CDC Update

Clinical Laboratory Improvement Advisory Committee Meeting

February 14, 2012

Devery Howerton, PhD

Director, Division of Laboratory Science and Standards

Laboratory Science, Policy and Practice Program Office

Office of Surveillance, Epidemiology and Laboratory Services

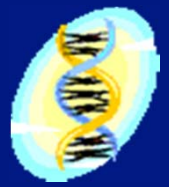
Topic Outline

- Standards, guidelines, reference materials
- Educational outreach
- Public health laboratory efficiency initiative

Standards, Guidelines and Reference Materials

- Reference materials for genetic testing
- Next generation sequencing: guidelines for quality practices to transition into clinical testing
- Good laboratory practice recommendations for biochemical genetic testing & newborn screening
- CLIA requirements for proficiency testing

Development of Reference Materials for Cytogenetic Microarray Analysis



Progress so far:

- **Selected DNA from 95 Coriell cell lines containing common cytogenetic abnormalities**
- **First 45 Samples:**
  - DNA was characterized using 4 commercial CMA platforms
  - Raw data was analyzed by 8 clinical cytogeneticists
  - A consensus genotype is being developed for each sample.
- **DNA from the remaining 50 samples is currently being characterized using the 4 commercial CMA platforms**

Next-generation Sequencing: Standardization of Clinical Testing (Nex-StoCT) Working Group

- Next-generation sequencing for the clinical laboratory = cost-effective large scale sequencing (gene panels, whole genome, etc.)
- Applied to selection/evaluation of cancer modalities, rare disease diagnosis, and potential for other clinical applications
- Complex technology - How are regulations and professional standards to be applied?
- Nex-StoCT Working group established

Next-generation Sequencing: Standardization of Clinical Testing (Nex-StoCT) Working Group

- **Face-to-face meeting (April 2011) + continued consultation**
  - 41 experts; focus on heritable conditions
  - Considered test validation, quality control, and proficiency testing/alternate assessment
- **Outcomes: Principles and Guidance**
  - Manuscript in preparation
  - Sharing outcomes with other national efforts (that include FDA, CLSI, CAP, ACMG, AMP)
- **Next steps:**
  - GeT-RM project to develop a clinically useful consensus human genomic sequence derived from characterized cell lines
  - Nex-StoCT 2 (planning in progress)

Good Laboratory Practice Recommendations for Biochemical Genetic Testing & Newborn Screening

Initial Review & Assessment	CLIAC Recommendations	Additional Input	CDC Recommendations
2008-2009	2009-2010	2010-2011	2011-2012

- **2008-2009: Initial information review and assessment by CDC**
  - Gaps/concerns affecting quality of biochemical genetic testing (BGT) and newborn screening (NBS) for inherited disorders
- **2009-2010: Development of CLIAC Recommendations**
  - 2009: CLIAC BGT workgroup & Feb. 2010: CLIAC meeting
  - CLIAC recommendations(http://wwwn.cdc.gov/cliac/default.aspx)
- **2010-2011: Additional input to complement CLIAC recommendations** (SACGHS, SACHDNC, APHL)
- **2011-2012: Preparation & publication of CDC MMWR recommendation -** In press, expected April 2012

Proficiency Testing (PT)
Status of Regulatory Revisions

- **Developed draft list of analytes for which PT will be required and proposed changes to microbiology**
- **Determination of proposed criteria for acceptable performance (scoring schemes) in development**
- **Meeting planned with PT programs for March 13-14**
  - Feasibility issues
  - Scoring schemes
- **Regulatory impact analysis: survey of laboratories in collaboration with APHL to evaluate how PT is used**

Educational Outreach

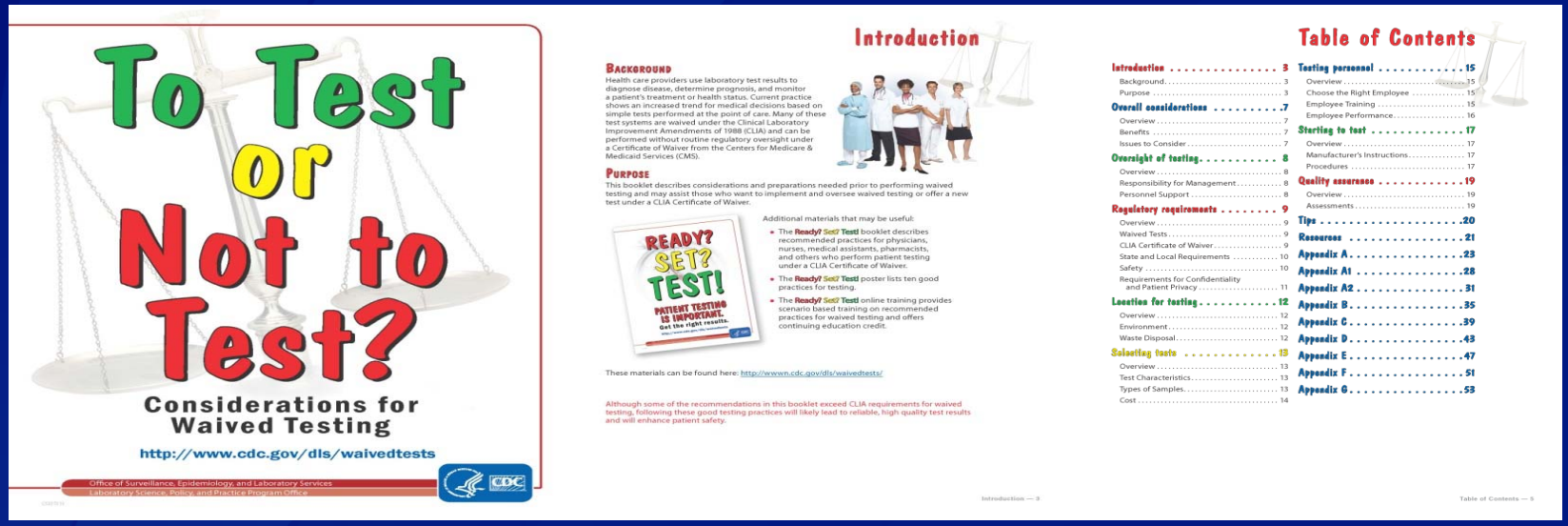
- Good laboratory practices for waived testing
- Evidence-based practice methods
- State training grants

Ready? Set? Test! online training

- An online training module provides scenario based training and offers continuing education credit for physicians, nurses, pharmacists, and others
- October 14, 2011 training CDC Train link went "live" on www.cdc.gov/dls/waivedtests
- November 10, 2011 began email promotions
- Kentucky PH Dept requiring all laboratory testing personnel who perform waived testing to complete the training

Ready? Set? Test! Online Course			
Total Registered	1457	**Credit Type**	**Total Hours Awarded**
Completed	589	CEU/CE	35.8
In Progress	847	CME	5
Withdrawn	21	CNE Contact Hours	137

To Test or Not to Test?
Considerations for Waived Testing booklet



- **To Test or Not to Test?** booklet describes
  - considerations and preparations needed prior to performing waived testing
  - may assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver
- Now available for distribution
- Presentation topic at COLA Symposia April 2012
- You can request copies of the products and register for the training at WaivedTesting@cdc.gov or by calling 404-498-2290.

On-Line Training for Evidence-Based Laboratory Practice

- **Module 1: An Overview of A-6 Methods-** ***in use by the laboratory community***
- **Module 2: Key Steps in Planning Quality Improvement Projects – near completion**
- **Additional modules under consideration**

www.futurelabmedicine.org

File Edit View Favorites Tools Help Convert Select

Favorites

Welcome to Module 1

Page Safety Tools

Laboratory Medicine Best Practices Initiative

Welcome to Module 1
The A-6 Cycle: Review and Evaluation Methods for Quality Improvement

This module is one of a multi-part tutorial intended to:

- Increase the awareness of the LMBP A-6 systematic evidence review methods
- Increase knowledge in the application of evidence-based principles to quality improvement projects

Target Audience

An important goal of this training is to reach those who provide approval or support for quality improvement (QI) projects, those who are active in the design and implementation of projects and those who contribute to QI projects.

CDC

LABORATORY MEDICINE Best Practices

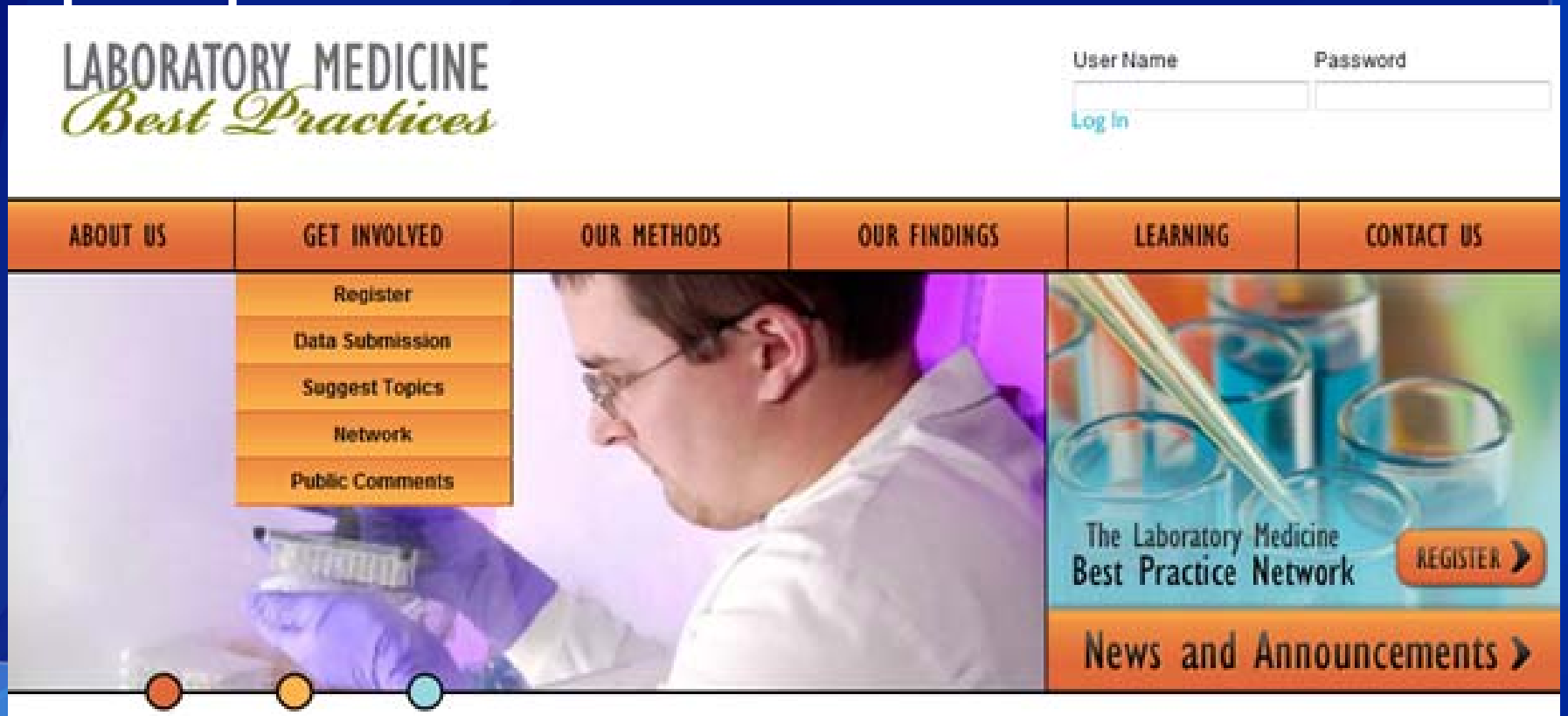
Trusted sites

start Inb... Foll... LM... LM... Wel... \\c... Mic...

www.futurelabmedicine.org

Information and Activities:

- **Tutorials, technical reports, review findings**
- **Calls for evidence, calls for review topics**
- **Announcements of publications and meeting participation**



CLIA State Training Grants

- **Through the Association for Public Health Laboratories (APHL) Cooperative Agreement**
- **12 states awarded training grants in December 2011**
  - Purpose: develop and deliver training on CLIA-related topics and/or quality management systems
  - Target audience: clinical and/or physician office laboratories
- **Topics include:**
  - Good laboratory practices for waived testing
  - Proficiency testing participation for quality improvement
  - How to avoid the most common CLIA deficiencies
  - Competency assessment
  - Quality management systems
  - Use of CLSI guidelines for antimicrobial susceptibility testing

Public Health Laboratory Efficiency Initiative

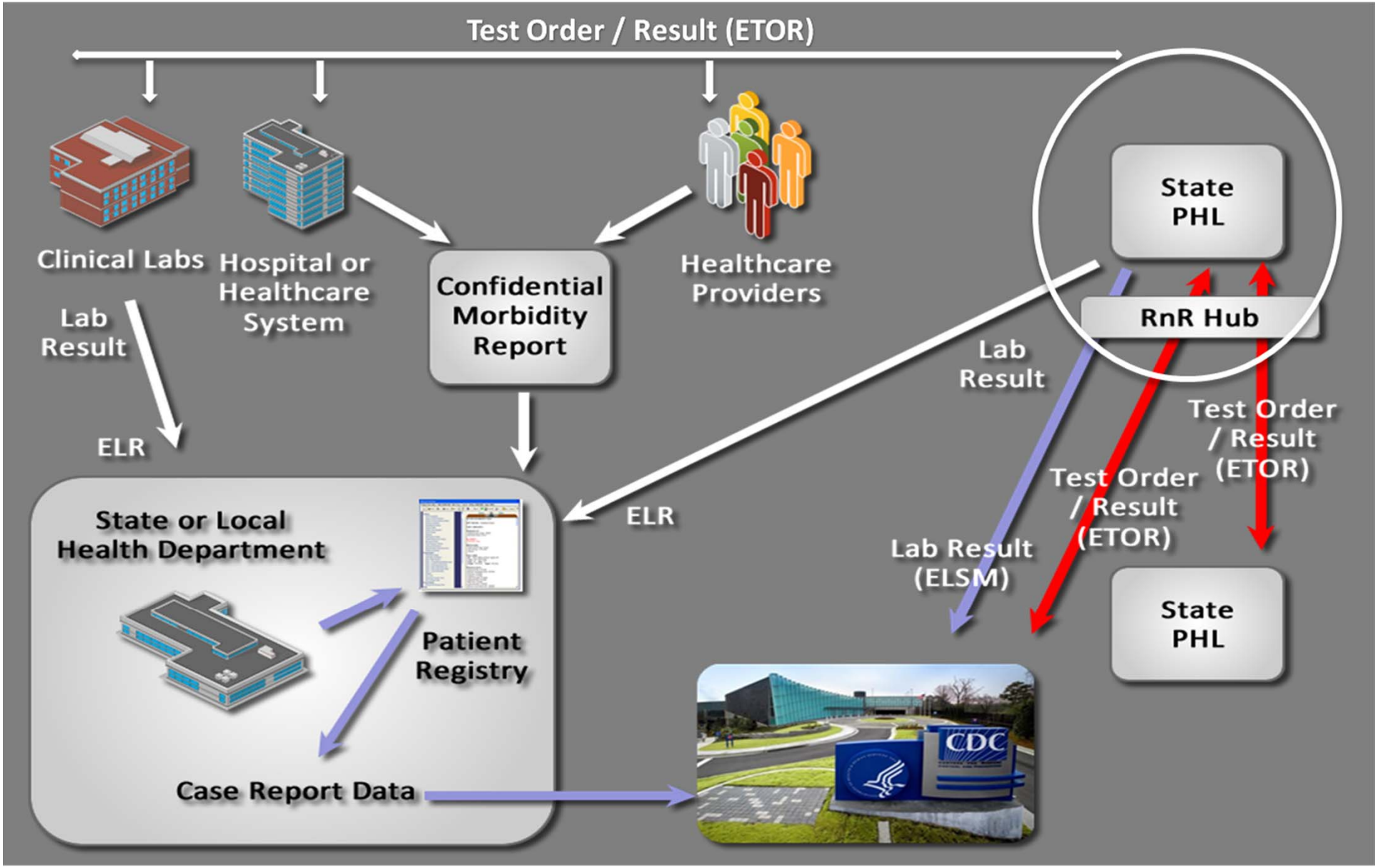
Laboratory Efficiencies Initiative (LEI): Addressing Today's Realities

- **State public health (PH) laboratory budget cuts**
- **PH laboratories have lost staff**
- **Eliminated or reduced some testing services**
- **Ability to maintain services might impair**
  - outbreak investigation,
  - emergency response,
  - surveillance, and
  - public health prevention programs

Laboratory Efficiencies Initiative (LEI) Operating Principles

- **Collaborative effort among states, localities, APHL and CDC in sustaining PH testing services**
- **State-driven strategies to enable solutions within and between states and public health programs**
- **Assessment of alternative management practices to**
  - identify other revenue sources
  - share/consolidate some services
  - increase efficiency, e.g., standardize platforms, streamline workflow, enhance informatics interoperability

The PHL e-health domain



Questions?

The findings and conclusions in this report are those of the authors and to not necessarily represent the official position of the Centers for Disease Control and Prevention.