20+ Years of CLIA: A Trip Down Memory Lane

Clinical Laboratory Improvement Advisory Committee

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Centers for Disease Control and Prevention
Laboratory Quality Questioned?

False Negative
Medical Labs, Trusted
As Largely Error-Free,
Are Far From Infallible
Haste, Misuse of Equipment,
Specimen Mix-Ups Afflict
Even Best Labs at Times
Regulation: Weak and Spotty
By Walt Bogdanich
Staff Reporter of THE WALL STREET JOURNAL

Physicians’ Carelessness With Pap Tests
Is Cited in Procedure’s High Failure Rate
By Walt Bogdanich
Staff Reporter of THE WALL STREET JOURNAL
Remember, quality is our top priority.

Question: Is it more important than safety?

Oh... I forgot about that one.

Question: Is quality more important than obeying the law?

Well, probably not.

If we could maximize shareholder value by selling lower quality items...

Wouldn't we have a fiduciary responsibility to do it?

I'm sure it's in the top four.

What if we had to lie to achieve quality?
The Impact of CLIA

- >200,000 laboratories
- 333,000 individual laboratorians
- > 8 billion laboratory tests (annually)
- Healthcare providers
- IVD manufacturing industry
- Healthcare consumers (Patients, Families, Communities)
A Brief History of CLIA

• Laws
  – SSA Act ’65: July 1965
  – CLIA ’67: December 1967 = Location
  – CLIA ’88: October 1988 = Complexity

• Regulations
  – CLIA ‘67 Update Proposed 1988; Final 1990
  – CLIA ’88 Proposed 1990; Final 1992
• CMS, FDA, and CDC joint responsibility
  – Access, Quality, Cost
• Complexity? Number and type of testing locations?
• Waived tests, PT, Personnel, QA/QC, Fees, Sanctions
• CLIAC
• CLIA Studies
• Technology
CLIA Regulatory Timeline

- 1988: Test categorization lists
- 1990:
- 1992:
- 1994:
- 1996:
- 1998:
- 2000:
- 2002:
- 2004:
- 2006:
- 2008:

- Statute enacted
- Proposed rules
- Final rules with comment
- Transfer test categorization from CDC to FDA
- Genetics Notice of Intent
- Cytology PT proposed rule
- Provider Performed Microscopy created
- Proposed requirements for waived testing
- Interpretive guidelines published
- Final rule revising technical standards

NOTE: Over 50 FR Notices/regulations published related to CLIA
CLIAC 1992-2007

- **Meetings** - 49
  - 36 Full CLIAC
  - 7 Subcommittee
  - 10 Workgroup

- **Chairs** - 4

- **Members**
  - 20 current
  - 71 past
  - 3 Industry liaisons

- **Speakers** - 171
  - 37 CDC
  - 8 CMS
  - 8 FDA
  - 118 others

**Topics**
- Assisted Reproductive Technology
- Bioterrorism
- Cytology (includes Cytology PT)
- Direct Assess Testing
- FDA Clearance/Approval Process
- Genetics
- Personnel
- Point of Care/Physicians Office Laboratories
- Proficiency testing
- Quality Control/Quality Assurance
- Survey Data/Information
- Test Categorization
- Unregulated Test Systems
- Waiver
Cumulative Number of Tests Categorized Over Time

- 7/1993 - 12,137
- 1/2000 - 25,708
- 2/2008 - 39,428

Legend:
- Blue: Waived
- Green: Moderate
- Cyan: High
CLIAC Recent Accomplishments

Feb 2006    Connectivity - clinical and public health laboratories
Mar 2006    Workgroup: cytology proficiency testing (PT)
Jun 2006    Cytology PT proposed rule
Sep 2006    Challenges to laboratories: “complex” testing in “traditional” locations
Nov 2006    Workgroup: impact of rapid and molecular tests for infectious diseases on public health
Feb 2007    Challenges to laboratories: “simple” testing in diverse sites
Sep 2007    CLIA research agenda and genetic testing oversight

Since 1992, CLIAC has made 62 recommendations, 84% implemented
Original CLIA Studies

1. Validity, reliability, accuracy of PT
2. Correlation between personnel standards and the reliability and accuracy of testing
3. Correlation between internal QA/QC and the reliability and accuracy of testing
4. Extent and nature of problems in diagnosis and treatment due to inaccurate laboratory testing
5. Effect on test accuracy of errors in the testing process
CLIA Associated Studies

Evaluation of Quality in Laboratory Practices and Standards

### Division of Laboratory Systems

**Laboratory Practice Evaluation Strategy**

- Logic Model -

### Objectives
- Conduct research to improve laboratory quality and patient safety
  - Guide
    - Policy decisions
    - Standards development
  - Measure effectiveness
    - CLIA program
    - Voluntary standards
  - Evaluate
    - Testing quality
    - Patient safety
  - Assess appropriateness of level of oversight
  - Assist in meeting CLIA-related information requests by Congress
- (Source: CMS/CDC interagency agreement)

### Inputs
- DLS Funding and Branch staff:
  - Practice Evaluation & Genomics
  - Standards
  - Systems
- CLIA:
  - Regulations
  - CLIA
  - CMS
  - FDA
- Partners:
  - Laboratory – affiliated (public & private)
  - Health care providers
  - Payers
  - Patient safety
- Public input:
  - Public health
  - Consumers/Patients
  - Clinicians
  - U.S. government
- Consultants/Researchers

### Projects/Initiatives
- Surveillance
  - Practices
  - Tests
- Development
  - Standards/practices
  - Processes
  - Networks

### Short-Term Outputs/Outcomes
- Information/Data
  - Demographic
  - Practices
  - Test use
  - Regulatory compliance
  - Identification of issues and priorities
- Evaluation/Measurement
  - Regulations
  - Practices
  - Priorities

### Intermediate Outcomes
- Available and comparable data
- Research agenda based on identified priorities
- Evidence-based:
  - Standards
  - Regulations
  - Performance measures
  - CLIA effectiveness
  - Resource use/efficiency

### Long-Term Outcomes
- Measurable quality improvement
- Increased accountability of laboratories and CLIA
- Greater responsiveness to national priorities
- Strengthened national public health
  - Quality/Outcomes
  - Preparedness
  - Infrastructure
  - Capacity
  - Access
  - Cost-effective

11/21/06 Draft
## CLIA Partners

<table>
<thead>
<tr>
<th>Category</th>
<th>Partners</th>
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<tbody>
<tr>
<td>Federal Agencies</td>
<td>HHS - CMS, FDA, CDC</td>
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<td>Other - DOD, Dept of Justice, USAID, VA</td>
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<tr>
<td>States and Professional Organizations</td>
<td>State Public Health and Clinical Laboratories</td>
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<td>Professional Laboratory Organizations</td>
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<td>Proficiency Testing Programs</td>
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<td>Accreditation Organizations</td>
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<td>HHS Advisory Committees</td>
<td>Secretary’s Advisory Committee on Genetics, Health, and Society</td>
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<td>International</td>
<td>WHO, CAREC, ISO, OECD</td>
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<td>Standards</td>
<td>CLSI, ISO</td>
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<tr>
<td>Others</td>
<td>Healthcare Providers, Manufacturers/Distributors, Physicians, Laboratories, the Public</td>
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**Note:** Partial list of partners.
Institutes on Critical Issues in Health Laboratory Practice

- 1989 – Quality Improvement
- 1995 – Laboratory Practice
- 2002 - Global PT
- 2003 – Quality Institute
- 2005 – Institute for Quality in Laboratory Medicine
- 2007 – Managing for Better Health
2003 Quality Institute
Participants Identified
Needs:

• Better indicators for the quality of laboratory services

• Annual report on the quality of laboratory services

• An independent organization to facilitate improvements in laboratory services
Patient safety + Laboratory = Pathways to better Public Health?

The Future?

- **Comprehensive research agenda** driving laboratory quality improvement through evaluation and development of evidence-based practices and standards
- **Regulatory and non-regulatory approaches** for standards development, dissemination and implementation evaluation
- **Staffing for the future:**
  - Health systems researchers
  - QMS experts
Major Accomplishments

- Overcame many obstacles to implementation - CLIAC
- Stimulated voluntary and mandated standards and guidelines
- Established a baseline for quality for all US clinical laboratories
- Stimulated changes in laboratory medicine
- Achieved access, quality, and cost