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
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...

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


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


**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
  - $7.25 \pm 1.09$ 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:
  
Adherence to Guidelines: 2001 National Survey of Hospital Coagulation Laboratory Practices


- **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))

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

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

CDC / NIH-ORD

CDC / External partners

CDC / Rand Corporation
Waived Testing: DLS Publications


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
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