

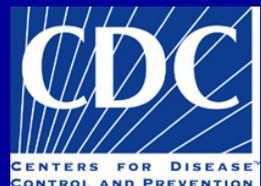
# Laboratory Systems Research...

## Past, Present and Future

CLIAC Meeting

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# Objectives for this Meeting

Feedback on research strategy:

- Comments on current activities
- Input on future research priorities
- Ideas for translating findings into practice
- Suggestions for evaluating impact, outcomes



# Meeting Outline

- Past: Summary of past activities
- Present:
  - Overview of current projects
  - Performance measurement
  - Evidence-based practice assessment
  - Institute for Laboratory Medicine Workgroup reports
- Future:
  - Delphi study
  - Future research agenda

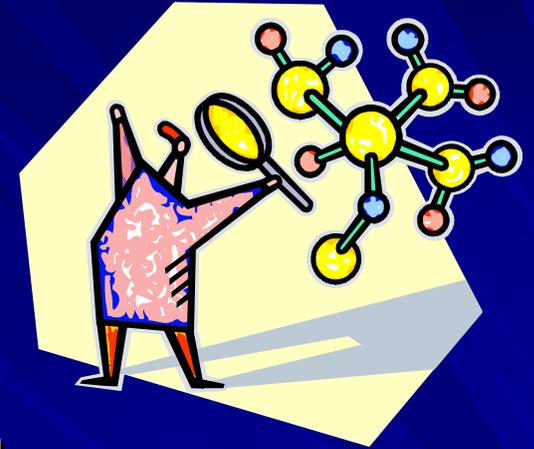


# General Questions to Consider

- What are future research priorities?
- Why do you think a specific focal area should be a priority?
- How should decisions be made about future efforts?
- Who should contribute to the decision-making process?
- Who might be willing/interested in collaboration, contributing resources?

# Background

**CLIA Studies** ...defined in the law:



- ✓ Usefulness of proficiency testing
- ✓ Correlation between personnel standards and performance
- ✓ Correlation between QC/QA standards and performance
- ✓ Nature of errors in the total testing process
- ✓ Consequences of errors

# Background (cont'd)

**Interagency agreement with CMS**... studies to:

- ✓ Guide policy & standards development
- ✓ Measure effectiveness of CLIA program
- ✓ Assess appropriate level of oversight
- ✓ Evaluate & improve testing quality & patient safety
- ✓ Provide information requested by CMS, HHS, Congress
- ✓ Evaluate regulatory impact – costs and benefits
- ✓ Monitor and evaluate PT programs

# Introduction

## Health Laboratory Systems Research

- **Objective:** contribute to the evidence base for policy-making to strengthen/improve laboratory systems and services in the U.S.
- **Driving forces:** CLIA, IOM reports, need to improve laboratory services and their delivery in the context of healthcare reform
- **Evaluation of impact:** outcomes, patient safety, public health
- **Translation into interventions:** standards (regulatory/voluntary), guidelines, evidence-based practices

# Summary of Past Activities

- Introduction/background
- Early years (1988-94): the basics
- Mid-years (1995-2001): exploring the field, meeting urgent needs
- Recent past (2002-2008): moving toward systems research; identifying and filling gaps
- Summary



# The Early Years

## In the beginning...

**EQLPS**

## Evaluation of Quality in Laboratory Practices and Standards

- CLIA questions
- Institute on Critical Issues in Health Laboratory Practice
- Literature review, report to Congress
- Consultation with experts
- Mining available data sets (CLIA OSCAR, NAMCS)
- Performance evaluation for HIV testing
- Strategy development
- Resource commitments

# Institutes on Critical Issues in Health Laboratory Practice

- 1986: Managing laboratory testing quality in changing healthcare environment
- 1989: Clinician and laboratorian teamwork
- 1995: Frontiers in lab practice research
- 2003: Quality Institute: Lab as a key partner in patient safety
- 2005: IQLM, recognizing excellence in practice
- 2007: Managing for better health

# 1986 and 1989 Institutes

## ■ 1986 recommendations/observations:

- Enhance communication between test-users and test-providers
- Develop quality management programs and standards for testing quality
- Focus research efforts on evaluating performance and improvement

## ■ 1989 recommendations/observations:

- Research agenda based on total testing process
- Impact of changing technology – point of care, rapid infectious disease testing
- Recognition of the need for collaborative efforts

# CLIA Studies: Early Publications

<http://wwwn.cdc.gov/dls/dlspubs.aspx>

- **Evaluating Laboratory Performance. Historical and Governmental Perspectives.** Boone DJ: *Arch.Pathol.Lab.Med.* 1988.
- **Quality of Laboratory Performance in Testing for Human Immunodeficiency Virus Type 1 Antibody. Variables Associated in Multivariate Analyses.** Gerber AR, Valdiserri RO, Johnson CA, Schwartz RE, Hancock JS, Hearn TL, *Arch. Pathol. Lab. Med.* 1991.
- **Literature Review of Research Related to the Clinical Laboratory Improvement Amendments of 1988,** Boone DJ. *Arch.Pathol.Lab.Med.* 1992.
- **Conducting Outcomes Research: Past Experience and Future Directions.** Boone DJ, Steindel SJ: *Clin.Chem.* 1995;41:795-798.
- **Toward Optimal Laboratory Use. Problems in Laboratory Testing in Primary Care.** Nutting PA, Main DS, Fischer PM, Stull TM, et al: *JAMA*, 1996.
- **Proficiency Testing in Laboratory Medicine: Uses and Limitations.** Shahangian S: *Arch.Pathol.Lab.Med.* 1998.

# Variation in Proficiency Testing Performance by Testing Site

## Findings – 1994 data:

- PT performance data (pass/fail) for 30 most commonly performed “regulated” analytes, tests, & specialties
- Statistically significant difference between performance in previously regulated sites (hospital and independent laboratories, HI) and all other testing sites (AOT, primarily POLs)
- Percentage of unsatisfactory testing event scores:
  - HI sites 1.3% - 5.6%
  - AOT: 3.6% - 15.0%
- Odds ratios ranged from 2.2 (bacteriology) to 7.5 (potassium)

# Middle Years

- 1995 Institute: Frontiers in Laboratory Practice Research
- Laboratory sentinel monitoring networks
- National Inventory of Clinical Laboratory Testing Services (NICLTS)
- Physician surveys on laboratory practice
- Coagulation testing practices and guideline adherence
- PT practices: international conference
- Computer-based cytology PT evaluation
- Evaluation of QA practices in genetic testing

# 1995 Institute: Frontiers in Laboratory Practice Research

- **Proficiency testing:** PT is important but incomplete measure and QI tool; explore enhancements & other models for performance measurement
- **Personnel standards:** research agenda to evaluate necessary competencies and competency assessment
- **Quality assurance:** focus research strategy on areas in the total testing process with the greatest impact; cost-benefit evaluations needed for QC; link studies to patient outcome

# 1995 Institute: Frontiers in Laboratory Practice Research (cont'd)

- **Outcome studies:** focus on high impact areas; multi-center epidemiological study approach; collaborative efforts to build comprehensive data sources; collaborate with clinicians, managers and payers
- **Analytic performance goals:** lack of consensus on approaches; recognition that collaboration needed among manufacturers, laboratorians and clinicians
- **Laboratory focused health systems research:** studies needed in 4 areas – information systems, testing appropriateness/value, organizational & delivery changes, guidelines

# Sentinel Monitoring Networks

<http://wwwn.cdc.gov/mlp/pnlmsmn.aspx>

## ■ Pacific Northwest, 1995-2005

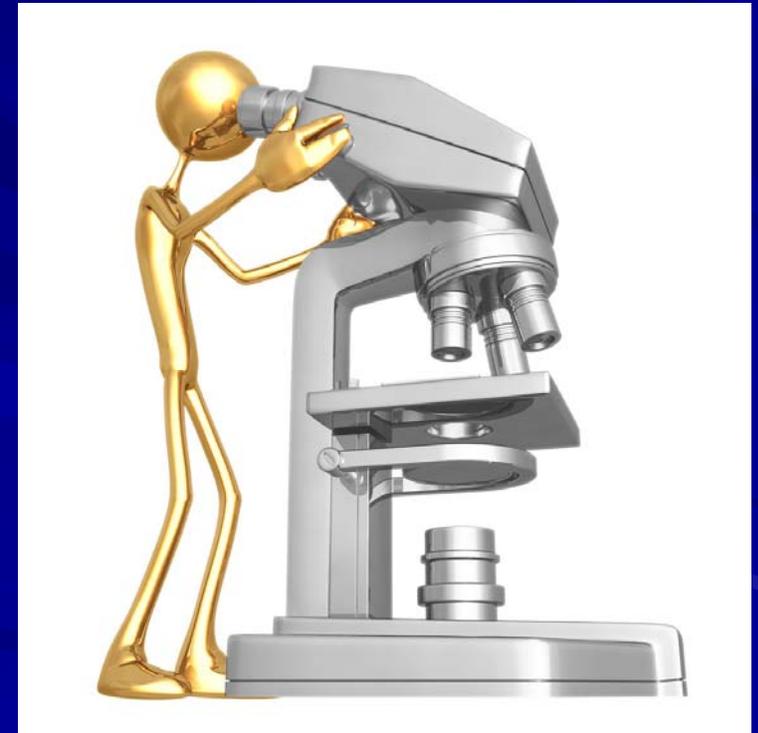
- Personnel changes
- Test menu and volume changes
- Waived and PPMP testing
- Molecular genetic testing
- Direct access testing
- Coagulation testing practices

## ■ New York, 1999-2001

- Waived and PPMP testing

## ■ Arkansas, 1999-2001

- Waived testing
- Laboratory organizational cultures



# NICLTS

## National Inventory of Clinical Laboratory Testing Services. 1996

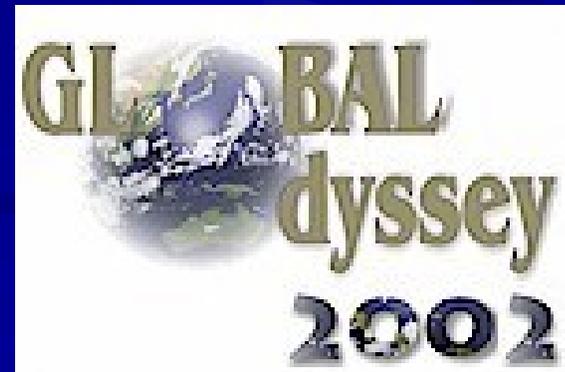
### ■ Stratified random sample of laboratories: demographics and test volumes

- 7.25 ± 1.09 billion tests/year
- 16% of sites performed 80% of testing
- Glucose analysis most frequently performed test
- Automated hematology and chemistry analyzers most frequent methods

### ■ Publications:

- **National Inventory of Clinical Laboratory Testing Services (NICLTS); Development and Test Distribution for 1996.** Steindel SJ, Rauch WJ, Simon MK, Handsfield JH: *Arch.Pathol.Lab.Med.* 2000;124.
- **Characterization of Microorganism Identification in the United States in 1996.** Steindel SJ, Simon MK. *Arch Pathol Lab Med* 2001;125.

- Adherence to Guidelines: 2001 National Survey of Hospital Coagulation Laboratory Practices
- Proficiency Testing Practices: International Conference on Proficiency Testing for Medical Laboratories, 2002



# Evaluation of QA Practices in Genetic Testing: The Beginning

- **1999: General Recommendations for Quality Assurance Programs for Laboratory Molecular Genetic Tests**

*(Contract with DynCorp Health Research Services)*

- **Laboratory Practice Survey**

**1999: Molecular Genetic Testing**

**2003: Biochemical Genetic Testing**

*(Cooperative Agreement with Mt. Sinai School of Medicine (PI: Dr. Margaret McGovern))*

McGovern MM, Benach MO, Wallenstein S, Desnick RJ, Keenlyside R: Quality Assurance in Molecular Genetic Testing Laboratories. *JAMA* 1999;281:835-840.

# Recent Past



- Quality Institute conferences: 2003, 2005
- Scope of rapid HIV testing
- Genetic testing reporting practices
- Genetic testing reference materials
- PT workgroup report
- Performance metrics and gap identification
- National status report

# Quality Improvement in Genetic Testing

## Promoting a Framework for Quality

CLIA

MMWR

ISO

JC

CLSI

OECD

## Promoting Analytic Validity



## Promoting Appropriate Test Use and Professional Competency

**COMMUNICATION:**  
Key to Appropriate Genetic Test Referral,  
Result Reporting and Interpretation



The Virtual Clinic  
From the CDROM: Genetics in Clinical Practice:  
A Team Approach

# Quality Improvement in Genetic Testing

Promoting Availability:  
Translating Research to the Health Care Setting



CDC / NIH-ORD



CDC / External partners

**Molecular Genetic Tests:  
Promoting Understanding of the  
Test result to Enhance  
Clinical Decision Making**

CDC / Rand Corporation

# Waived Testing: DLS Publications

- **Quality Control of Test Systems Waived by the Clinical Laboratory Improvement Amendments of 1988: Perceptions and Practices.** LaBeau KM, Simon M, Steindel SJ. *Arch Path & Lab Med* , 2000.
- **Practice Patterns of Testing Waived Under the Clinical Laboratory Improvement Amendments** Steindel SJ, Granade S, Lee J, Avery G, Clarke LM, Jenny RW, LaBeau KM.. *Arch Pathol Lab Med.* 2002
- **Scope of rapid HIV testing in hospitals across the United States.** Bogart LM, Howerton D, Lange J, Becker,K, Setodji CM, & Asch SM. *Public Health Reports*, 2008.
- **Good Laboratory Practices for Waived Testing Sites.** Howerton, DA, Anderson N, Bosse D., Granade S., and Westbrook G, *MMWR*, 2005.
- **Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988,**  
<http://www.cdc.gov/hiv/topics/testing/rapid/index.htm#lab>

# Laboratory Medicine Quality Improvement CDC External Partner Projects

- **University of Pittsburgh Medical School,  
Dept. of Pathology**

Assessment of Standardized Quality Assurance  
Activities in Pathology and Laboratory Medicine:  
Multi-institutional studies with clinical outcomes



- **College of American Pathologists**

Patient specimen identification errors – considering  
clinical and economic consequences in 4 scenarios

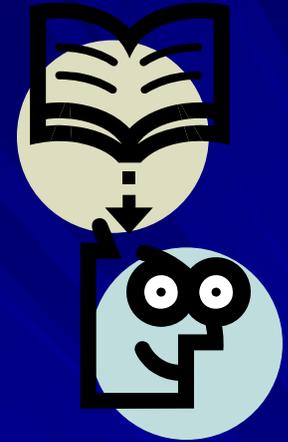


- **National Quality Forum**

National Voluntary Consensus Standards for Patient  
Safety and Communication Practices for Laboratory  
Medicine



# Laboratory Medicine: A National Status Report



1. Value of Laboratory Medicine
2. Market Profile
3. Workforce
4. Total Testing Process – Factors Affecting Quality
5. Quality Systems and Performance Measurement
6. Laboratory Information Systems
7. Regulation
8. Reimbursement

# Summary

- Impossible to do justice to 20 years of studies in 30 minutes!
- Studies have progressed from collecting basic information to developing an evidence base and systems improvement
- Basic data and information are still needed
- We are grappling with many of the same issues now as those recognized “in the beginning”

# Discussion

