CDC Update

Devery Howerton, PhD
Director, Division of Laboratory Science and Standards

CLIAC Meeting
August 29, 2012
Atlanta, Georgia
Outline

- Recognition of CLIAC’s 20 years of service
- Cytology workload workgroup meeting
- Proficiency testing update
- Genetic testing guidance
- Quality improvement research agenda
In Recognition of the 20th Anniversary of the Clinical Laboratory Improvement Advisory Committee
CLIAC Duties Listed in Current Charter

Provide scientific and technical advice to CDC, FDA, CMS on

- Specific questions related to possible revision of the CLIA standards including
  - Impact of proposed revisions to the standards on medical and laboratory practice
- General issues related to improvement in clinical laboratory quality and laboratory medicine
  - Studies designed to improve laboratory services
  - Provision of non-regulatory guidelines to accommodate technological advances such as
    - New test methods
    - Electronic submission of laboratory information
CLIA Regulatory Timeline

Statute enacted

Proposed rule

Final rule with comment

First CLIAC meeting

Transfer test categorization from CDC to FDA

Interpretive guidelines published

Cytology PT proposed rule


Test categorization lists

Provider Performed Microscopy created

Proposed requirements for waived testing

Proposed rule for patient access to results

Final rule revising technical standards

Cytology PT proposed rule withdrawn

NOTE: Over 50 FR Notices/regulations published related to CLIA
Committee at First Meeting: October 28-29, 1992
CLIAC 1992 - 2012

- 46 CLIAC Meetings through 2012
- 7 Subcommittee Meetings
- 15 Workgroup Meetings
- Examples of Topics Addressed

  Assisted Reproductive Technology  Proficiency Testing
  Bioterrorism  Quality Control/Quality Assurance
  Cytology (includes Cytology PT)  Survey Data/Information
  Direct Access Testing  Test Categorization
  FDA Clearance/Approval Process  Unregulated Test Systems
  Genetics  Waiver
  Personnel  Electronic Health Records
  Point of Care/Physicians Office Laboratories  IQCP
CLIAC Members and Chairs

- **Chairs**
  - Dr. Toby Merlin – May 1999 to March 2003
  - Dr. David Sundwall – Sept. 2003 to Feb. 2005
  - Dr. Paula Santrach – Current Chair since Feb. 2012

- **Members**
  - 20 current
  - 116 total as of August 2012
  - 4 industry liaisons
Dr. Regina Benjamin, U.S. Surgeon General
CLIAC Member
1994 to 1999
Impact of CLIAC Recommendations

- Changes to CLIA regulations
  - Quality control
  - Personnel
  - Provider-performed microscopy
  - Test categorization
  - Proficiency testing

- Voluntary standards/guideline development
  - CLSI M50: Quality Control for Commercial Microbial Identification Systems
  - CDC MMWR Publications
Impact of CLIAC Recommendations

- CDC MMWR Publications
  - MMWR - Good Laboratory Practices for Waived Testing Sites
  - MMWR - Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions
  - MMWR - Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders

- Development of educational material for good laboratory practices (posters, booklets, online training)
Clinical Laboratory Improvement Advisory Committee
February 2012

First Row - Left to Right: Dr. Linda Sandhaus, Dr. Devery Howerton (CDC Ex Officio Representative), Dr. Paula Santrach (Chair), Dr. May Chu (Designated Federal Official), Dr. Anand Dighe, Dr. Alberto Gutierrez (FDA Ex Officio Representative);
Second Row: Dr. David Wilkinson, Dr. Anthony Okorodudu, Dr. Robert Sautter, Ms. Karen Lacy, Dr. Judy Daly, Dr. Christine Bean, Dr. Paul Kimsey, Ms. Julie Gayken, Rev. Eugene Augustine, Jr. (Consumer Consultant), Dr. John Fontanesi;
Third Row: Ms. Andrea Murphy (Management and Program Analyst), Ms. Nancy Anderson (Executive Secretary), Dr. Linda Ward, Dr. Robert Baldor, Mr. Robert Di Tullio (AdvaMed Liaison Rep.), Dr. Martha Crenshaw, Dr. Rosemary Zuna, Dr. Edward Chan;
Not Present: Dr. Jeffrey Kant, Dr. Gail Vance, Ms. Judy Yost (CMS Ex Officio Representative)
CLIAC Website Updates

- 2013 CLIAC Member Nominations
  - Submit potential candidates for consideration by October 1, 2012
    - Note that not all candidates may be selected at this time, but will entered into a database for the future
    - Nomination slate depends on outgoing expertise and demographic balance required for Federal Advisory Committees
  - Provide candidate name(s), contact information, credentials and expertise
  - Send information or questions to CLIAC@cdc.gov
- Sign-up for CLIAC email notices
- Download of meeting presentation PDFs now available for mobile devices
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Workload in Image-Assisted Gynecologic Screening Workgroup

- Consultative meeting held August 15-16, 2012
- Sponsored by CDC and hosted by the FDA
- Participants included
  - Cytopathologists
  - Cytotechnologists
  - Cytology Screening Device Manufacturers
  - CDC, CMS, and FDA staff
Workgroup Roster

- **Workgroup Members**
  - Tarik Elsheikh, MD – Chair
  - William Crabtree, PhD, SCT (ASCP) – Co-chair
  - George Birdsong, MD
  - John Fontanesi, PhD
  - Gary W. Gill, CT(ASCP)
  - Ronald Luff, MD, MPH
  - Fern Miller, MSM CT(ASCP)
  - Janie Roberson, SCT(ASCP)
  - Thomas H. Roberts, MD
  - Brenda L. Schultz, SCT(ASCP)

- **Image-assisted Screening Device Manufacturers**
  - Karen Atkison and Mark Sistare, PhD - BD Diagnostics
  - Mark Kieras and Suzanne Werneke - Hologic, Inc
Workgroup Charge

- Provide input to CDC, CMS, and FDA on the challenges associated with establishing a maximum workload limit for individuals that screen Pap smears utilizing semi-automated screening devices, and suggestions for how to obtain data to determine the maximum workload limit. Topics addressed will include:
  - Definition of slide “screening time” when performing semi-automated cytology screening
  - Operational study design for collecting data and information that can be used to determine the maximum workload limit when using semi-automated screening devices. (See next slide for details)
  - Guidance on the best methods for calculating and monitoring individual and general laboratory workload limits.
Workgroup Charge – Operational Study Design

Input will be solicited from workgroup members regarding:

- Study questions
- Criteria for evaluating various workload limits, e.g., the accuracy of screening at various screening speeds and the laboratory’s percentage of abnormal cases
- Criteria for screening time for a full 8 hour workday, portions thereof, and maximum hours of gynecologic screening per 24 hours.
- Guidelines for exclusion of non-screening time (data entry, QA responsibilities, preparation of slides, etc.) from 8 hour workday
- Practical approaches for data and information collection
- Potential study partners
Meeting Outcome and Next Steps

- Workgroup participants provided input on items identified in Charge
- CDC, CMS, and FDA will assimilate workgroup suggestions and develop a feasible study plan
- CDC will solicit a proposal and fund a study
- Additional input may be solicited from workgroup experts
- CLIAC will be kept informed of progress and additional advice or recommendations may be sought at future meetings
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## Proficiency Testing (PT) Update

### CLIA rule revision accomplishments to date

<table>
<thead>
<tr>
<th>Period</th>
<th>Accomplishments</th>
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<tbody>
<tr>
<td>Fall 2010</td>
<td>CLIAC recommends 23 potential changes</td>
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<tr>
<td>Spring 2011</td>
<td>CDC developed a framework for inclusion of analytes/tests</td>
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<tr>
<td>Winter 2011</td>
<td>CDC compiled list of proposed analytes/tests to be added or removed, changes needed for microbiology</td>
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| Spring 2012| CDC and CMS met with PT programs for consultation on proposed analyte changes, grading, and potential changes to microbiology PT  
  - Narrowed the list of potential new analytes/tests based on feedback concerning cost, stability, scoring issues, etc. |
| Currently  | CDC is developing proposed acceptance limits  
  - Based on PT programs’ data and/or biological variability  
  - Proposed limits will be tested and fine-tuned, in collaboration with PT programs |
PT Update: Laboratory Survey

- Internet-based survey targeting CLIA-certified laboratories that participate in PT
  - 20,500 Certificate of Compliance and 16,200 Certificate of Accreditation laboratories

- Purpose: systematic analysis to understand
  - How laboratories use PT for quality monitoring and improvement
  - PT practice variation by laboratory types
  - Need for educational materials to promote good PT practices

- Survey has been developed and pilot tested
- Proceeding with OMB clearance and anticipate a Spring 2013 launch
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Genetic Testing Guidance

- MMWR publication April 6, 2012: “Good laboratory practices for biochemical genetic testing and newborn screening for inherited metabolic disorders”

- Web-based training course on good laboratory practices for molecular genetic testing for inherited disorders:
  - just released!
  - available at the following site: [www.nltn.org/321-12.htm](http://www.nltn.org/321-12.htm)
  - link is also available on CDC website: [http://wwwn.cdc.gov/clia/default.aspx](http://wwwn.cdc.gov/clia/default.aspx)

- Guidance on technical aspects of quality management using next generation sequencing: publication in review
Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders

Recommendations and Reports

Clinical Laboratory Improvement Advisory Committee

Chairperson: Carol L. Greene, MD, University of Maryland School of Medicine, Baltimore, Maryland.

Members: Bruce Balzar, MD, PhD, University of California — San Diego; Rady Children’s Hospital, San Diego, California; Michele Caggana, ScD, New York State Department of Health, Albany, New York; Joel Charrow, MD, Children’s Memorial Hospital, Chicago, Illinois; Tina Cowan, PhD, Stanford University Medical Center, Stanford, California; Harry Hanson, PhD, Atlanta, Georgia; Julie Ann Naude, MD, Quest Diagnostics — Nichols Institute, San Juan Capistrano, California; Stephen Rash, MD, University of Colorado Denver, Aurora, Colorado; David L. Smallay, PhD, Tennessee Department of Health, Nashville, Tennessee; Erin Smool, PhD, University of Maryland School of Medicine, Baltimore, Maryland; Vicki Saltos, MD, Baylor College of Medicine, Houston, Texas; Georgette D. Vladutiu, PhD, The Buffalo General Hospital, Buffalo, New York; Emily S. Wines-Dunn, PhD, RdDx Advisors, Livermore, California.

Clinical Laboratory Improvement Advisory Committee (2010–2011)

Chairperson: Elissa Paumier, EdM, American Society for Clinical Laboratory Science, Bethesda, Maryland.

Members: Ellen Barlow, PhD, Stanford University Medical Center, Palo Alto, California; Christine Stea, PhD, New Hampshire Department of Health and Human Services, Concord, New Hampshire; Susan Cohen, Bethesda, Maryland; Judy Daly, PhD, Primary Children’s Medical Center, Salt Lake City, Utah; Nancy Elder, MD, University of Cincinnati, Cincinnati, Ohio; Marilyn D. Francis, The MITRE Corporation, McLean, Virginia; John Fournier, PhD, University of California — San Diego, School of Medicine, San Diego, California; Jule Gayken, HealthPartners and Regions Hospital, Bloomington, Minnesota; Geraldine Hall, PhD, Cleveland Clinic Foundation, Cleveland, Ohio; Carol L. Greene, MD, University of Maryland School of Medicine, Baltimore, Maryland; Norman Harbaugh, Jr., MD, Kids Health First Pulmonary Allergy, Atlanta, Georgia; Lee H. Hillman, MD, David Geffen School of Medicine at University of California — Los Angeles, Los Angeles, California; Paul Kinney, PhD, California Department of Public Health, Richmond, California; James Nichols, PhD, Baylor College of Medicine, Spring, Texas; Minute Maid, New Mexico; Gary Overdorf, MD, University of New Mexico School of Medicine, Albuquerque, New Mexico; Stephen Rash, MD, University of Colorado Denver, Aurora, Colorado; Rebecca, MD, Case Western Reserve University Hospitals and Medical Center, Cleveland, Ohio; Paula Santrach, MD, Mayo Clinic, Rochester, Minnesota; James N. Schwartz, MD, Piedmont HealthCare, Charlotte, North Carolina; David L. Smallay, PhD, Tennessee Department of Health, Nashville, Tennessee; Carl Van, MD, Indiana University School of Medicine, Indianapolis, Indiana; Emily Wines-Dunn, PhD, RdDx Advisors, Livermore, California; Rosemary Zuna, MD, The University of Oklahoma Health Science Center, Oklahoma City, Oklahoma.

Designated Federal Officials: Thomas L. Hoots, PhD, National Center for Emerging and Zoonotic Infectious Diseases, May, CDC, Office of Surveillance, Epidemiology, and Laboratory Services, CDC, Atlanta, Georgia.

Ex-Officio Members: Albertos Castaneda, PhD, Centers for Disease Control and Prevention, Rockville, Maryland; Judith Yost, MA, Centers for Medicaid & State Operations, Centers for Medicare & Medicaid Services, Baltimore, Maryland; Dewey Howerton, PhD, Office of Surveillance, Epidemiology, and Laboratory Services, CDC, Atlanta, Georgia.

Liaison Representatives: Laron Cole, MS, Advanced Medical Technology Association, Washington, DC.
Feedback from MMWR
Continuing Education Activity

- Participation to date:
  - Registered: 107
  - Completed: 69 (43% CEU, 33% CNE, 16% CME, 6% CHES)

- General comments and suggestions:
  - “The contents were very helpful”; “informative”; “excellent”; “great learning experience”; “keep up the great work”
  - “Would have liked to see more information on how to explain the lab practices for genetic testing/newborn screening in easier terms to patients/parents”
  - “a lot to absorb”; “hard to read”
  - “make it worth more CE hours”; “make the CE activity system more user-friendly”
Feedback from MMWR Continuing Education Activity (continued)

- Changes to competence, skills, practice:
  - “The document helped me improve my understanding of quality management of newborn screening testing”
  - “After reading the materials I will start to collect newborn screenings on time”
  - “better understanding of lab practice”
  - “Enhanced my knowledge of newborn screening and how it relates to CLIA”
  - “I am more aware of biochemical genetic testing and screening for newborns”
  - “It reaffirmed my understanding of the quality practices required by NB Screening and assisted me with designing a performance validation protocol”
  - “I have more knowledge of inherited metabolic diseases”
Good Laboratory Practices for Molecular Genetic Testing: Online Course

- **Audience**
  - Laboratory professionals directing, supervising, or performing molecular genetic testing
  - Laboratory professionals interested in molecular genetic testing for heritable diseases
  - Healthcare professionals providing laboratory services for molecular genetic testing
  - Clinical molecular genetic testing training programs

- **Continuing Education Credits**
  - ASCLS P.A.C.E.® Program: 2.0 contact hours through APHL
  - Florida Laboratory Licensees: 2.0 contact hours in Supervision Administration, Quality Control/Quality Assurance and Safety
  - CME: 2.0 AMA PRA Category 1 Credits™ through CDC
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Quality Improvement Research Agenda

- Presentations/discussion tomorrow on two ongoing initiatives:
  - Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)
  - Laboratory Medicine Best Practices Program (LMBP)

- Developing plans for new projects to:
  - Evaluate uptake and impact of laboratory practice guidelines and best practice recommendations
  - Investigate novel pre- and post-analytic challenges for transitioning next generation sequencing into the clinical laboratory
  - Assess needs for patient education about laboratory testing
  - Evaluate cytology workload limits using semi-automated screening devices
Questions for CLIAC Concerning Investigational Initiatives

- Provide feedback tomorrow on the CLIHC and LMBP initiatives
- What other research initiatives do you think could be conducted to improve the quality of laboratory services within the framework of the IOM improvement aims:
  - Safety
  - Patient-centeredness
  - Efficiency
  - Effectiveness
  - Timeliness
  - Equity
QUESTIONS?

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Mailstop F-11, Atlanta, GA 30333
E-mail: CLIAC@cdc.gov  Web: http://wwwn.cdc.gov/cliac/default.aspx

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.