

CDC Update

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

CLIAC Meeting
March 6, 2013
Atlanta, Georgia



Topic Outline

- ❑ Cytology workload study
- ❑ Proficiency testing update
- ❑ Healthcare News
- ❑ Genetic testing guidance
- ❑ On-line training products
- ❑ Quality improvement research

Workload in Image-Assisted Gynecologic Screening

- ❑ Issues previously presented to CLIAC
 - 9/1/2010 – CMS survey teams had identified quality issues in laboratories that used image-assisted screening
 - 9/1/2010 - FDA noted concerns that workload was not be counted properly and an alert would be sent out
 - 2/14/2012 - ASC Task Force recommended that the workload for cytotechnologists using image-assisted screening is too high
- ❑ Expert consultant meeting held August 15-16, 2012 with CDC, CMS and FDA
- ❑ Workload study in development
 - CDC developed study design, discussed with CMS and FDA staff
 - CDC anticipates beginning workload study in 4th quarter of 2013 under contracts to be awarded

Proficiency Testing Regulatory Revision Progress to Date

- 
- CLIAC recommended 23 potential changes to the current rule

- 
- CDC compiled proposed changes to the list of analytes/tests included in non-microbiology specialties
 - CDC drafted list of microbiology specialty changes

- 
- CDC and CMS met with PT program staff to discuss potential changes
 - Revisions made on the basis of PT program feedback

- 
- CDC developed potential acceptance criteria and plans to work with PT programs to evaluate the impact on performance scoring

Coming in 2013!

PROFICIENCY TESTING SURVEY

Reminder!

Help CDC and APHL to understand how laboratories throughout the United States use proficiency testing (PT) and how you perceive its value.

Results from the study will be compiled and shared anonymously as a summary document used in learning tools, presentations at professional conferences and potentially published in a professional journal in the field of laboratory science.

Please visit [URL] to begin your survey.
Email ptsurvey@aphl.org to request a paper copy.

- Chance to win a free training of your choice
- Approximately 20 minutes to complete
- Survey closes XXXX, 2013
- One entry per laboratory

Win a free laboratory training course of your choice for your participation!

- \$105 value
- Hour-long recorded online course for you and your staff
- APHL trainings address relevant, contemporary issues in laboratory testing, and usually provide continuing education credits.



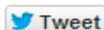
Healthcare News

- ❑ Weekly compilation of clinical laboratory and related information
- ❑ Access and subscribe to the newsletter at:
http://www.cdc.gov/osels/lspppo/healthcare_news.html
- ❑ October 2012 - Began using GovDelivery for distribution to 7,953 individuals
 - 10,161 current subscribers
 - Indirect subscribers through listservs broaden distribution



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Healthcare News

A Weekly Compilation of Clinical Laboratory and Related Information from The Division of Laboratory Science and Standards

February 7, 2013

News Highlights

- [Capitol Hill Briefing on Value of Clinical Laboratory Testing](#)
- [How Often Are Biopsies Wrong?](#)
- [CDC Has Launched a New Infectious Diseases Laboratory Test Directory and an Updated CDC Specimen Submission Form \(Form 50.34\)](#)
- [Lyme Culture Test Causes Uproar](#)
- [Hanging A Price Tag on Radiology Tests Didn't Change Doctors' Habits](#)
- [Rekindling the Patient ID Debate](#)
- [Can Computers Predict Medical Problems? VA Thinks Maybe](#)
- [Are Citizens' Voices Heard in Rulemaking?](#)
- [U.S. Proposes Scrapping Some Obsolete Medicare Regulations](#)

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Capitol Hill Briefing on Value of Clinical Laboratory Testing

The foundation for 70% of physician decision-making, clinical laboratory tests are one of the most critical elements in preventing chronic illness, curtailing epidemics, and improving cancer care. At the same time, clinical lab tests are making the U.S. health care delivery system more cost-

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Office of Surveillance, Epidemiology, and Laboratory Services

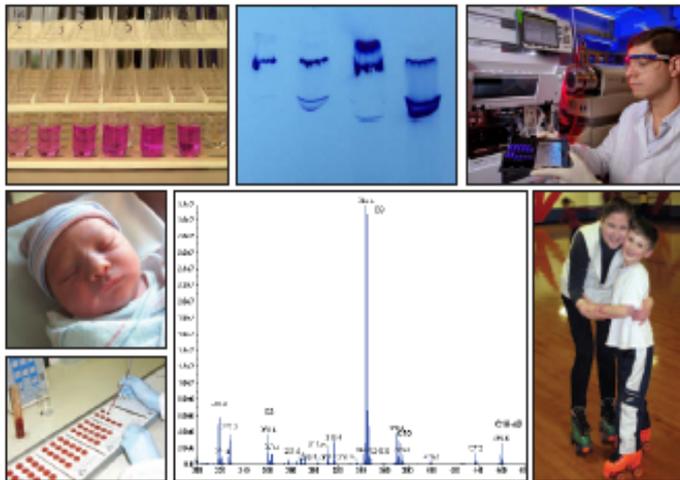
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Atlanta, GA 30333,
USA

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(800-232-4636)
TTY: (888) 232-6348
24 Hours/Every Day

 OSELS@cdc.gov

Genetic Testing Guidance

Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders



Clinical Laboratory Improvement Advisory Committee

Biochemical Genetic Testing Good Laboratory Practices Workgroup (2009–2010)

Chairperson: Carol L. Greene, MD, University of Maryland School of Medicine, Baltimore, Maryland.
Members: Bruce Bashop, 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 Hannon, PhD, Atlanta, Georgia; Julie Ann Neidlich, MD, Quest Diagnostics—Nichols Institute, San Juan Capistrano, California; Stephen Raab, MD, University of Colorado Denver, Aurora, Colorado; David L. Smalley, PhD, Tennessee Department of Health, Nashville, Tennessee; Erin Stroval, PhD, University of Maryland School of Medicine, Baltimore, Maryland; V. Reid Sutton, MD, Baylor College of Medicine, Houston, Texas; Georgijane D. Vladutis, PhD, The Buffalo General Hospital, Buffalo, New York; Emily S. Winn-Duan, PhD, Ra Dx Advisors, Livermore, California.

Clinical Laboratory Improvement Advisory Committee (2010–2011)

Chairperson: Eliza Pasternak, EdM, American Society for Clinical Laboratory Science, Bethesda, Maryland.
Members: Ellen Baron, PhD, Stanford University Medical Center, Palo Alto, California; Christine Bean, 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 Fontana, PhD, University of California—San Diego, School of Medicine, San Diego, California; Julie 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 Pediatric Alliance, Atlanta, Georgia; Lee H. Hillborn, 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, Baystate Medical Center, Springfield, Massachusetts; Gary Overnarf, MD, University of New Mexico School of Medicine, Albuquerque, New Mexico; Stephen Raab, MD, University of Colorado at Denver, Aurora, Colorado; Linda Sandhaus, MD, Case Western Reserve University Hospitals and Medical Center, Cleveland, Ohio; Paula Santrach, MD, Mayo Clinic, Rochester, Minnesota; Jared N. Schwartz, MD, Presbyterian Healthcare, Charlotte, North Carolina; David L. Smalley, PhD, Tennessee Department of Health, Nashville, Tennessee; Carl Vance, MD, Indiana University School of Medicine, Indianapolis, Indiana; Emily Winn-Duan, PhD, Ra Dx Advisors, Livermore, California; Rosemary Zana, MD, The University of Oklahoma Health Science Center, Oklahoma City, Oklahoma.
Designated Federal Officials: Thomas L. Hearn, PhD, National Center for Emerging and Zoonotic Infectious Diseases, May Chu, PhD, Office of Surveillance, Epidemiology, and Laboratory Services, CDC, Atlanta, Georgia.
Ex-Officio Members: Alberto Gutierrez, PhD, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland; Judith Yust, MA, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, Baltimore, Maryland; Devery Howerton, PhD, Office of Surveillance, Epidemiology, and Laboratory Services, CDC, Atlanta, Georgia.
Liaison Representative: Luann Ochs, MS, Advanced Medical Technology Association, Washington, DC.

850 print copies distributed
- 500 via CMSCLIA staff
- 200 via CDC Newborn Screening QA program

387 continuing education credits awarded



Good Laboratory Practices for Molecular Genetics Testing

[fact sheets](#) [course folders](#) [exit](#)

HOME

- INTRODUCTION 1
- NEEDS AND REQUIREMENTS 2
- PERSONNEL AND TEST METHODS 3
- TEST PERFORMANCE VERIFICATION 4
- QC AND SOP 5
- TEST DIRECTORY, REQUEST & REPORT 6
- RETENTION AND ASSESSMENT 7
- SUMMARY 8

Good Laboratory Practices for Molecular Genetics Testing

[Start the course](#)



QUALITY LABORATORIES, HEALTHIER PEOPLE

Good Laboratory Practices for Molecular Genetic Testing: Online Course

- Easy to access:
 - <http://www.aphl.org/courses/Pages/321-12.aspx?>
- Participation (Sept 2012 – Feb 2013)
 - 380 ASCLS PACE credits to 190 individuals
 - 68 CME credits to 34 individuals
 - Knowledge gain from the course averaged 27 points (post-test minus pre-test, range = 0-89)
- Feedback
 - 98-100% - course successfully met learning objectives
 - 90% - would help them perform their jobs better

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sumtotal-systems.com

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HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

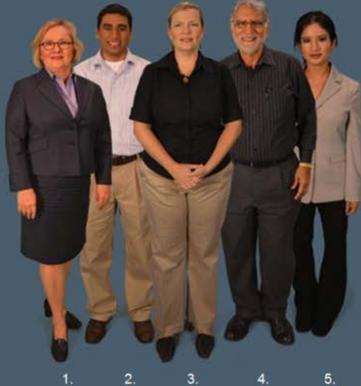
SUMMARY 8

Meet the team:

- Michelle Jones, MD is our laboratory director.
- Nicholas Greene, MD, PhD is fresh off a fellowship in medical genetics where he completed laboratory specialty training in molecular genetics and has just come to work for the hospital network.
- Julle Johnson, MT (ASCP) is your direct supervisor.

Also in your section are:

- Raja Parekh, MLT
- And
- Brianna Rossi, MT (ASCP)



1. 2. 3. 4. 5.

PREV PAGE NEXT PAGE

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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

This is your workspace.

The folder below at your right contains resources referred to in this section. You will be able to save or download the information to your own computer.

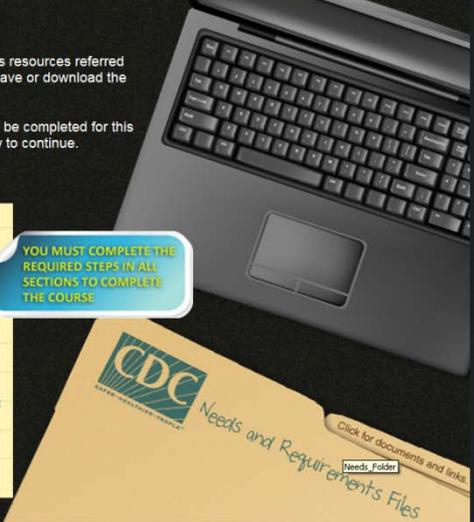
Below are required steps that need to be completed for this section. Select one of the steps below to continue.

Required Steps

- Check regulatory requirements
- Check your e-mail
- Check FDA list of approved tests
- Evaluate the laboratory space

CONTINUE TO NEXT SECTION

YOU MUST COMPLETE THE REQUIRED STEPS IN ALL SECTIONS TO COMPLETE THE COURSE



Click for documents and links

Needs Folder

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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

Review Question

True or False

The CLIA general QC requirements apply to molecular genetic testing for heritable diseases.

True

False

PREV PAGE NEXT PAGE

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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

Needs and Requirements Files

The following resources pertain to this section of the course. You can save or download them to your own computer.

- Test Information to Provide Users of Laboratory Services [Link to CMS web site](#)
- Unidirectional workflow for molecular amplification procedures [Link to FDA web site](#)
- CLIA Oversight for Molecular Genetic Testing
- E-mail from Dr. Greene

PREV PAGE

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fact sheets course folders exit

HOME

INTRODUCTION 1

NEEDS AND REQUIREMENTS 2

PERSONNEL AND TEST METHODS 3

TEST PERFORMANCE VERIFICATION 4

QC AND SOP 5

TEST DIRECTORY, REQUEST & REPORT 6

RETENTION AND ASSESSMENT 7

SUMMARY 8

Dr. Jones: Dr. Greene, thank you for that summary. This checklist will be a great tool for any future projects too.

This has definitely been a team effort. Thank you all for your hard work.

You have completed the course!

Take the final exam



PREV PAGE

QUALITY LABORATORIES, HEALTHIER PEOPLE

Comments from e-learners

- ❑ Very informative, enjoyed the simulated activity
- ❑ Interactive nature of the presentation was particularly effective
- ❑ Interesting first person format. Much more interesting than usual continuing education modules.
- ❑ The use of audiovisual aids was also very good.
- ❑ I like that it was presented as a working environment.
- ❑ Content and organization was excellent. Not only learned about molecular techniques but more importantly how to approach new test implementation.
- ❑ The ...sample documents will... serve as guidelines in future validations and in writing and implementing new procedures.
- ❑ All the guidance documents and links are distributed into well-organized sessions and the review questions help a lot. I'm amazed at how good this course is. Thank you designers!

Next-Generation Sequencing (NGS) Guidance

- ❑ NGS Standardization of Clinical Testing (Nex-StoCT) Working Groups
- ❑ The complexities of NGS technologies present significant challenges for meeting regulatory and professional standards.
- ❑ Detailed presentation & discussion this afternoon

Assuring the quality of next-generation sequencing in clinical laboratory practice

To the Editor:

We direct your readers' attention to the principles and guidelines (**Supplementary Guidelines**) developed by the Next-generation Sequencing: Standardization of Clinical Testing (Nex-StoCT) workgroup. These guidelines represent initial steps to ensure that results from tests based on next-generation sequencing (NGS) are reliable and useful for clinical decision-making. The US Centers for Disease Control and Prevention (CDC) convened this national workgroup, which collaborated to define platform-independent approaches for establishing technical process elements of a quality management system (QMS) to assure the analytical validity and compliance of NGS tests with existing regulatory and professional quality standards. The workgroup identified and addressed gaps in quality practices that could compromise the quality of both clinical laboratory services and translational efforts needed to advance the implementation and utility of NGS in clinical settings.

The workgroup was composed of experts with knowledge of and experience with NGS and included clinical laboratory directors, clinicians, platform and software developers and informaticians, as well as individuals actively engaged in NGS guideline development from accreditation bodies and professional organizations. Representatives from US government agencies also participated.

These guidelines address three topics that are components of quality management in a clinical environment: (i) test validation, (ii) quality control (QC) procedures to assure and maintain accurate test results and (iii) the independent assessment of test performance through proficiency testing (PT) or alternative approaches. Discussions were limited to the analytic and informatics processes required for accurate variant calling. The workgroup did not address how variants are prioritized, interpreted or reported.

The workgroup recommendations are summarized in **Table 1**. Although the workgroup focused on detection of DNA sequence variations associated with heritable human disorders, many of the principles and recommendations described are also relevant to the application of NGS to other areas of laboratory medicine, including the

diagnosis, prognosis and treatment of cancer and infectious-disease testing.

Validation is the process of establishing analytical performance specifications for a clinical test system developed in house to confirm that the system is suitable for its intended use¹. During the validation process, the laboratory must demonstrate that the

Table 1 Selected workgroup recommendations for establishing NGS test systems for clinical use

Requirements for test establishment	Objective	NGS-specific recommendations*
Validation	Document reliability of the platform, test, and informatics pipeline before testing of patient specimens	<ul style="list-style-type: none"> •Platform validation: establish that the system provides reliable sequence analysis across the genomic regions targeted by the test. •Test validation: establish that the system correctly identifies disease-associated (and other) variants in targeted regions of the genome (Supplementary Guidelines, section 4). •Informatics pipeline validation: establish that the algorithm(s) reliably analyze platform data to produce an accurate sequence. •Establish and validate alternate methods (for example, Sanger sequencing) to derive high quality sequence for problematic genomic regions.
Quality control	Document reliability of the sequence analysis during patient testing	<ul style="list-style-type: none"> •Utilize a combination of QC materials, both intrinsic and/or spiked in, that mimic genomic complexity and the types of mutations the test is designed to detect. •During patient testing, quality metrics (for example, quality scores, depth and uniformity of coverage, mapping quality, GC bias and transition/transversion ratio) should be assessed and compared to those established during validation. •Clinically actionable findings should be confirmed by independent analysis using an alternate method.
Proficiency testing	The independent assessment of test performance	<ul style="list-style-type: none"> •PT challenges should target the analysis of both disease-associated and naturally occurring sequence variations across the genomic regions targeted by the test to measure the reliability of sequence analysis. •Electronic sequence files may permit a comparison of alignment and variant calling methods across laboratories but will require additional consideration of platform differences. •PT programs should consider the different genomic regions targeted by each recipient laboratory's assays to properly compare inter-laboratory performance.
Reference materials	The use of materials for quality management of the analytical phase of testing	<ul style="list-style-type: none"> •RMs with both naturally occurring and disease-associated sequence variations are needed for test validation, QC procedures and the independent assessment of test performance. •Synthetic DNA and electronic reference data files may serve as RMs for rare or challenging sequence variations. •Efforts should be undertaken to establish a suitable NGS RM and the sequence of the RM should be refined as the technology changes. Such a RM should be annotated to indicate regions of high and low sequence reliability.

*See **Supplementary Guidelines** for complete recommendations. RM, reference material.

Nature Biotechnology
November 2012

SIRAS course developed with CDC support

<http://www.jointcommission.org/siras.aspx>



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[Home](#) > [Strategies for Improving Rapid Influenza Testing in Ambulatory Settings \(SIRAS\)](#)



Friday 1:05 CST, February 15, 2013

Strategies for Improving Rapid Influenza Testing in Ambulatory Settings (SIRAS)



Online Course

[Register](#)

The Joint Commission is offering 2 web-base courses: Strategies for Improving Rapid Influenza Testing in Ambulatory Settings (SIRAS).

- A free continuing education (CE) course designed for MDs, PAs and RNs
- A free, no-credit SIRAS training module for medical office staff who collect respiratory specimens for influenza testing

Key Points

- The correct diagnosis of influenza relies on the practitioner's ability to understand performance implications of RIDT and the impact of circulating influenza strains
- RIDTs, if correctly interpreted, provide quick results and can play a key role in guiding clinical decisions
- The courses provide guidance on the use of both RIDT results and information about circulating strains for providers
- Key to good testing is the collection of the appropriate specimen
- The courses also provide a demonstration of proper techniques for performing specimen collection at the point of care

[Register](#) for the course.

Resources

Websites

Videos

[Aspirate Nasal Wash](#)

[Nasal Stopper Swab](#)

[Nasal Swab](#)

[Nasal Throat Swab](#)

[Nasopharyngeal Swab](#)

[Pediatric Nasal Aspirate Wash](#)

[Pediatric Nasal Swab](#)

Note:

SIRAS Uptake and Impact

Uptake: mid-October 2012 launch through Jan 2013:

- ❑ 4094 hits to the site
- ❑ 1415 registered for course
- ❑ 1155 completed all or part of the course
- ❑ 260 viewed the specimen collection module
- ❑ 5172 viewed the specimen collection videos on YouTube

Impact: through December 2012:

100% (327/327)	reported course was useful
99% (321/323)	improved understanding of the subject
47% (133/281)	planned to change practice
43% (121/281)	the course validated current practices

Clinical Laboratory Integration into Healthcare Collaborative (CLIHCTM)

- Published "Decoding Laboratory Test Names: A Major Challenge to Appropriate Patient Care"; *J. Gen. Internal Med.* (Nov 2012)
- Presented "Your Role on the Clinical Team" at ASCP annual meeting (Oct 2012)
- Developing partnerships to expand development of clinical decision support to guide test selection (building on PTT Advisor mobile app experience)

LABORATORY MEDICINE *Best Practices*



- ❑ New LMBP™ topics for systematic reviews
 - Reducing unnecessary blood utilization
 - Appropriate coagulation testing in the ED or pre-surgery
 - Lipid biomarkers as indicators of CVD
 - Continued ASM collaboration – urine specimen transport
- ❑ New project in development to evaluate uptake and impact of best practice recommendations

Future Plans

- ❑ Projects in development to support evaluation of the implementation and impact of CDC and other laboratory practice recommendations and guidelines
- ❑ Expanded efforts and partnerships for genetic testing reference materials
 - PGX
 - HLA
 - Cancer
 - NGS



QUESTIONS?

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Mailstop F-11, Atlanta, GA 30333

CLIA Information Line: 1-404-498-2290 TTY: 1-888-232-6348

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.