A P H L ASSOCIATION OF
PUBLIC HEALTH LABORATORIES

BGT-NBS MMWR CE Ad Awareness and Perception Survey - 2014 APHL NBSGTS Program

Email Support

To ensure full functionality in this survey please use the following browsers; Internet Explorer 7 or higher, Chrome, or Firefox. Only use the navigation buttons on the bottom of this page if you need go back and forth between survey pages. Using your browsers back and forward buttons should not be used as you may encounter error messages.

Thank you for agreeing to participate in this survey, which will help APHL and CDC assess the effectiveness of the following efforts to raise awareness of the free online CE activity for the 2012 CDC guideline "Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders" at the 2014 APHL NBSGTS Program:

- Ad in the print version of the meeting program (Hide Ad)

Free CEs for Laboratory and Health Professionals Involved in Newborn Screening

HOW?

① **Read** *MMWR Recommendation and Reports: Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders*

② **Take and pass a test** to document knowledge gained and earn your CEs!

This announcement was supported by Cooperative Agreement # U60HM000803 funded by the Centers for Disease Control and Prevention (CDC). The language used in this announcement is solely the responsibility of the authors and does not necessarily represent the official views of CDC or the DHHS.

For more information, go to www.cdc.gov/TCEOnline and search for course number WB2010.

Evaluating Awareness, Understanding, and Utilization of Good Laboratory Practices in Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Diseases

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BACKGROUND

In 2013, APHL was awarded a cooperative agreement to evaluate the impact of the "Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders" published by CDC in a 2012 Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports publication. The good laboratory practice recommendations were developed based on the recommendations from Clinical Laboratory Improvement Advisory Committee (CLIAC) as a result of evaluating and considering existing regulatory, accreditation, and voluntary laboratory standards. Additional input from two federal advisory committees (the Secretary's Advisory Committee on Genetics, Health, and Society and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children) and the laboratory community was also considered and incorporated into the recommendations. Due to limited data on awareness and use of the recommendations in the laboratory community, APHL and CDC decided to convene small discussion groups to collect information related to the dissemination of the MMWR document and the factors that might encourage or impede the use or implementation of the recommended practices in different laboratory settings.

METHODS

- 2 facilitated discussion groups were convened in December 2013, in Atlanta, GA
- Director-level individuals from biochemical genetic testing (BGT) and newborn screening (NBS) laboratories who were anticipated to have knowledge of the CDC document were invited to participate; some invitees were unable to attend due to schedule conflicts
  - BGT group (N=8):
    - Private genetics laboratories (N=4)
    - University-affiliated genetics laboratories (N=2)
    - Hospital-affiliated genetics laboratories (N=2)
  - NBS group (N=5):
    - Public health NBS laboratory programs serving multiple states (N=2)
    - State public health NBS programs with 100,000-400,000 annual births (N=2)
    - Hospital-affiliated laboratory performing contractual NBS testing (N=1)
- A 12-question discussion guide was used by the facilitator at both group discussions; audio-recordings, together with notes and observations from the facilitator, the note-taker and the observers from APHL and CDC were used to analyze results.

RESULTS*

Topic	NBS Group	BGT Group
1. Awareness	All participants were aware of the MMWR document and considered the recommendations scientifically sound. Some were informed during the process of developing the recommendations	Some were consulted during the process of developing the recommendations
2. Knowledge, understanding and perception of the recommended practices	Acknowledged the document as a good summary of accepted good laboratory practices and overall quality systems. Most useful recommendations included test performance establishment (test validation) and recommended personnel qualifications. Lacks specific QC procedures compared to accreditation checklist. Misinterpretation of the wording of a few recommendations (results reporting, requesting second specimen)	Misinterpretation of the wording of a few recommendations (recommended test report elements, reflex testing, personnel competency assessment and samples for establishing test performance for rare disease testing)
3. Use and implementation of the recommended practices	Most recommended practices were already implemented. No one was aware of the continuing education (CE) activity or the available CE credits. Useful for training materials and resource justification. Useful for development of procedures for establishing performance specifications of new tests.	Useful for orienting fellows and new staff. Useful for justifying personnel qualifications, developing quality improvement plans, introducing new test platform, and validating new tests
4. Format/presentation	Challenging to read due to document length and structure. Differing opinions for providing recommendations for NBS and BGT in one document	Mixed opinions on combining BGT and NBS in one document, most thought it was useful
5. Suggestions for improvements and future efforts	Develop supporting materials and specific training efforts to improve dissemination and understanding of the recommendations. Use the document for personnel competency assessment. Share the document internationally. Use the document as educational material for laboratory surveyors and inspectors. Include participants from smaller laboratories in future discussion groups. Make available companion documents that include only recommendations for NBS. Provide clarifications for differences in state and CLIA requirements. Need better engagement of NBS community to vet content of recommendations. Provide guidance for additional areas (e.g., screening tests not requiring samples, interacting with public and media, and improving consistency in performance reporting from different states)	Consider providing samples for additional PT programs. Provide guidance and clarification for: o Recommendations relating to informed consent o QC practices for multi-analyte testing o Test validation and QC practices for rare disease testing and tests using invasive samples o Recommended test report elements o Recommendations regarding reflex testing

*These results reflect the direct feedback from the two discussion groups and have not been verified through any on-site observation or inspection process.

DISCUSSION AND LESSONS LEARNED

- Feedback from the discussion groups revealed helpful insights about the current status of awareness, understanding and use of the recommended practices.
- Although all discussion group participants were aware of the CDC recommendations, various degrees of understanding of the intent of the document and many areas of the recommendations were evident.
- The MMWR document provides a comprehensive guide for quality laboratory practices; it is also time-demanding to read through and not sufficiently easy to use for many laboratory professionals.
- Identifying areas that need clarification or guidance is important to improving understanding and application of the recommended practices.
- Describing the connection of BGT and NBS laboratories in contributing to screening, diagnosis and management of heritable metabolic disorders would be useful for members of both communities.
- Providing opportunities for members of the NBS and BGT laboratory communities to participate in the process of developing practice recommendations and provide feedback should increase acceptance and use of the recommendations.

NEXT STEPS

Based on the input from the discussion groups, major next steps of the project will include:

- Convening taskforces of NBS and BGT professionals in various laboratory capacities to obtain input on training needs and evaluation approaches (Note: The taskforces have met and have offered suggestions for developing training/education tools and measuring impact of the good laboratory practice recommendations).
- Marketing the MMWR and its related continuing education credits through flyers and journal advertisements to encourage use.
- Conducting case studies to obtain in-depth information about whether or how the recommendations have been used in specific settings.
- Developing supplemental materials, training tools, webinars and other products to meet the competency improvement needs of the laboratory community and stakeholders and to facilitate the use of the good laboratory practice recommendations in practice.
- Developing evaluation tools to assess the improvements in understanding and use of the recommended practices as a result of the training and marketing efforts.

Free CEs for Laboratory and Health Professionals Involved in Biochemical Genetic Testing

CME (physicians and non-physicians): *2.25 credit hours*
CNE: *2.2 credit hours*
CEU: *2 contact hours (0.2 units)*
CHES: *2.5 credit hours*

① **Read** *MMWR Recommendation and Reports: Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders*

- Developed by considering national and international quality standards applicable to biochemical genetic testing and newborn screening laboratory practices
- Clarifies applicable CLIA requirements and provides recommendations for additional quality assurance and quality management practices
- Intended as a guide for ensuring the quality of laboratory services for biochemical genetic testing and newborn screening for inherited metabolic disorders

② **Take and pass a test** to document knowledge gained and earn your CEs!

Suggested Uses

- Prepare for an upcoming accreditation or laboratory certification inspection
- Strengthen your laboratory's quality improvement program
- Enrich your own continuing education
- Assist in developing a competency testing plan for your staff

Target Audience

- Laboratory professionals working in biochemical genetic testing or newborn screening laboratories
- Physicians, nurses and other health professionals who use or evaluate biochemical or newborn screening laboratory services

"A good summary of the requirements for biochemical genetic testing particularly from a CLIA requirement perspective."

"Information was helpful to ensure that newborn screenings are handled and testing is run properly."
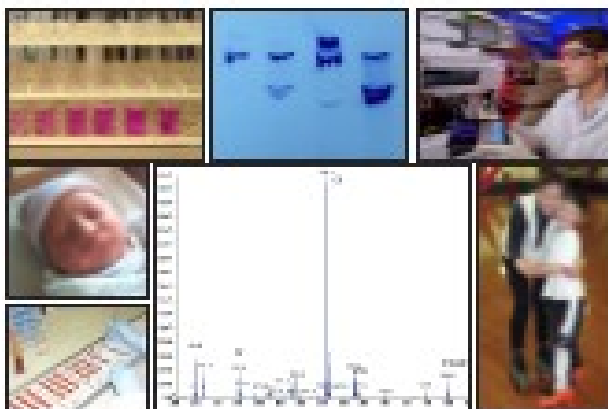
(?) **For more information, go to www.cdc.gov/TCEOnline and search for course number WB2010.**

(Note: The 2012 CDC guideline "Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Medical Disorders"

is accessible at: http://www.cdc.gov/mmwr/pdf/rr/rr6102.pdf).

Hide Guideline

Your feedback is extremely important. We anticipate that it will take less than 5 minutes to complete these questions. Your responses will be anonymous and no identifying information will be kept.

To proceed through the survey, select your answer for each question and click the "Next Page" button to move forward.

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1. Did you see or get information about the CE activity for "Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders" published by CDC in 2012 at the 2014 APHL Newborn Screening and Genetic Testing Symposium?

Please check all that apply.

☐ Yes, from the ad in the printed program

☐ Yes, from the APHL-CDC poster

☐ Yes, from the paper flyer

☐ Yes, from others at the symposium - *please specify below*

[   ]

☐ No

2. **Before** attending the 2014 APHL Newborn Screening and Genetic Testing Symposium, were you aware of this CE activity?

○ Yes

○ No

3. Have you used that CE opportunity?

○ Yes

○ Not yet, but planning to

○ No

4. Have you recommended or would you recommend this CE activity to someone else?

○ Yes, I have recommended this CE activity to someone else
○ Yes, I would recommend this CE activity to someone else
○ No
○ Not sure

4a. Who did you recommend the CE activity to?
Please check all that apply

☐ Coworkers in the laboratory
☐ Sample submitters
☐ Health practioners who see reports of results
☐ New employees or trainees
☐ Others - please specify below

5. Based on the CE information you obtained at the Symposium, will you take the CE activity?

○ Yes
○ No
○ Not applicable

6. Which of these best describes your work setting?

○ Public health newborn screening laboratory
○ State newborn screening follow-up program
○ Private laboratory
○ Hospital/medical center
○ Academic institute
○ Non-profit organization
○

— Industry

○ Other - please specify below

[   ]

7. Which of these best describe your job responsibilities?

○ Newborn screening laboratory professional

○ Newborn screening follow-up professional

○ Diagnostic laboratory professional

○ Healthcare professional

○ Academic scientist

○ Educator

○ Student

○ Policymaker, legislator, or staff

○ Other - please specify below

[   ]

8. What are the number of years you have had in this role?

○ 0-3 years

○ 4-6 years

○ 7-10 years

○ 11-15 years

○ More than 15 years

This is the end of the survey.
Please click on the "Submit Responses" button below to submit your responses.

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