Beyond the

Quality Institute Conference
2003

Making the Laboratory a Key Partner in Patient Safety

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SAFER • HEALTHIER • PEOPLE™
Is it Safe to have a Laboratory Test?

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

Medical/ Public Health Services Cycle

Laboratory Services Cycle
Ideal Testing Process

Medical/ Public Health Services

Laboratory Services
Total Testing Process

- Patient and Family
  - Action
    - Interpretation
    - Test Solution
      - Laboratory
    - Question
      - Care provider
    - Analysis
      - Ordering
    - Preparation
      - Identification
    - Collection
      - Transportation

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 8th 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
How Hazardous Is Health Care?

From Lucian Leape – QI Conference Keynote
About 12.5% of laboratory errors have some effect on patient health (Bonini et al. Clinical Chemistry 48:5, 691-698, 2002).


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

<table>
<thead>
<tr>
<th>Sigma</th>
<th>% Accuracy</th>
<th>DPMO</th>
<th>Cost of Poor Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>99.9997%</td>
<td>3.4</td>
<td>&lt; 1% of Revenue</td>
</tr>
<tr>
<td>5</td>
<td>99.98%</td>
<td>233</td>
<td>5 – 15% of Revenue</td>
</tr>
<tr>
<td>4</td>
<td>99.4%</td>
<td>6,210</td>
<td>15 – 25% of Revenue</td>
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<tr>
<td>3</td>
<td>93.3%</td>
<td>66,807</td>
<td>25 – 40% of Revenue</td>
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<tr>
<td>2</td>
<td>69.1%</td>
<td>308,537</td>
<td>Not Competitive</td>
</tr>
</tbody>
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Source: *Six Sigma* by Mikel Harry, Ph.D. and Richard Schroeder, 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

- Pre-analytic phase:
  - Perceived need for test
  - Test request requisition
  - Patient preparation
  - Specimen acquisition
  - Specimen processing

- Analytic phase:
  - Specimen analysis
  - Report generation
  - Report retrieval
  - Report interpretation

- Post-analytic phase:

32-75% of errors occur in the pre-analytic phase.

4-32% of errors occur in the analytic phase.

9-55% of errors occur in the post-analytic phase.

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

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
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
Partners In Patient Safety

Laboratory Professionals  Clinicians
Accrediting Organizations  Patients
Administrators  Policy makers
Diagnostic industry  Payers

http://www.phppo.cdc.gov/mlp/qiconference/
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?
Institute for Laboratory Medicine
A steep climb
Is it Safe to have a Laboratory Test?

Safe, but could be safer