CDC Update

Shambavi Subbarao, Ph.D., MSc
Director
Division of Laboratory Programs, Standards, and Services,

CLIAC Meeting
March 5, 2014
Atlanta, Georgia
Overview

- Improving the Impact of Laboratory Practice Guidelines and Recommendations
- Cytology Workload Study
- Educational Product Development and Distribution
- Clinical Decision Support
- Genetic Testing Reference Materials
- Laboratory Health Information Technology (LabHIT)
- CDC Library Exhibit: Assuring Laboratory Quality-CLIA History Exhibit
Improving the Impact of Laboratory Practice Guidelines

• The practice of clinical medicine and public health depends, in part, upon voluntary adoption of laboratory practice guidelines (LPGs).

• The 2011 IOM report “Clinical Practice Guidelines We Can Trust” called for more focus on increasing awareness & uptake.

• Little has been done to understand barriers and facilitators, especially so that LPGs could be better written and more easily adopted/adapted.

• DLPSS has initiated a cooperative agreement with CAP, ASM, and CLSI to create metrics to measure and improve how their LPGs are designed, disseminated and promoted.
Improving the Impact of Laboratory Practice Guidelines with Metrics

1. Identify Gaps

2. Creation/Revision

3. Dissemination & Promotion

4. Collect Data
   - Awareness
   - Adoption
   - Adaptation
   - Implementation
   - Impact

Data Collection & Analysis by Organization
Laboratory Practice Guidelines Metrics Projects

- Explore new ways to improve the impact of important LPGs
  - Using new metrics for each phase of the LPG life cycle
  - Quantitative (surveys) and qualitative (focus groups) metrics
  - Metrics should be appropriate to the organization and adopted long-term

- LPGs should be targeted, prioritized
  - What is the most important change and who needs to change?

- At the conclusion, awardees should institutionalize customized metrics-based approaches for their LPGs

- 5-year projects with Expert Panels to advise the work
Evaluation of Laboratory Practice Recommendations

• Evaluate the dissemination, implementation, and impact of
  • Practices to reduce blood sample hemolysis in emergency departments— an LMBP™ evidence-based recommendation. Cooperative agreement with Cleveland Clinic
  • BGT and NBS good lab practices —MMWR report (from CLIAC Workgroup). Cooperative agreement with APHL
  • Use the CDC logic model and framework for evaluation design
Cytology Workload Contract

- Awarded to ASCT Services, Inc.
- Two Year Contract
  - First year conduct a survey of all U.S. cytology laboratories
  - Second year conduct time measure study in selected laboratories that use one of the two approved imaging systems
    - Hologic Thin Prep Imaging System
    - BD Focal Point Guided Screening System
- Results will be used by CDC, CMS, and FDA to determine appropriate gynecologic cytology screening workload maximums using image-assisted devices
CDC/ASCT Services, Inc.
Opportunity to Participate in
Cytology Workload Practices Survey

The Centers for Disease Control and Prevention (CDC) has contracted with ASCT Services, Inc. to conduct an on-line survey of Cytology Workload Practices in early 2014.

We want you to participate! Here’s how: the survey link will be emailed to cytology supervisors and cytotechnologists. If you do not receive an email with the link and want to participate, the survey link will be available on the ASCT Services website.

This is a unique opportunity for cytotechnologists to contribute information that will be used to evaluate current workload requirements and develop guidelines for assessing cytotechnologist workload. Prizes for completing the survey are available!

For more information email:
workloadsurvey@asctservices.com

This survey is supported by a contract (200-2013-57614) funded by the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry.
Educational Product Development and Distribution

• “Good Laboratory Practices for Molecular Genetic Testing” (eMGT)
  o 46 states, 8 countries, CE data analysis
  o 50% improvement in pre- (60%) vs post-(90%) test scores

• “Strategies for Improving Rapid Influenza Testing in Ambulatory Settings” (SIRAS)
  o 4 modules, @ 30 min formats;
  o 1460 CE credits awarded ;
  o 31,944 views (specimen collection videos )

• LMBP™ modules (6 mo.update)
  o Overview of A6 Cycle method= 61/77(79%) completed
  o Quality Improvement study design = 160/252 (63%) completed

• Individualized Quality Control Plan workbook in development
Waived Testing Good Laboratory Practice Product Distribution

- Posters = 4,510
- Ready? Set? Test! Booklets = 16,615
- Postcards = 19,906
- To Test or Not To Test? Booklets = 5,635

http://wwwn.cdc.gov/clia/Resources/WaivedTests/
## Ready? Set? Test! Online Course Participation (Nov 2011-Feb 2014)

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Ready? Set? Test! Credit Type(s) Awarded: 0.1 CEU/CE; 1 CME; 1 CNE Contact Hours; 0.1 Pharmacist Contact Hours

http://www.cdc.gov/clia/Resources/WaivedTests/
Clinical Decision Support

- **Using PTT advisor**
  - As model algorithm for coagulation testing and mobile app
  - Design algorithms for new anticoagulants with different mechanisms of action (dabigatran, rivaroxaban, apixaban, etc)
    - Guide physicians in appropriate monitoring of patients
    - Incorporate professional society recommendations
Genetic Testing Reference Materials

- GeT-RM & NCBI collaboration = produced a web portal format of whole genome human sequence data from NGS
  - Two extensively characterized human cell lines, commercially available
  - Labs compare their data with the posted sequence through interactive functions
  - Supports new assay validation, quality control, proficiency testing
  - NIST will also add data to this portal

- DNA-based reference materials for
  - HLA markers
  - Drug metabolism / response markers (pharmacogenomics)
LabHIT Team & Communication in Informatics Vision:

Laboratory information contributes to optimized healthcare decision making.

Logic Model

Engagement
- Forum to Engage and Coordinate Laboratory Efforts
- Laboratorians Participate Early in EHR/HealthIT Planning
- Regulations and Guidelines Incorporate Lab Input

Interoperability
- Support Harmonization (SNOMED® & LOINC®)
- Harmonized Interfaces
- Meaningful Comparisons of Lab Information

Usability
- Explore Innovative Information Display
- Results Interpreted Correctly
- Adverse outcomes reduced

Laboratory information contributes to optimized healthcare decision making.
Engagement: Regulations and Guidelines

Incorporate Laboratory Input

- LabHIT Team reviewed and provided comments and sent LabHIT Alerts to liaisons for several announcements from the Office of the National Coordinator on Health Information Technology:
  - ONC Proposed Meaningful Use Stage 3 Regulations
  - ONC Proposed Patient Safety Action and Surveillance Plan
  - ONC Request for Information on Advancing Interoperability
  - ONC National Survey on Health Information Exchange in Clinical Laboratories
  - ONC Request for Comment on a Risk-Based Regulatory Framework and Strategy for Health IT
  - ONC SAFER Guides for EHR self-assessments

- Presentation at ASCP-API Annual Meeting (October 2013)
Interoperability: Meaningful Comparisons of Laboratory Information

- **Key Projects**
  - CLIA Test Report Profile for EHR Certification Tool
  - aLOINC Project – Standardize a set of orderable laboratory test names

- **Team supporting more than 12 workgroups developing structure and content standards for laboratory information**
  - HL7 Laboratory Order Interface (LOI)
  - HL7 Laboratory Results Interface (LRI)
  - HL7 Electronic Directory of Service (eDOS)
  - SNOMED
  - LOINC
  - HL7 Value Sets, including Ask at Order Entry Questions
On Deck for LabHIT

- **More workgroup opportunities**
  - Planning stage for HL7 Functional Behaviors Guide for Laboratory
  - Possible development of top LOINC result code set

- **Promote the Safety Assurance Factors for EHR Resilience (SAFER) Guides for EHR self assessment**
  - Test Results Reporting and Follow-up
  - Computerized Provider Order Entry
  

- **Promote reporting of EHR-laboratory related adverse events to Patient Safety Organizations**
CDC’s History Assuring Laboratory Quality

- Please visit the exhibit highlighting almost 50 years of CDC’s contributions to the CLIA regulatory program!
- Historical documents and memorabilia from CLIA’67 through the current era of CLIA’88 are on display in the CDC Library (1st floor, Roybal Bld. 19) through April 30, 2014.
For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

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