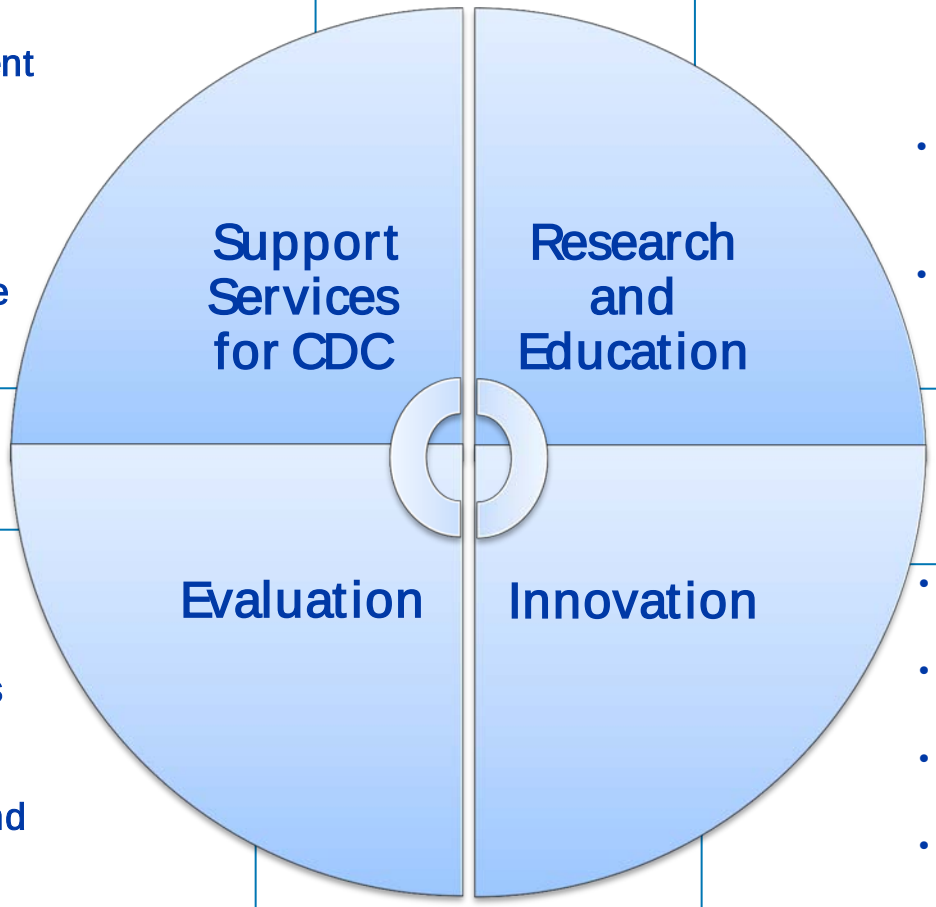
CDC Update

Barbara Zehnbauer, Ph.D.
Acting Director
Division of Laboratory Programs, Standards, and Services

CLIAC Meeting
November 5, 2014
Atlanta, Georgia

Division of Laboratory Programs, Standards, and Services

- Dual Use Research of Concern
- Specimen management (CASPIR)
- Instructional Design
- Training Distribution
- Web Broadcast
- CDC TRAIN Assistance



- Clinical laboratory and public health/healthcare integration
- Regulatory and voluntary standards development
- Training- public health and clinical workforce

- Measurement of training effectiveness
- Measurement of impact of laboratory practice guidelines and laboratory based continuing education programs

- Multimedia enhanced distance learning
- Clinical decision support
- Passive surveillance with CMS data
- Collaboratives for genetic testing (GeT-RM) and Next-Gen sequencing

DLPSS Role in Ebola Response

- **Advice on clinical laboratory issues, especially safety**
  - **“Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories,” 2012 MMWR**
  - **“Guidelines for Biosafety Laboratory Competency,” 2011 MMWR**
  - **Short videos demonstrating biosafety procedures**
  - **Provide information to the Emergency Operations Center (EOC) on hospital and laboratory capacity in the United States**
  - **Staff support of EOC triaging and responding to laboratory inquiries and assisting with on-site assessments**

DLPSS Part of CDC Laboratory Safety Efforts

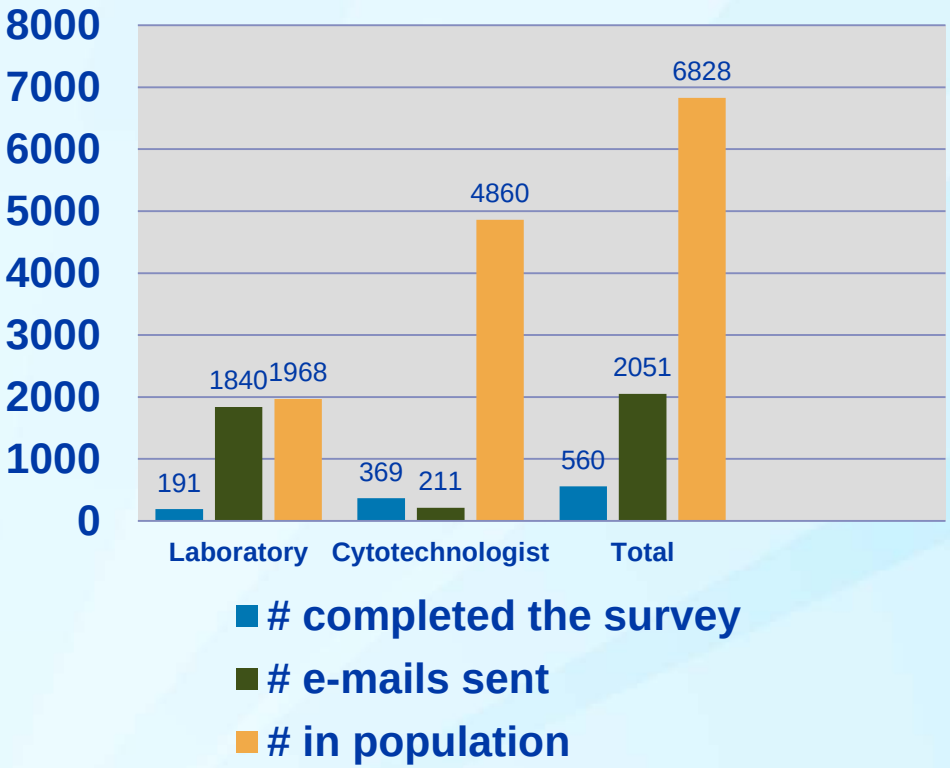
- CASPIR, “CDC and ATSDR Specimen Packaging, Inventory and Repository”
  - 6 million specimens (1/3 of CDC total), 650 collections
  - Redundant IT accession systems, with bar coding
  - CSELS has taken a systems approach
  - During sweep process, added signed attestations for 125 custodians
  - Objective analysis of inventory data
- Training
  - Inventory of existing training for safety emphasis and specifics
  - Design new internal CDC training

Cytology Workload Assessment and Measure Contract

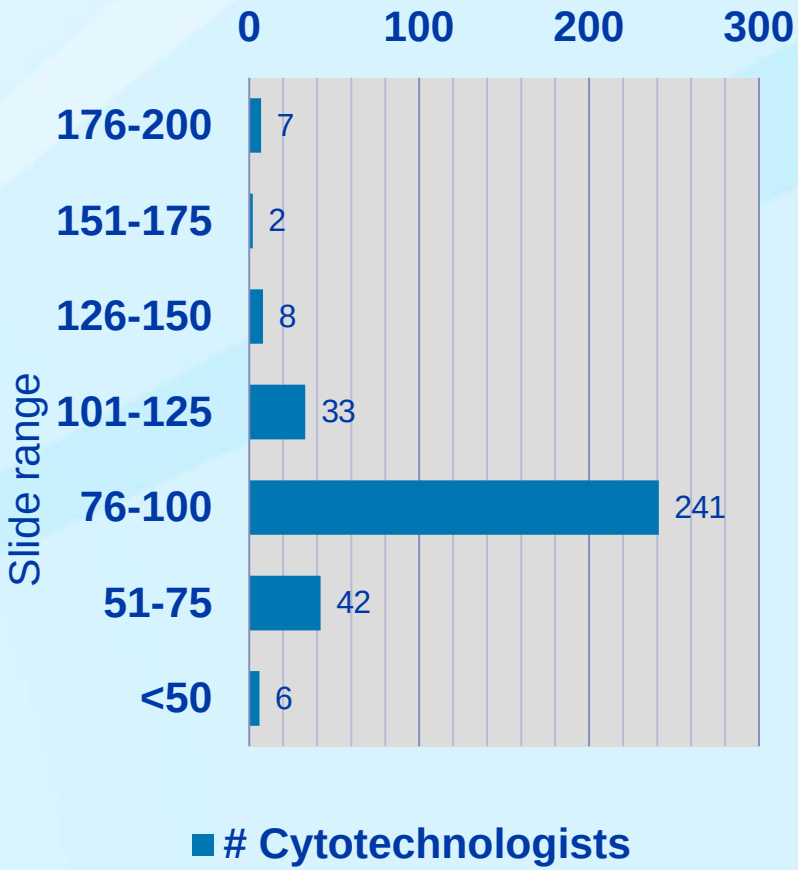
- **CDC awarded a two year contract to American Society for Cytotechnology Services, Inc.**
  - 2014 - Conduct the national survey
  - 2015 - Conduct time measure study of individuals using image-assisted screening devices in their workplace for a full 8-hour workday
- **Assessment of survey of workload practices emailed to 2,051 laboratories**
  - 76 laboratories (501 FTEs) that completed the survey indicated an interest in participating in time measure study (50% of these are large laboratories)
  - Most laboratories report the same maximum workload amount for all cytotechnologist in the laboratory
  - Individuals working in large laboratories screen for more hours in the day and screen higher numbers of slides
  - Supervisors more likely than cytotechnologists to be familiar with laboratory policy describing how individual workload is determined
  - Laboratories use a variety of metrics to count sides for workload

Year 1: Survey Laboratories and Cytotechnologists

Participation in Survey



Reported Workload Slide Maximum



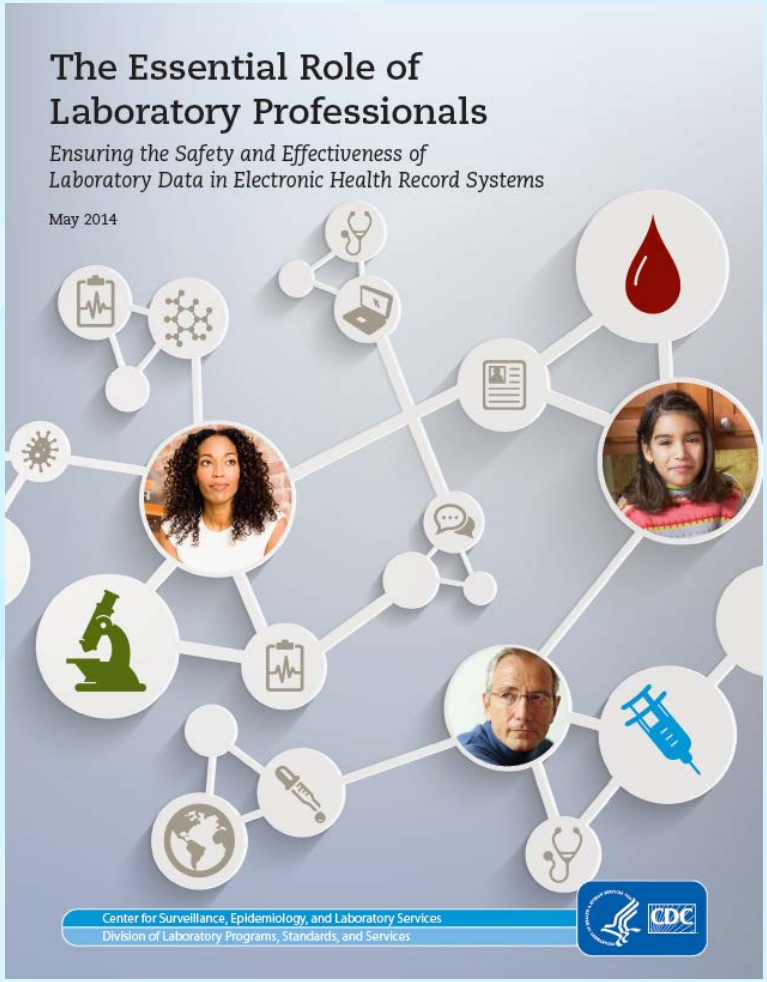
The majority of laboratory e-mails addresses were obtained by solicitation of interest at meeting sites and from state societies.
Cytotechnologist completing the survey may have received a forward and not be counted in the # e-mails sent

LabHIT Report: *Ensuring the Safety and Effectiveness of Laboratory Data in EHRs*

- **Includes**
  - Focus Areas for Action
    - Engagement
    - Data Integrity and Usability
    - Innovation
  - Informed by Communication in Informatics Workgroup, recommended by Clinical Laboratory Improvement Advisory Committee (CLIAC)
- **Announcement in**
  - May 16, 2014

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report

- **Download**
  - http://www.cdc.gov/labhit



*a*LOINC Order Code Initiative

- **Accomplishments**
  - Developed document on “How to Deal with the Variations in Orderable Panels”
  - Developed document “Business rules for Comparing a User Panel to a LOINC Panel”
  - Analyzed volume data to determine the most commonly ordered laboratory tests
  - Public Health Subworkgroup develop list of test commonly ordered by provider through public health agency

Progress Toward a Proposed Rule for Proficiency Testing

- Identified candidate analytes and changes to propose for microbiology
  - Based upon a process using criteria recommended by CLIAC
  - Vetted with all PT programs
- Developed proposed acceptance limits (AL) for PT program simulation
  - For new and some existing analytes
  - Error goals based on biological variability
  - 2 or 3 limits were simulated per analyte by PT programs using real PT results from 2011-12, peer grouped as usual
  - CDC will analyze data with statistical modeling to propose ALs

LPG Metrics
Cooperative Agreement Projects

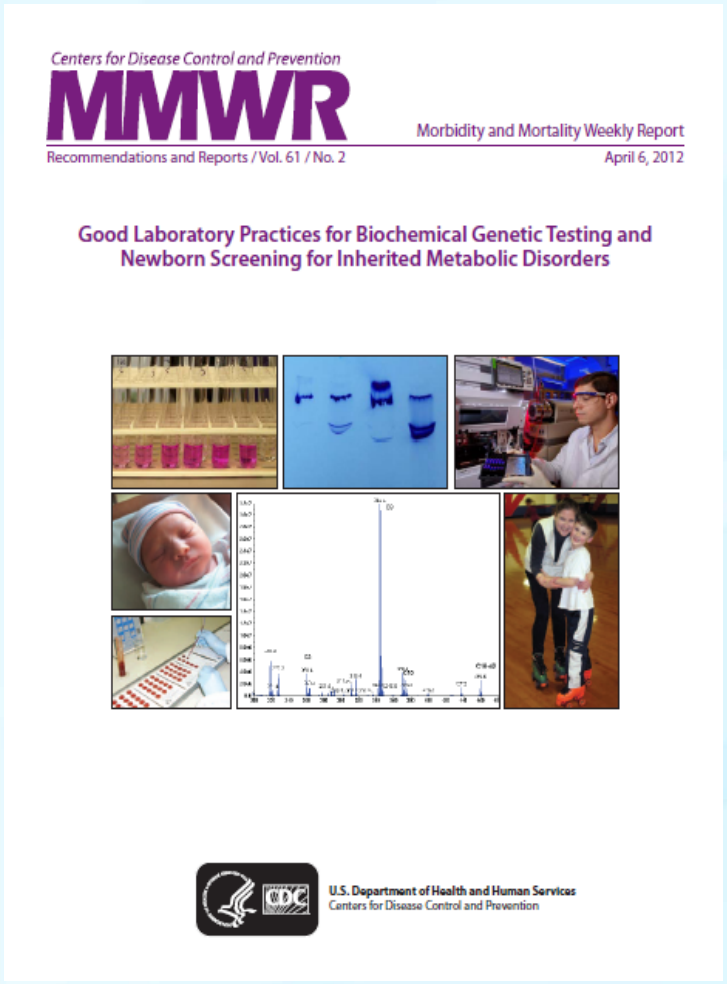
Partners have identified LPGs, assembled expert panels, and finalized their first survey questionnaires

- ASM
  - Early detection of sepsis
  - Reduce blood culture contamination
- CLSI
  - POC Glucometer testing in hospitals (POCT12) and remote sites (POCT13)
- CAP
  - Immmunohistochemistry Validation
  - Acute Leukemia Algorithm

LPG Metrics
Cooperative Agreements Projects

- **DLPSS is providing support**
  - Regular conference calls with all three partners to exchange information and provide training
  - Training on focus groups
  - Statistical consultation
  - Introducing users to Epi Info 7, a free tool for surveying & analysis
  - OMB clearance
  - Toolkit for other organizations

Evaluating Impact of Laboratory Practice Guidelines and Recommendations



- Cooperative Agreement with APHL, July 2013
- Limited data on advances in quality improvement
- Use: New testing, QMS, LDT, Personnel qualifications
- Limitations: Difficult to implement & understand
  - Next Steps:
    - Training
    - Metrics to assess changes in practice
    - Case studies
    - Kirkpatrick training evaluation model
    - Disseminate guideline, training and CE activities

APHL-CDC Report

- Published Oct. 2014:
  - APHL website: www.aphl.org
  - CDC/DLPSS website: http://www.cdc.gov/ophss/csels/dlpss/index.html

Improving Newborn Screening Preanalytic Activities through Electronic Birth Notification

- Co-operative Agreement with APHL - Oct. 2014: MT, IN
  - Pilot a surveillance network: integrate birth notification with specimen collection, submission, and transport
  - Goal: improve timeliness and quality of NBS pre-analytic phases

Laboratory Medicine Best Practices (LMBP™)

- Ongoing activities
  - Evaluate effectiveness of implementation of LMBP™ recommendations to reduce blood sample hemolysis
  - Collaboration with ASM (systematic reviews and evaluation impact of recommendations)
  - 2 contracted systematic reviews
- LMBP™ educational modules
  - 547/834 (66%) completed as of 9/2014
  - 88% can apply knowledge gained

NGS data standards

Collaboration with State of Virginia Genomics Workgroup (of HIE) and CDC Cancer Surveillance Branch

- Pilot project to message genomic data across HIE to central cancer registry
- Clinical case simulations developed
- Query and retrieval by healthcare providers

Genetic Testing Reference Materials (Human)

In progress:

- 7 HLA loci – 109 cell lines
- 28 pharmacogenetic loci – 137 cell lines

In development:

- Solid tumor reference materials for molecular oncology testing

Clinical Decision Support

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™)

- Laboratory test selection algorithms - Coagulation testing
  - Targeting clinical conditions (VTE, DVT, PE, etc.)
  - Including new anti-coagulants
  - Mobile application delivery

Test Utilization Trends

- Study possible influence of test recommendations
  - MarketScan commercial claims and encounter
  - Medicare supplemental database
- Model = PSA testing

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
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