CDC Update

Barbara Zehnbauer, Ph.D.
Acting Director
Division of Laboratory Systems

CLIAC Meeting
April 15, 2015
Atlanta, Georgia
Division of Laboratory Systems

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

- 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

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

Support Services for CDC
Research and Education
Evaluation
Innovation

Innovation Evaluation Support Services for CDC Research and Education
DLS Role in Ebola Response

- Advice on clinical laboratory issues, especially safety
  - Support laboratories, clinical and public health, both at home and abroad
  - Coordinate with CDC Emergency Operations Center laboratory teams
  - Videos demonstrating biosafety procedures
  - Amer. Biol. Safety Assoc. certified staff supports triage/ response to inquiries from laboratories and field epidemiologists
DLS and CDC Laboratory Safety Efforts

- Supporting Laboratory Safety workgroup recommendations
  - Creating improved laboratory training in
    - Safety and quality management
    - Competency-based curriculum
  - Laboratory Leadership Service fellowship – CSELS/DLS & DSEPD
- External accreditation for all CDC laboratories
  - CLIA for clinical labs; ISO17025 for research labs
- CASPIR, “CDC and ATSDR Specimen Packaging, Inventory and Repository”
  - Advancing improved IT accession systems, with bar coding
  - Revising specimen collection
Promoting Good Laboratory Practices for Waived Testing - Update to 2014 CLIAC Recommendation

- Development of a voluntary self-assessment checklist-type tool based on recommended practices in the “Ready? Set? Test!” booklet

- Updates being made to “Ready? Set? Test!” and “To Test or Not To Test?” booklets to address off-label use of waived tests
Distribution of Waived Testing Educational Products

Waived Testing Good Laboratory Practice Product Distribution
Posters=4,633  Postcards=21,144  Ready? Set? Test! Booklets=21,145  To Test or Not To Test? Booklets=7,322


<table>
<thead>
<tr>
<th>Course Registration</th>
<th>Credit Type</th>
<th>Total Hours Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Registered</td>
<td>CEU/CE (0.1 hours)</td>
<td>127.1</td>
</tr>
<tr>
<td>Completed</td>
<td>CME (1.0 hours)</td>
<td>234</td>
</tr>
<tr>
<td>In Progress</td>
<td>CNE Contact Hours (1.0 hours)</td>
<td>397</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>Pharmacists Contact Hours (0.1 hours)</td>
<td>6.3</td>
</tr>
</tbody>
</table>

http://wwwn.cdc.gov/clia/Resources/WaivedTests/
Ready? Set? Test! Online Course

- Free training based on booklet promoting good laboratory practices for waived testing
- Includes knowledge checks and realistic waived testing scenarios to reinforce learning
- Templates, checklists, resources to save/download
The content was relevant to the learning objectives

I can identify at least two good laboratory practices for recording and reporting results

I can identify at least two good laboratory practices for testing

I can identify properly labeled patient samples

I can identify at least two good laboratory practices to ensure the right sample type is obtained from the correct patient

I can identify three or more good laboratory practices to prepare my laboratory or testing site to produce high quality test results

I can identify the basic requirements for performing waived testing

If given an opportunity, I can apply the knowledge gained as a result of this activity
Cytology Workload Assessment and Measure

- **Purpose** – evaluate gynecologic cytology workload requirements for cytotechnologists using image-assisted devices

- **American Society for Cytotechnology Services, Inc.** – onsite observations of image-assisted screening in 8-hour workday

- **Status of Time Measure Study**
  - 71 Laboratory Observations of Cytotechnologists to be completed by 4/30/2015 – need 29 more volunteers
  - To participate, contact: Timemeasure@asctservices.com
Workload Assessment Project Next Steps

- Partnering with schools of cytotechnology to collect student data to estimate expected workloads for newly trained employees
- CDC will provide a copy of time measure tool to each school that participates
- Students in their last month of training will participate
- CDC will collect and analyze all data
- Compare data to ASCT contracted data
- Target date to begin May 2015
Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™)

- **CDS Tools**
  - Vetting new coagulation test selection algorithms
    - New anticoagulants
    - Interruption of treatment
    - Reversal of anticoagulation
    - Targeting specific conditions (VTE, DVT, PE, etc.)

- **Mobile applications**
  - CDC GA Tech Seed Grant
    - Translating coagulation algorithms to mobile app
  - Evaluating Mobile Application CDS utility
    - PTT Advisor app
    - Veteran's Administration hospital physicians - pilot
CLIHC™ Projects

- Emory Medical Quality Improvement
  - Survey Emory clinicians to better understand their laboratory test nomenclature challenges and solutions

- Education
  - A ‘Dueling Docs’ scenario based skit highlighting importance of clear communication for appropriate laboratory test utilization is being developed for the CLIHC website

- Partnerships
  - Institute of Medicine (IOM): Diagnostic Errors in Health Care – Report expected 2015 with laboratory focus
  - Society to Improve Diagnosis in Medicine (SIDM) Coalition to Improve Diagnosis
  - CLMA’s Increasing Clinical Effectiveness (ICE) coalition
  - Coordinating Council on the Clinical Laboratory Workforce (CCCLW)’s Measuring Value Initiative
Laboratory Practice Guidelines (LPG) Metrics Projects

Project Goals

- Improve uptake and use of LPGs
- Identify gaps in awareness/use
- Partners develop surveys to better understand gaps and strategies to address them
- Use AGREE II tools to assess quality of representative LPGs to learn how to improve them

CDC will create a clearinghouse to promote use of LPG Metrics

- Survey design/sampling
- Focus groups
- IOM reports and related research
LPG Metrics Awardees’ Projects

- **Clinical and Laboratory Standards Institute**
  - Evaluate awareness, distribution, and utility of two POC glucose monitoring (GM) LPGs for sites with (POCT 12) and without (POCT 13) laboratory support
    - LPGs chosen because both documents are relatively unknown by most of the ~85,000 testing sites

- **College of American Pathologists**
  - Immunohistochemistry (IHC) Assay Validation
    - Follow-up survey to CAP 2010 assessment
    - IHC labs to include CAP and Non-CAP PT customers
  - Acute Leukemia Algorithm
    - Joint LPG with American Society of Hematology
    - 2016 Acute Leukemia Practices and Procedures Pre-Survey will provide the baseline data to measure uptake of the published LPG
LPG Metrics
Awardees’ Projects

- **American Society for Microbiology**
  - Evaluate effectiveness of four evidence-based recommendations (LMBP™)
    - Reduction of Blood Culture Contamination
    - Rapid ID of Bloodstream Infections
    - Proper Handling of Urine Specimens
    - Laboratory diagnosis of *C. difficile* colitis
  - Initial assessment of these LPGs by survey
    - Laboratory Response Network (LRN) to disseminate survey links
      - May establish use of LRN for surveys of sentinel clinical labs
      - Enhance public-private linkages in the states
Newborn Screening (NBS) Laboratory Testing

- **Improve NBS** - integrate birth notification with NBS specimen collection, submission, transport, process tracking to improve timeliness & quality

- **Current milestones:**
  - MT: Established 2-way messaging system between state NBS lab and birthing facility
  - IN: 3 large hospital systems + 4 additional hospitals participating; birth notification/filter paper card match rates being analyzed
Systematic reviews in progress:

- **Laboratory Test Utilization**: What practices can Labs use to support and optimize appropriate Lab Test Utilization (the right test for the right patient at the right time?)
  - Practices to assess:
    - Computerized Physician Order Entry (CPOE), CDS, education, feedback, test review, lab test utilization teams, reflex testing
  - Results pending at discharge
  - Specimen rejection
LMBP™ ASM
Systematic reviews collaboration

- **Completed**
  - Blood Stream Infection, Rapid Identification Methods
  - Urine Specimen Handling Collection and Transport

- **New**
  - *Clostridium difficile* – 4 focus areas:
    1. Highest diagnostic accuracy testing algorithms
    2. Increased diagnostic yield for repeat of enzyme immunoassay (EIA) or nucleic acid amplification testing
    3. Clinical utility of toxigenic culture and cytotoxin assay
    4. Clinical utility of PCR-positive and cytotoxin-/EIA-negative results
- ~700 cell lines for > 25 human genetic disorders characterized and publicly available
- **New**: HLA Loci and expanded pharmacogenomics haplotype characterized
  - Formed international workgroup to harmonize nomenclature and assay design
Standards for Next-Generation Sequencing in Clinical Laboratories

- **CDC-facilitated national workgroups**
  - “Design and Optimization of a Next-Generation Sequencing Informatics Pipeline” (in press, Nature Biotechnology)
  - A Clinical Grade Variant Template as a model for Sharing Genomic Data generated within the clinical laboratory (e.g., for external quality assurance, to outsource analysis, etc.) (manuscript in preparation)

- **IOM Action Collaborative** (Roundtable on Translating Genomic-based Research for Health)
  - Developing Guiding Principles for Integrating Genomic Information Into the Electronic Health Record Ecosystem
CDC Laboratory Training Website
http://www.cdc.gov/labtraining/

- Access to over 50 Online Courses
- Access to live course schedules and announcements
- Course Listings section lists all courses available from the CDC Laboratory Training Group
- Select a Course Format Tab
- Select a Course Topic
Highlighted Training

• **The Methods of Antimicrobial Susceptibility Testing Educational Resource (MASTER)**

• **Basic Microbiology Blended Learning Curriculum**
  - Self-study eLearning modules for didactic course content
  - Locally mentored hands-on exercises for experiential course content.

• **Preparedness**
  - Sentinel Laboratory “Rule out or Refer” Training
  - Sentinel Laboratory “Rule out or Refer” Training Virtual Knowledge Assessment
  - “Packaging and Shipping of Division 6.2 Materials”
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.