CDC Update

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CLIAC Meeting
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Atlanta, Georgia

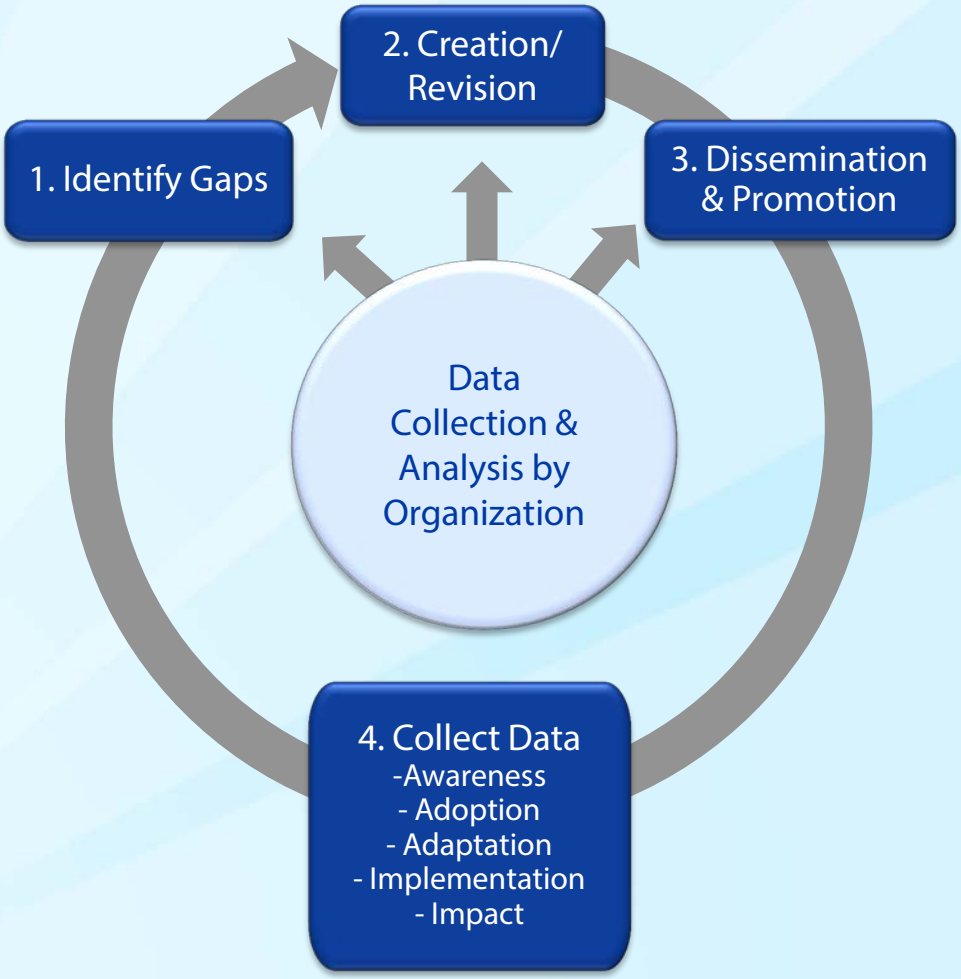
Overview

- 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



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

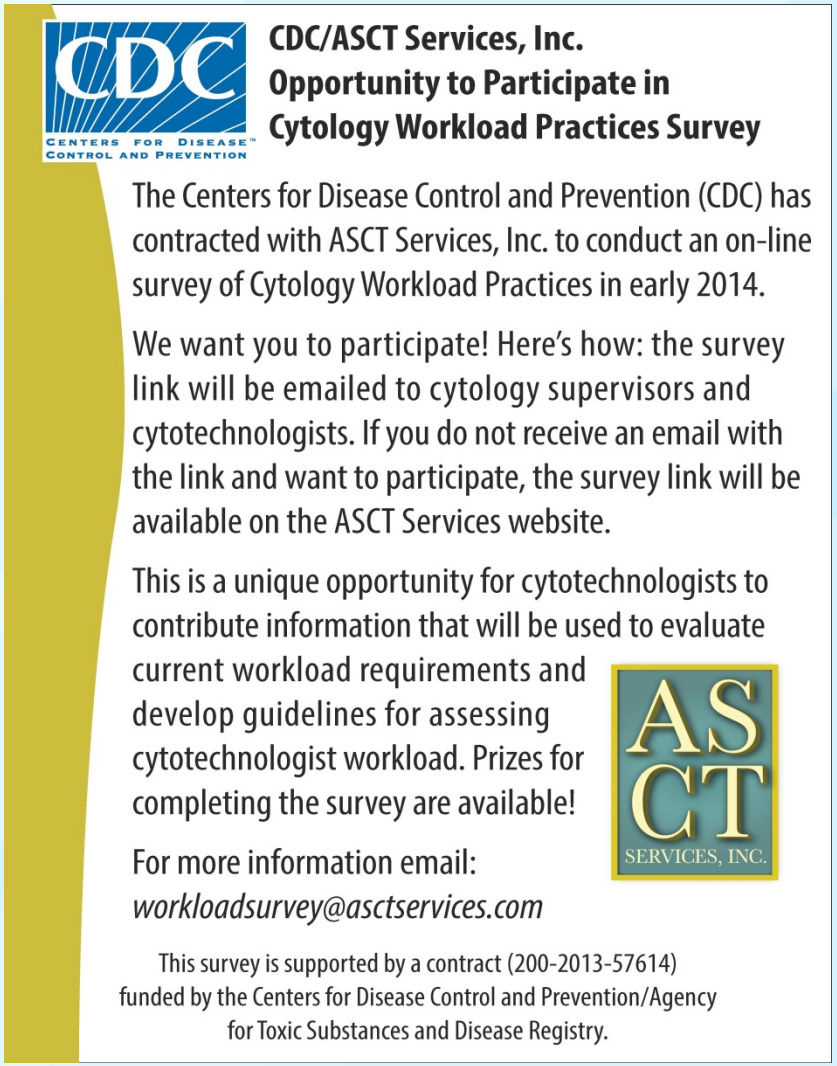
- **Awarded to ASCT Services, Inc.**
- **Two Year Contract**
  - First year conduct a survey of all U.S. cytology laboratories
  - Second year conduct time measure study in selected laboratories that use one the two approved imaging systems
    - Hologic Thin Prep Imaging System
    - BD Focal Point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

Marketing

Advance

ASC Bulletin

ASCT website and newsletter



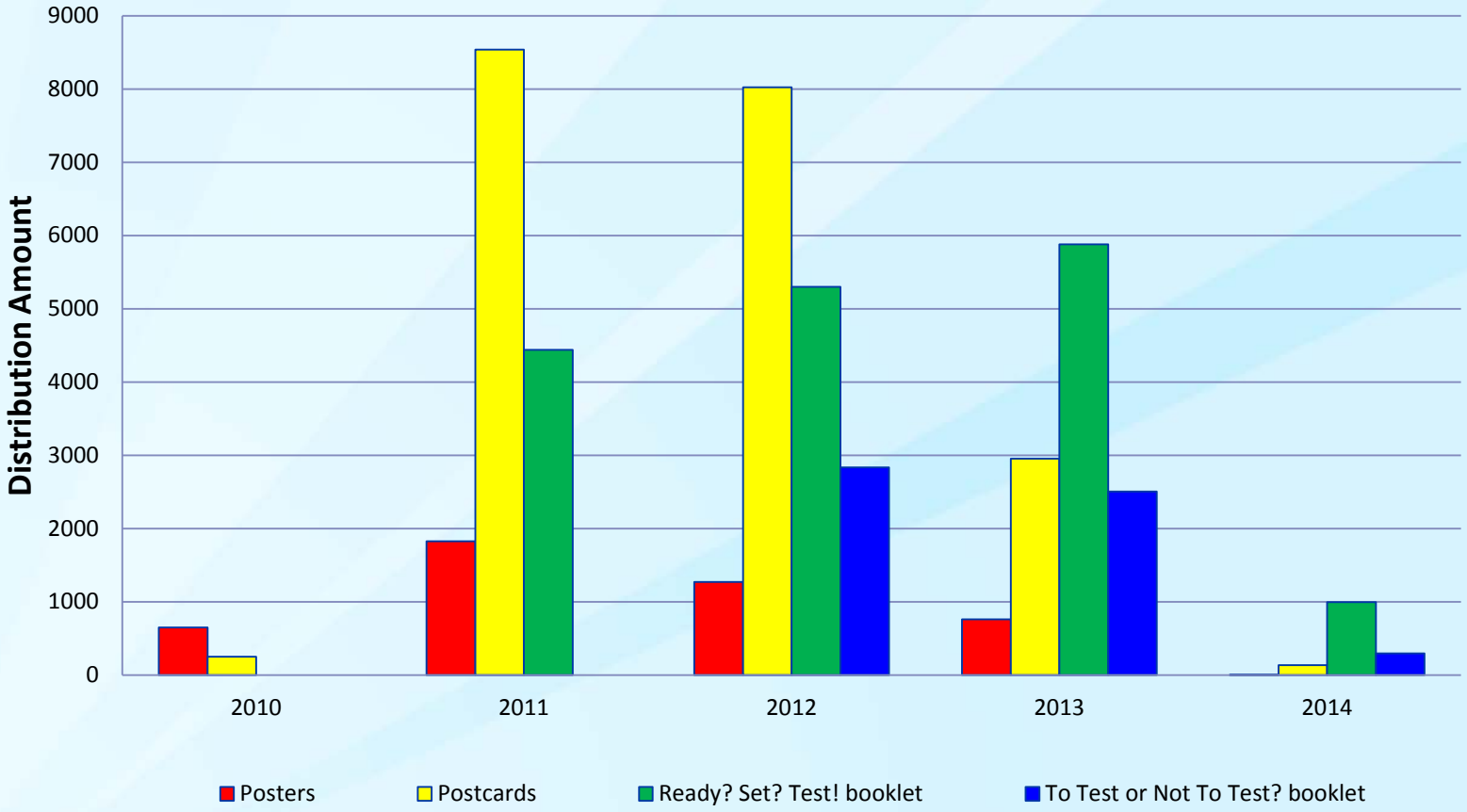
Educational Product Development and Distribution

- “Good Laboratory Practices for Molecular Genetic Testing” (eMGT)
  - 46 states, 8 countries, CE data analysis
  - 50% improvement in pre- (60%) vs post-(90%) test scores
- “Strategies for Improving Rapid Influenza Testing in Ambulatory Settings” (SIRAS)
  - 4 modules, @ 30 min formats;
  - 1460 CE credits awarded ;
  - 31,944 views (specimen collection videos)
- LMBP™ modules (6 mo.update)
  - Overview of A6 Cycle method= 61/77(79%) completed
  - 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 **Postcards=19,906**

Ready? Set? Test! Booklets=16,615 **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)

Total Registered	2648
Completed	2229
In Progress	364
Withdrawn	54

Credit Type	Total Hours Awarded
CEU/CE	102.7
CME	178
CNE Contact Hours	359
Pharmacists Contact Hours	4.0

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

http://wwwn.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

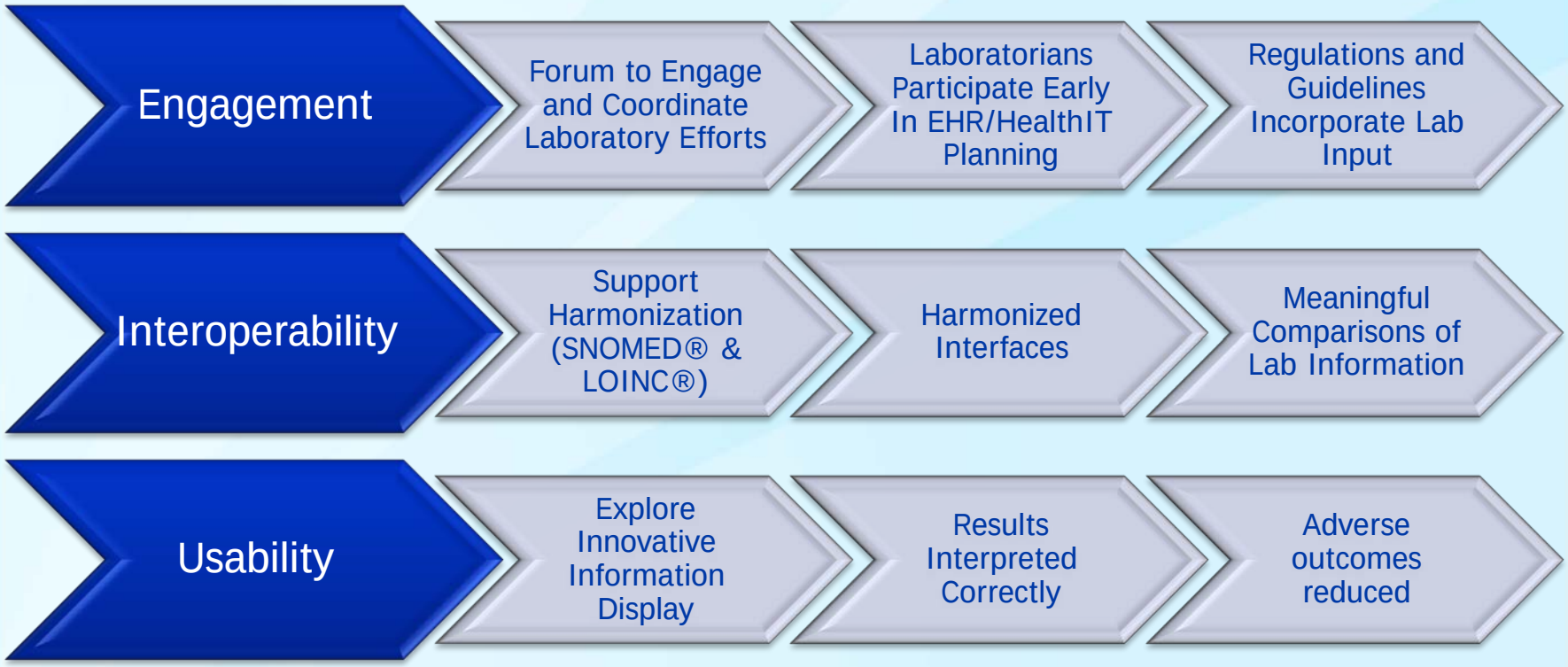
Genetic Testing Reference Materials

- **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: 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

  http://www.healthit.gov/policy-researchers-implementers/safer
- **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

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