilities:
  - Federally established
  - Within other organizations
  - Coalition with other institutions
  - Stand alone

# Quality Institute

## ■ Stakeholder participation

- Board of Directors should consist of various stakeholders

## ■ Mission

- Surveillance of laboratory services
- Resource
- Education – public, payers, administrators
- Data clearinghouse

## ■ Relationship to other organizations

- Should not duplicate efforts of other organizations

# Quality Institute Conference - Conclusions

- Support for development of:
  - Quality Indicators
  - National Report on Quality of Laboratory Services
  - Quality Institute
- Critical need to develop policies, programs, and activities to:
  - Reduce errors in use of laboratory services
  - Assure patient safety
  - Improve quality of laboratory services

# Quality Institute Conclusions

- Large opportunity for improvement, particularly pre-analytic and post-analytic areas
- Need for Quality Indicators for Total Testing Process
- Need to enhance communications between users and providers of laboratory services

# Quality Institute Conference -Conclusions

- Need for surveillance of the quality of laboratory services
- Need to build new coalitions to focus on interface between the laboratory and clinical practice
- Need to disseminate best practices



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# Partners In Patient Safety

*Laboratory Professionals  
Accrediting Organizations  
Administrators  
Diagnostic industry*

*Clinicians  
Patients  
Policy makers  
Payers*



<http://www.phppo.cdc.gov/mlp/qiconference/>



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# Next Steps: within CDC

- Communicate
  - Presentations within CDC
  - Publication of Proceedings
- Continue link with partners
- Encourage other partners to join
- Assemble and disseminate information
  - Existing quality indicators
  - Successful patient safety initiatives

# Next Steps: QI Follow-up

- Steering committee develops project teams to:
  1. Create an awards program to recognize innovative practices
  2. Develop a core set of Quality Indicators
  3. Develop a QI Network of Sentinel Laboratories

# Next Steps: QI Follow-up

- Continue plans to:
  - Build coalition on National Report
  - Build coalition on Quality Institute
  - Plan second QI
    - Date – October 14-16, 2004
    - Location – Atlanta
- Under consideration
  - QI = Institute of Laboratory Medicine
  - Begin formation of ILM - BOD?



Flowchart of Problem Resolution

# Institute for Laboratory Medicine

## A steep climb





DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Is it Safe  
to have a Laboratory Test?**

**Safe, but could be safer**



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