



20+ Years of CLIA: A Trip Down Memory Lane



**Clinical Laboratory Improvement
Advisory Committee**

February 20, 2008



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Laboratory Quality Questioned?

DU CEN ID

Lax Laboratories
 The Pap Test Misses
 Much Cervical Cancer
 Through Labs' Errors

Cut-Rate 'Pap Mills' Process
 Slides Using Screeners
 With Incentives to Rush

Misplaced Sense of Security?

By WALT BOGDANICH
 Staff Reporter of THE WALL STREET JOURNAL



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

man Kodak Co. say they work for "the
 great yellow father."
 Santa Claus, exclamation point. "I don't
 says. "is the only place in the world I've
 story is called the "tag"

**Physicians' Carelessness With Pap Tests
 Is Cited in Procedure's High Failure Rate**

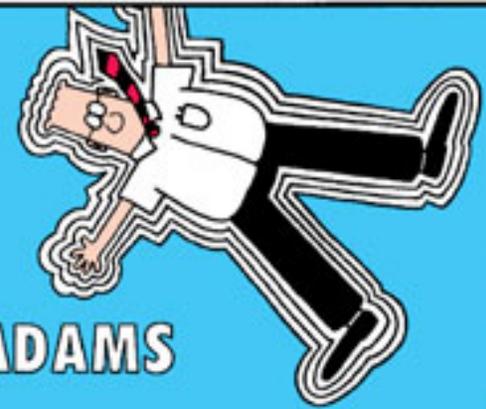
By WALT BOGDANICH
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hurry, so the smear may not be taken ade-
 quately.

matter of dispute Malcolm L. Margolin, a
 West Coast official with ACOG, says he be-
 lieves many physicians aren't adequately



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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

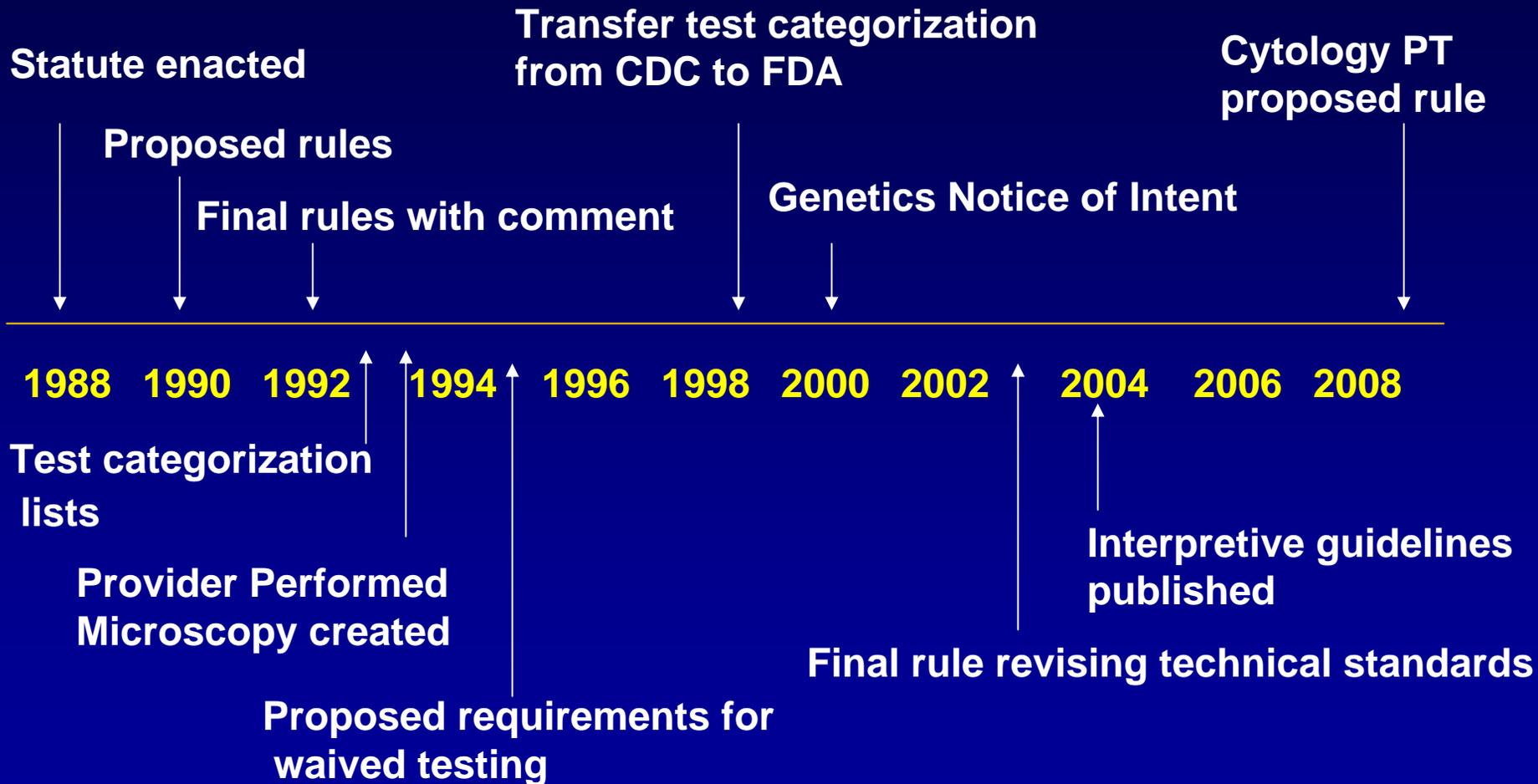
- Laws
 - SSA Act '65: July 1965
 - CLIA '67: December 1967 = Location
 - CLIA '88: October 1988 = Complexity
- Regulations
 - CLIA '67 Update Proposed 1988; Final 1990
 - CLIA '88 Proposed 1990; Final 1992





- 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



NOTE: Over 50 FR Notices/regulations published related to CLIA



CLIAC 1992- 2007

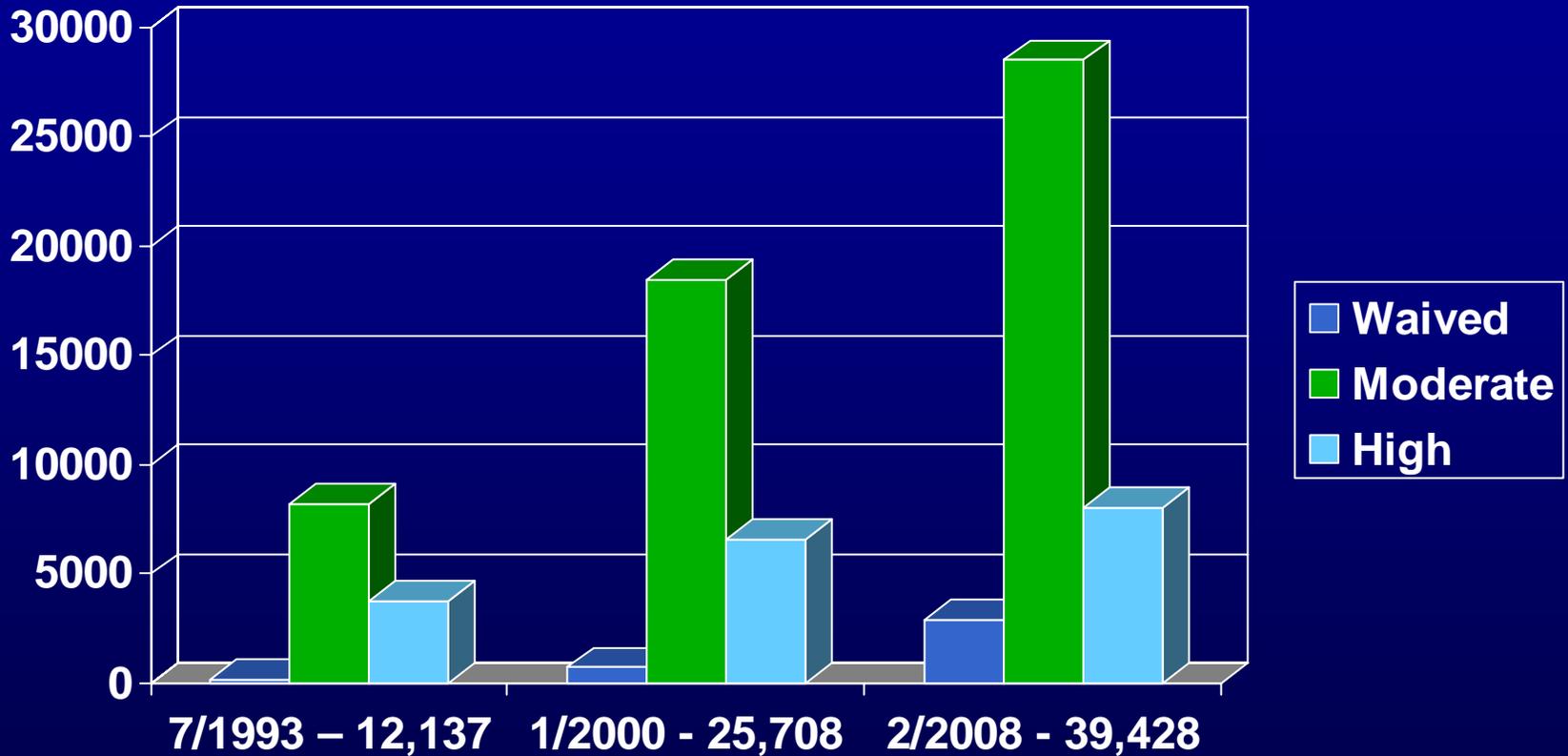
- **Meetings** - 49
 - 36 Full CLIAC
 - 7 Subcommittee
 - 10 Workgroup
- **Chairs** – 4
- **Members**
 - 20 current
 - 71 past
 - 3 Industry liaisons
- **Speakers** – 171
 - 37 CDC
 - 8 CMS
 - 8 FDA
 - 118 others

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



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

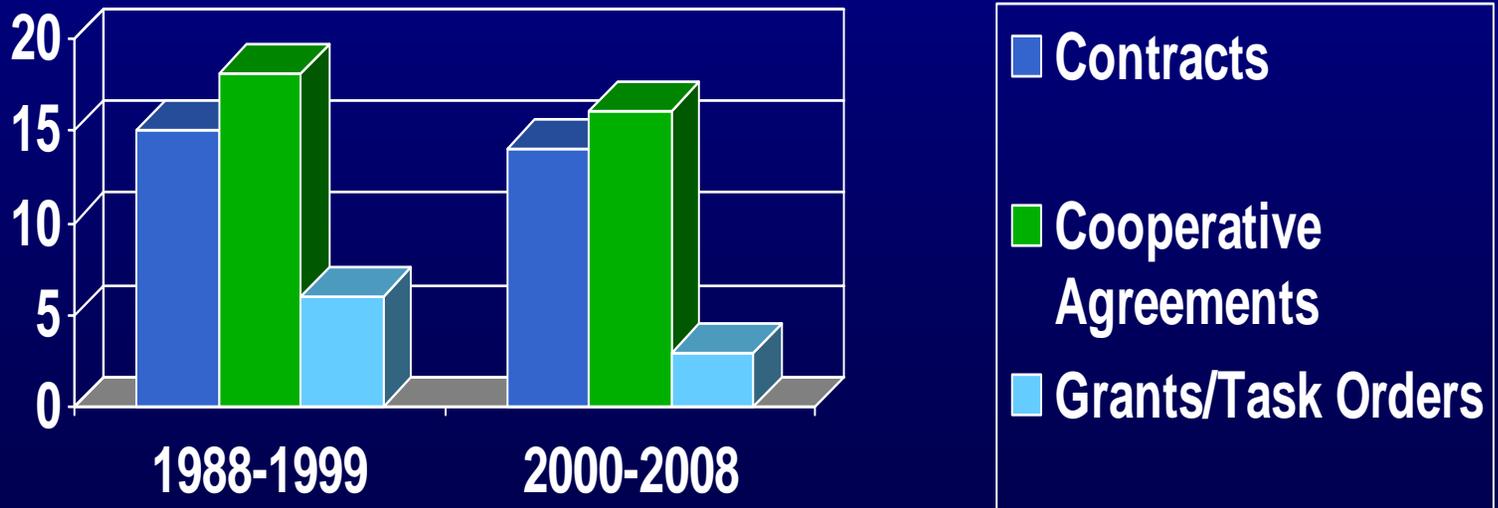
1. Validity, reliability, accuracy of PT
2. Correlation between personnel standards and the reliability and accuracy of testing
3. Correlation between internal QA/QC and the reliability and accuracy of testing
4. Extent and nature of problems in diagnosis and treatment due to inaccurate laboratory testing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



CLIA Associated Studies

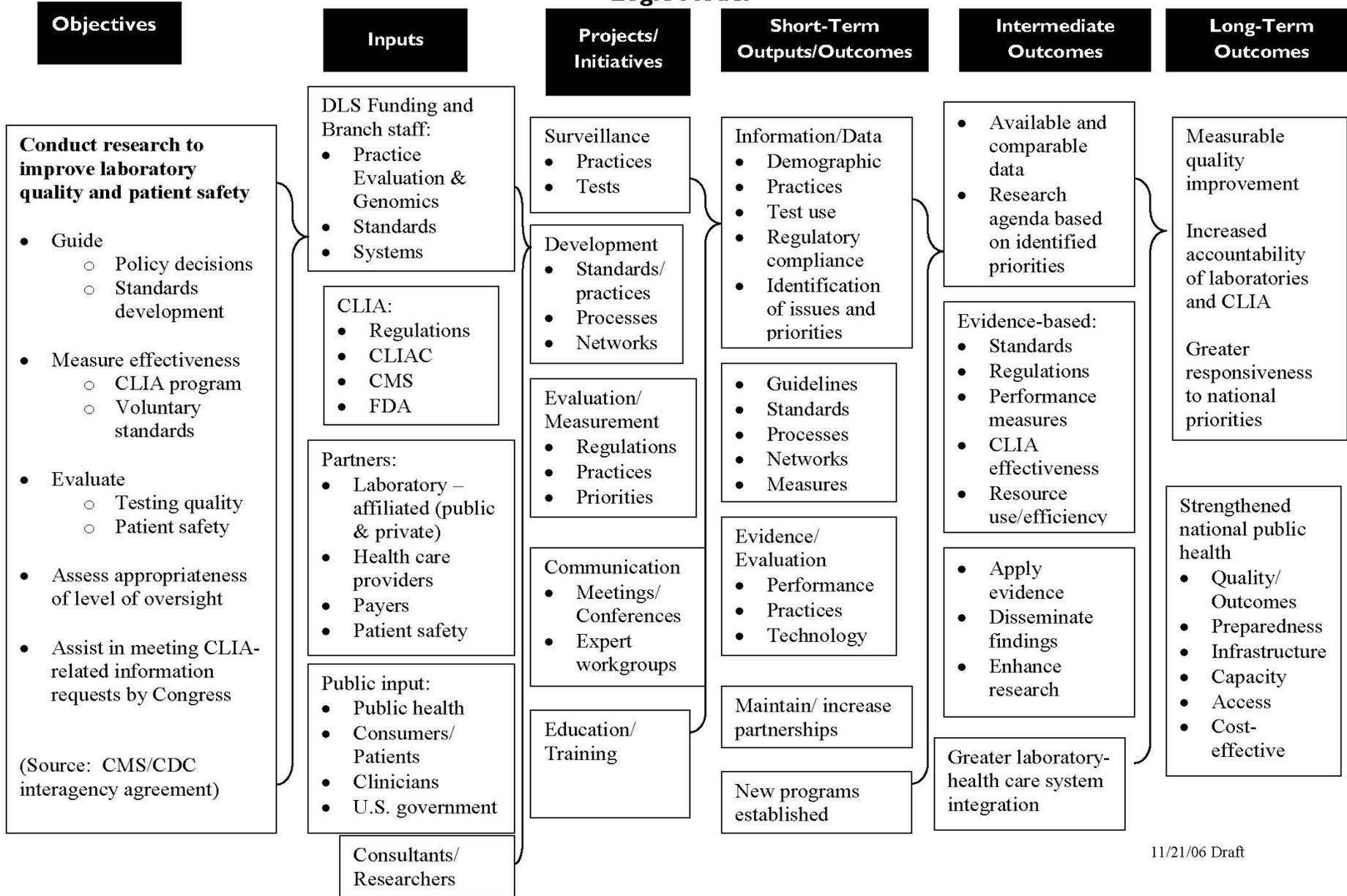
EQUALS

Evaluation of Quality in Laboratory Practices and Standards



N=72

Division of Laboratory Systems Laboratory Practice Evaluation Strategy -Logic Model-





CLIA Partners

Federal Agencies	HHS - CMS, FDA, CDC Other - DOD, Dept of Justice, USAID, VA
States and Professional Organizations	State Public Health and Clinical Laboratories Professional Laboratory Organizations Proficiency Testing Programs Accreditation Organizations
HHS Advisory Committees	Secretary's Advisory Committee on Genetics, Health, and Society
International	WHO, CAREC, ISO, OECD
Standards	CLSI, ISO
Others	Healthcare Providers, Manufacturers/Distributors, Physicians, Laboratories, the Public

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?

Unsupportable Clinical Decisions
Unexplained Variability in Care
Lack of Credible Evidence



Price CP. Clin Chem 2000;1041-50.



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 - CLIA
- 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





Celebrate!



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