

Utilization of CDC Recommendations for Good Laboratory Practices in Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Diseases:

Current Status, Lessons Learned and Next Steps to Advance
and Evaluate Impact



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EXECUTIVE SUMMARY

In April 2012, the Centers for Disease Control and Prevention (CDC) published “Good Laboratory Practice Recommendations for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders” as a *Morbidity and Mortality Weekly Report* (MMWR) Recommendations and Reports publication (1). To assess awareness and use of the recommendations in the MMWR document by the key intended audience – laboratory professionals in biochemical genetic testing (BGT) and public health newborn screening (NBS) laboratories – two facilitated discussion groups were held: one with NBS laboratory professionals and one with BGT laboratory professionals. The groups were held in Atlanta, Georgia, on December 4, 2013, with five and eight participants, respectively. The results presented in this report reflect the feedback from these two discussion groups, summarized into the eight topic areas listed below with clarifying information from the Association of Public Health Laboratories and CDC project team members noted where appropriate.

1. Participants’ awareness of CDC recommendations and their information sources:

- All participants in both groups were aware of the MMWR document; nearly all participants had learned about the document via email or at a professional conference where the document was discussed.
- Although the recommendations were developed through extensive collaboration, several NBS participants said that they wished there had been additional opportunities for review and vetting by laboratory professionals prior to publication in the MMWR.

2. Participants’ knowledge and understanding of the recommended practices:

- Many participants in both groups viewed the document as a good summary of existing regulatory or voluntary standards and current practice, rather than as a set of new recommendations to implement in their laboratories.
- Most participants reported that there was little need for clarification of the content of the document, although it was evident that some areas of the recommendations (e.g., results reporting and reflex testing) were misunderstood.

3. Use and implementation of the recommended practices:

- Both groups indicated that most of the recommendations have already been implemented.
- In both groups, participants indicated that the recommendations are most helpful regarding the factors to consider before introducing new tests, the overall quality management structure, and the development and validation of new tests that are not FDA-approved.
- Other useful areas include defining personnel qualifications and responsibilities and training new employees and fellows.

4. Comments on MMWR format/presentation of the recommendations:

- Both groups mentioned that the recommendations were challenging to read due to the dense format of information.
- There were mixed opinions on the usefulness of combining the NBS with the BGT practices, although the discussion finished with the idea that combining the two aspects would lead to a greater understanding of overlapping roles.

5. Concerns, barriers and perceived problems:

- Both groups mentioned the challenges of using multiple, redundant guidelines.
- Participants in the NBS group said they were not accustomed to using an MMWR document as a reference document.
- Some recommendations were identified in the BGT group as difficult to implement, such as the results reporting and reflex testing mentioned in #2 above, and could benefit from more explanation.

6. Further dissemination, communication, ways of using the recommendations:

- Many participants reported limited sharing of the document with colleagues in the clinical community and with laboratory staff, due to concern over length and density of the text.
- Some participants shared the recommendations with fellows for training purposes.

7. Current measurement of impact:

- Discussion group participants did not have measurements of impact because they did not think they had changed their laboratory practices. They felt there were few differences between the recommended practices and their current practices.

8. Participants' suggestions for improvements:

- Provide supporting materials and examples to make the recommendations easier to understand and use.
- Clarify how to use the MMWR document by laboratory personnel, including for competency improvement and assessment.
- Use the recommendations as a reference document for laboratory inspectors.
- Include participants from smaller laboratories in future discussions to broaden the use of the recommendations.
- Share the recommendations with international audiences, particularly in Asia and Latin America, where there is less existing guidance for laboratories.
- Provide more information on recommended practices for results reporting, reflex testing, quality control on multianalyte testing, informed consent and improving consistency in test performance standardization.
- Emphasize the availability of the continuing education (CE) activity and CE credits.

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

- Convene taskforces of NBS and BGT professionals in various laboratory capacities from large, medium and small laboratories. The taskforces will offer suggestions for developing training products and education tools to improve the understanding of the recommended practices by the NBS and BGT communities, and provide advice for developing systems to track and measure the impact of the good laboratory practice recommendations.
- Conduct case studies by following up with a few discussion group participants to obtain additional clarification and in-depth information on how the recommendations had been used in their specific setting, which areas of the recommendations were utilized by which laboratory personnel and which laboratory activities had been influenced. The outcomes of these case studies are expected to lead to information on the impact of the recommended practices in specific but representative laboratory settings, which will serve to not only provide critical information to the systematic evaluation and complement the suggestions from the taskforces regarding further training needs.
- Develop 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.
- Develop evaluation tools to assess the improvements in understanding of the recommended practices and improved use of the recommendations in practice.

INTRODUCTION

Background of CDC Recommendations

Biochemical genetic testing and newborn screening tests are essential laboratory services for the screening, diagnosis and patient management of heritable metabolic disorders, which collectively have an incidence of at least 1/1,500 persons in the United States (US). With the nationwide implementation of the recommended uniform screening panel of heritable metabolic diseases and the consideration of additional conditions by state NBS programs, continuing quality assurance challenges have presented not only for public health laboratories and other NBS facilities, but also for BGT laboratories that perform subsequent diagnostic testing.

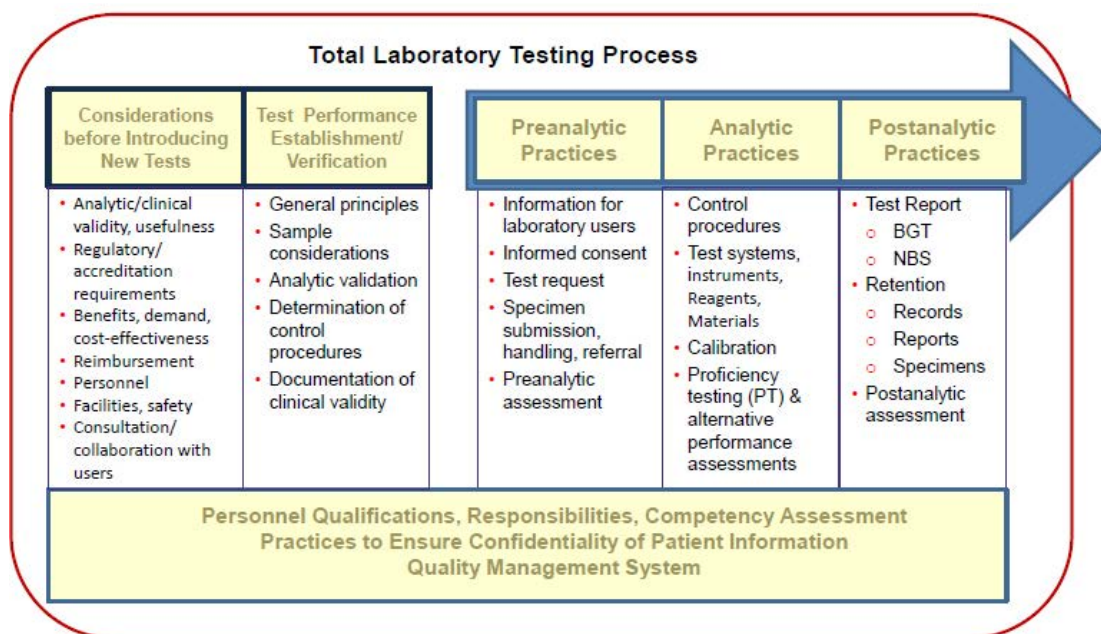
All laboratories that test US specimens for patient care, health assessment and health management purposes must comply with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. Under the CLIA regulations, laboratories performing biochemical genetic testing must meet the general quality systems requirements for non-waived testing and the personnel requirements for high-complexity testing. Laboratories that perform public health newborn screening are subject to the same CLIA requirements and applicable state requirements. However, CLIA regulations do not contain specialty or specific requirements for biochemical genetic testing or newborn screening. In the lack of uniform guidance and understanding for how to apply the general CLIA requirements to these areas of laboratory practices, variations in laboratory practices that raised quality assurance concerns have been reported (2, 3, 4, 5). These reports indicated areas in need of quality improvement that will likely benefit from the development and implementation of good laboratory practice guidelines.

In April 2012, CDC published “Good Laboratory Practices for Biochemical Genetics Testing and Newborn Screening for Inherited Metabolic Disorders” in the *Morbidity and Mortality Weekly Report* (MMWR) Recommendations and Reports (1) (hereafter referred to as the BGT and NBS recommendations). The BGT and NBS recommendations were developed based on recommendations developed by the Clinical Laboratory Improvement Advisory Committee (CLIAC). Additional input from regulatory and accreditation standards, voluntary laboratory standards and 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) were also considered and incorporated into the recommendations. The good laboratory practice recommendations address key areas of laboratory practices by:

1. Providing clarifications for applicable CLIA requirements to help laboratories with compliance, and
2. Providing recommendations for additional quality assurance measures for these areas of genetic testing.

The BGT and NBS recommendations are intended to provide a comprehensive guide for essential quality practices needed for quality management and continual improvement in laboratory services for heritable metabolic diseases. The key areas of the recommended practices are illustrated in Table 1 below. The ultimate intent of the recommendations is to improve the quality of laboratory services, improve health outcomes of patients and families, and improve overall public health.

Table 1. Key Areas of Recommended Practices



The intended outcomes of this guideline span a broad spectrum, with varying focus for each of the multiple intended audience groups as summarized in Table 2 below.

Table 2. Intended Audience and Outcomes of BGT/NBS Recommendations

| Intended Audience | Intended Outcomes |
|---|--|
| BGT laboratory professionals | <ul style="list-style-type: none"> Improve quality of test performance Improve provision of laboratory services to users |
| NBS laboratory professionals | <ul style="list-style-type: none"> Improve quality of laboratory practices for NBS programs Improve quality of test performance |
| Medical and public health professionals who evaluate laboratory practices and policies (e.g., laboratory inspectors, surveyors, and third-party payers) | <ul style="list-style-type: none"> Provide a resource for assessing laboratory practices Facilitate improvements to laboratory quality systems |

| Intended Audience | Intended Outcomes |
|--|--|
| Healthcare professionals and other users of laboratory services | <ul style="list-style-type: none"> • Provide a resource to improve users' understanding of laboratory responsibilities and recommended practices, especially those affecting the laboratory-use interfaces. • Improve use of BGT services • Improve collaboration and follow-up for NBS |
| Standard-setting organizations and professional societies | <ul style="list-style-type: none"> • Facilitate development of future laboratory quality standards and practice guidelines |
| Health professionals who develop or use standards for electronic communications in clinical and public health practice | <ul style="list-style-type: none"> • Provide a resource for developing information technology systems that accommodate the recommended laboratory practices • Provide a resource for developing electronic communication standards affecting BGT and NBS |

Evidence from many sources indicates that the CDC guideline has been recognized both nationally and internationally. Although there has been limited participation in the CE activity that CDC provides for the BGT and NBS recommendations, the diverse participants (including laboratory professionals, healthcare professionals and health educators) considered it a valuable educational resource. However, little is known about the extent to which the recommendations are understood by the diverse target audience groups and utilized in practice. These gaps in knowledge hinder not only the identification of metrics for evaluating the impact of the CDC guideline, but also the ability and strategies of individual laboratories, programs and organizations to effectively adopt and utilize the recommended practices, achieve continual quality improvement in laboratory services for heritable metabolic diseases and improving health outcomes and public health.

APHL-CDC Cooperative Agreement on the Evaluation Project

In 2013, APHL began a cooperative agreement with CDC to evaluate the effectiveness and the impact of the BGT and NBS recommendations. This project was designed based on a science impact framework for advancing and measuring the impact of scientific products at progressing stages (see Appendix A) and used the CDC Evaluation Framework as a guide (6). By systematically evaluating the implementation, impact and contribution of the BGT and NBS recommendations as they are disseminated, recognized and incorporated into laboratory practice, the goal is to advance quality improvement in laboratory services for heritable metabolic disorders and to improve health outcomes for patients and families.

The cooperative agreement is based on two major activities:

1. Developing a framework for evaluating and advancing the use and acceptance of the BGT and NBS recommendations, and
2. Determining the factors that influence the implementation, effectiveness and impact of the recommendations as they are disseminated, recognized and incorporated into clinical and public health laboratory and program practice.

METHODS

APHL and CDC decided to use small discussion groups to collect information related to the dissemination of the BGT and NBS recommendations and to explore what factors may encourage or impede the implementation of the recommendations in different laboratory or program settings. Prior to the discussion groups, APHL and CDC recognized that limited data were available on laboratories' awareness and use of the BGT and NBS recommendations for laboratory practices, or the incorporation of the recommendations into laboratory procedures and practices.

Participant Information

Invitations to participate in the discussion groups were sent to laboratorians who were anticipated to have knowledge of the MMWR recommendation document. Due to scheduling conflicts not all who were invited were able to attend.

There were five participants in the NBS discussion group, including two from state public health laboratory programs serving multiple states, one from a large state (about 400,000 annual births) public health laboratory program, one from a medium state (about 135,000 annual births) public health laboratory program and one from a private laboratory.

There were eight participants in the BGT discussion group, including three from large private genetics laboratories, one from a medium private genetics laboratory, two from university-affiliated genetics laboratories and two from hospital-affiliated genetics laboratories.

Discussion Groups

The two discussion groups, primarily director-level laboratorians with decision-making responsibilities, discussed experiences with the BGT and NBS recommendations in their facilities. The same moderator was responsible for conducting both groups, and the sessions were recorded by a note taker. Participants were made aware that APHL and CDC project team members were observing behind one-way glass to view the group process and to seek additional clarification on their responses if needed.

The goals of the discussion groups were:

1. Provide feedback on how the BGT and NBS recommendations are currently being used, and
2. Define topics and questions that may be included in a nationwide survey regarding the use of the practices in the BGT and NBS recommendations.

Informed consent for participation, audio-recording and site observation was obtained from all participants at the beginning of each discussion group. Each discussion group lasted approximately three hours. At the start of the discussion groups, participants were told that their feedback would be anonymous. Topics for the moderator's discussion guide (Appendix A), consisting of 11 questions (combined into eight questions for this report) supplemented by question probes, were structured with input and guidance from the subject matter experts

at CDC and APHL. The same questions were asked at both the BGT and NBS groups, with the various probes used to expand the questions if needed and to obtain further detail. At the conclusion of each session, participants were asked to write down three best or promising methods to communicate information about the BGT and NBS recommendations to the clinical or laboratory community, and why it is a best/promising approach to share this information.

Summary of Feedback

Audio-recordings of each discussion session, together with the notes and observations from the moderator, observers and note-taker, were used to analyze the discussion group results. A thematic analysis was conducted of the written notes as well as the audio files when necessary.

RESULTS/MAJOR FINDINGS

The major feedback and findings from the discussion groups in response to the question guide are summarized in Table 3.

Table 3: Major Feedback and Findings from NBS and BGT Groups

| Research Question | NBS Group | BGT Group |
|--|---|---|
| 1. Awareness of BGT and NBS recommendations | <ul style="list-style-type: none"> All were aware of the recommendations Some were informed during the process of developing the recommendations Learned by email listserv and presentations at meetings | <ul style="list-style-type: none"> All were aware of the recommendations Some were consulted during the process of developing the recommendations Learned of by email listserv (including MMWR email update) and presentations at meetings |
| 2. Knowledge and understanding of the recommended practices | <ul style="list-style-type: none"> Acknowledged the document as a good summary of accepted good laboratory practices Perceived lack of specific quality control (QC) procedures compared to accreditation checklist Misinterpreted a few recommendations (results reporting, requesting second specimen) Perceived needs for fully implementing certain recommended practices (information system improvements) | <ul style="list-style-type: none"> Acknowledged the document as providing a good overview of laboratory quality systems and quality practices Stated that the most useful recommendations included considerations for introducing new tests, test performance establishment (test validation), quality systems Misinterpreted 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 | <ul style="list-style-type: none"> Already implemented the recommended practices Useful for personnel qualifications Useful for training materials and reference for fellows Useful for development of procedures for establishing performance specifications of new tests | <ul style="list-style-type: none"> Most recommended practices already implemented Useful for orienting fellows and new staff, personnel qualifications, quality improvement plans, introducing new test platform and validating new tests |

| Research Question | NBS Group | BGT Group |
|--|---|--|
| <p>4. Comments on MMWR format/presentation of the recommendations</p> | <ul style="list-style-type: none"> • Challenging to read due to document length and structure • Differing opinions for providing recommendations for NBS and BGT in one document | <ul style="list-style-type: none"> • Challenging to read • Mixed opinions on combining BGT and NBS in one document, most thought it was useful |
| <p>5. Concerns, barriers and perceived problems</p> | <ul style="list-style-type: none"> • No new information • Challenges with using multiple guidelines and regulations • No reflection of NBS programs in different states • Not familiar with using MMWR as a reference document • Perceived gaps (e.g., personnel qualifications should include board certification for laboratory directors, need for improved information systems to implement recommended reporting practices) | <ul style="list-style-type: none"> • Redundancy with other guidelines • No barriers to using the document, but specificity and clarifying examples are lacking for some recommendations • Some recommendations are “unusual” and difficult to implement |
| <p>6. Further dissemination of the recommendations</p> | <ul style="list-style-type: none"> • Most did not disseminate • Few shared with staff • In future will share with follow-up group and fellows | <ul style="list-style-type: none"> • Shared with/used for training staff • Shared/used for training fellows • Shared with other BGT colleagues |
| <p>7. Current measurement of impact</p> | <ul style="list-style-type: none"> • No metrics or indicators used to measure impact | <ul style="list-style-type: none"> • No metrics or indicators used to measure impact |

| Research Question | NBS Group | BGT Group |
|---|--|---|
| <p>8. Participants' suggestions for improvements</p> | <ul style="list-style-type: none"> • Make available companion documents that include only recommendations for NBS • Provide clarifications for differences in state and CLIA requirements • Provide as education material to laboratory surveyors and inspectors • Make available materials to use for personnel competency assessment • Need better engagement of NBS community to vet content of recommendations • Include participants from smaller laboratories in future discussion groups • Share the document internationally • Provide guidance for the following: <ul style="list-style-type: none"> o screening tests not requiring a patient sample o interacting with public and media, especially regarding patients' privacy rights o improving consistency in performance reporting from different states, and on standardization of test performance establishment | <ul style="list-style-type: none"> • Translate and share internationally • Use to educate laboratory inspectors • Use to educate laboratory trainees and fellows • Include participants from smaller laboratories in future discussion groups • Add information on details for rare disease testing • Add use of disclaimers on test results • Clarify reporting of applicable tests on family members • Clarify recommendations regarding reflex testing • Add explanatory information on QC practices for multianalyte testing and include examples • Add further information on informed consent • Add clarifying information on QC for cerebrospinal fluid samples • Consider providing samples for additional proficiency testing programs |

Major Findings from the NBS Discussion Group

1. Awareness of the MMWR document

Participants in the NBS discussion group first learned of the MMWR document via email notifications from professional association email listservs or from presentations by one of the document's preparers at conferences (specifically, APHL's Newborn Screening and Genetic Testing Symposium and the American College of Medical Genetics annual meetings). None of the participants reported learning about the document first via the MMWR website or subscription.

Several of the participants had seen or heard about early drafts of the MMWR document, but stated that they had not been asked to vet the final set of recommendations.

There was a uniform lack of awareness of the CE activity and the availability of several types of CE credits associated with the document. Only one participant reported using the document for training purposes.

2. Knowledge and understanding of the recommended practices

Most participants reported that there was little need for clarification of the content of the document, and that their laboratory staff members could understand it, given sufficient time to read and digest. They agreed, with limited specific questions, that the document did summarize accepted good laboratory practice. Participants commented that the recommendations lacked specific QC procedures as compared to College of American Pathologists (CAP) checklists, but expressed that this lack was appropriate and likely intentional since such specifics could readily be found elsewhere.

Some participants noted a small number of specific recommendations that they would not implement, along with their rationale:

- Reporting specific values if they are normal, participants stated they would report them only if the results are abnormal. Pediatricians and primary care physicians are only informed of quantitative results that require additional follow-up, to save time and resources.¹

¹ The participants might have misunderstood the CDC recommendations because reporting quantitative results for normal specimens is not recommended. The recommendations were specifically for out of range and invalid screens. The specific section is as follows: **Newborn Screening Test Reports**

For a screening result that is outside the expected range of normal test results established for a particular condition (i.e., out-of-range result) or indicates problems with the specimen or the testing process that might compromise the quality of test results according to established criteria (i.e., invalid screen), the following information should be communicated to the newborn's primary care provider without delay:

- The newborn's identifying information (name, date of birth and time of birth), place of birth, and national or local health number
- Parent information (mother's name, home telephone number and address, if available)
- The date and time of specimen collection and arrival in the laboratory
- Analytes evaluated and type of test method, or whichever is appropriate
- **Screening test results in appropriate measurement units**
- **The normal range and cutoff values appropriate for the newborn's conditions, including gestational age, birth weight, and health or disease status**
- Notation of whether the results are out-of-range or invalid
- Required actions, including a repeat screen, confirmatory testing, clinical actions and evaluation, as well as the timeline, steps, and instructions to complete the necessary actions, etc.

- Requesting and testing a second sample from an infant when an abnormal value was found:

“The document recommends, I can’t remember what page, to request a second sample on abnormal results with no additional details. We are not going to retest every child in [location] who has an abnormal result...we go ahead and report it as abnormal, we go through diagnostic testing.”²

- One participant said that, while important, information technology improvements needed to fully implement the recommended reporting processes were likely difficult to implement, due to the associated cost.

3. Use and implementation of the recommended practices

- Current use of the recommendations: Nearly all participants reported that they had already implemented the good laboratory practices outlined in the MMWR document. One participant had used the recommendations to guide development of standard operating procedures and as a reference for implementing new laboratory-developed tests.
- Areas of the recommendations that are most useful: Participants appreciated that the personnel qualifications section was useful.
 - o One person said, “...useful for the description of recommendations for qualifications of individuals who are working within laboratories... in my institution by our quality services managers when they’re looking for qualified individuals for promotions.”
 - o One participant said she was using the recommendations “...for construction of standardization of test development for the implementation of new newborn screening tests,” and
 - o One participant reported that he “...will take a closer look at [the MMWR document] again and see if there may be a few things in there that are helpful for [implementing new tests].”

4. Comments of MMWR format and presentation of the recommendations

Participants reported that combining recommendations for NBS and BGT laboratory practices in the same document was both ambitious and less effective than having two documents. One participant found the combination confusing.

² This participant might have misunderstood the CDC recommendations because the intent of this recommendation was for laboratories to inform primary care providers of the required steps that are necessary after an out-of-range result or invalid screen, rather than requesting a second specimen whenever abnormal results are detected. As in footnote 1, in the “Newborn Screening Test Reports” section, under the lead-in statement “For a screening result that is outside the expected range of normal test results established for a particular condition (i.e., out-of-range result) or indicates problems with the specimen or the testing process that might compromise the quality of test results according to established criteria (i.e., invalid screen), the following information should be communicated to the newborn’s primary care provider without delay: required actions, including a repeat screen, confirmatory testing, clinical actions, and evaluation, as well as the timeline, steps, and instructions to complete the necessary actions, etc.”

“It’s very difficult to get through [the document] and figure out whether or not they’re talking about the biochemical genetics or the newborn screening...”

Alternatively, several participants stated there was benefit in bringing the two types of laboratories together:

- BGT and NBS laboratories conduct parallel or overlapping testing, and therefore have many things in common.
- Learning about NBS would be good for BGT fellows and others, as an understanding of both areas is important to correlate testing and results.

Several participants reported that the document was challenging to read, and since the material was redundant with existing regulations from other sources, they were reluctant to ask their staff members to take the time to read it.

“[My staff] probably wouldn’t take the time to read this. This is very lengthy, very difficult to get through...”

“Now that we read it, we don’t feel it is very friendly the way it’s laid out.”

5. Concerns, barriers and perceived problems

Overall, participants said that the MMWR document did not contain new information and that their laboratories already had the recommended practices in place:

- Procedures were already guided by regulatory agencies or other documents.
- Procedures were similar to those in Clinical and Laboratory Standards Institute (CLSI) documents.

In the few instances in which there were differences between existing CLIA, CAP and CLSI guidelines, and the recommendations in the MMWR document, participants perceived the CDC recommendations to be more stringent (referring mainly to reporting practices). Because of limitations in laboratory information systems, lack of medical provider education, or lack of laboratory personnel or expertise, their laboratories defaulted to the current practices.

In addition, one participant mentioned there are challenges in using multiple documents for test development and other laboratory practices, as they are not exactly alike.

Participants commonly reported that, in the absence of regulatory or other incentives to do otherwise, there was no motivation to comply with another source of voluntary guidelines.

“As a program, I’m looking particularly for quality measures that affect production...I didn’t see anything here that would make me change anything that we’re already doing.”

In addition to the barrier of perceived redundancy with existing regulations, another barrier was that the recommendations did not include examples or specific practices from different states.

“Individual state programs are different, and it’s kind of a mixed argument or discussion we’ve had for a while, should there be more conformity... each state does what is appropriate for their state...maybe there’s not enough allowances for the individual practices because every state is very different and the equipment and the staffing and additional second tier testing is very different in every state.”

Many NBS laboratory practitioners are not familiar with using MMWR documents as resources. Participants did not view the MMWR document (or MMWR documents in general) as reference sources, and stated that they generally used MMWR publications for primarily informational purposes.

One participant said that the personnel qualifications included in the MMWR document for laboratory directors was insufficient, since they did not include board certification as a criterion. Other participants reacted to this comment by saying few directors of public health NBS laboratories are American Board of Medical Genetics (ABMG)-certified but they did feel directors of NBS laboratories should have more stringent qualifications than the CLIA minimum requirements.

6. Further dissemination and ways of using CDC recommendations

Participants stated that they had not shared the MMWR document with members of the clinical community. In general, participants said that clinicians relied on them to sort through laboratory-related information and summarize relevant points. While most participants’ laboratories engaged in ongoing communication with hospitals that submitted samples for screening, they reported that in terms of guidance, the hospitals were primarily interested in how to give a good sample and would not be a good audience for the recommendations.

None of the participants had made efforts to circulate the MMWR document among staff members at their laboratories.

One participant said she would share the MMWR recommendations with the short-term follow-up group in her state, because they were in a different chain of command than the laboratory.

One participant suggested that the MMWR document would be highly useful to international laboratories outside the United States and Europe that currently lack recommendations and guidelines; several other members of the group agreed with this suggestion.

“...there are laboratories in Latin America and Asia that are performing these activities that [could] use these documents to help guide their own functions.”

Participants listed several other specific areas of use:

- Augmenting laboratories’ attempts to provide education to stakeholders, such as physician specialty groups, to demonstrate the benefit of more comprehensive reporting of test results;

- Convincing administrators to make investments in laboratory quality improvements;
- Outlining changes that may be needed in laboratory information systems to comply with reporting guidelines;
- Providing a comprehensive description of qualifications and responsibilities for laboratory personnel in NBS laboratories for use by managers and human resource specialists;
- Training laboratory staff members that are new to a specific area of testing.

7. Current measure of impact

Since the participants thought they had already implemented the recommended practices, participants reported that the recommendations had not had any impact on their quality improvement plans and therefore no metrics or indicators were used to measure the impact of the recommendations included in the MMWR document.

“We have quite a quality assurance program in place already, which... pretty much addresses everything that’s already in this document, and that is also geared up toward meeting the regulatory demands that we have with CAP.”

8. Participants’ suggestions for improvements

Participants suggested the following improvements to the current MMWR recommendations:

a) Ways to improve user-friendliness of the recommendations:

- Limit recommendations to NBS laboratory practices, since their staff had little need to understand what happens in BGT laboratories; however, several participants said that the document was an excellent way for staff in BGT laboratories to learn about how NBS practices differ from biochemical genetic diagnostic testing, and recommended that the MMWR document be used for training.
- Include description of those instances in which state requirements are more stringent than CLIA regulations.

b) Ways to further disseminate the recommendations:

- Educate regulatory agencies and accreditation organizations about using the BGT and NBS recommendations. There are frustrations with CLIA inspections: it is often time-consuming, taking days out of the normal schedule, there is no opportunity for discussion or learning, there is variability depending on specific inspectors, there is never an opportunity to change an inspector’s opinion, and there is no ability to standardize inspection requirements across regions. The participants expressed that it would be helpful if regulatory programs including CLIA and accrediting organizations such as CAP, would use these recommendations to conduct inspections. Two participants informed the group that it was indeed used for that purpose:

“...documents like this are being used to... guide further discussion on adapting laboratory standards that can be used for laboratory inspections.”

“... literally was like almost a recap of the CAP checklist.”

- Advise laboratories that the good laboratory practice recommendations can be used for competency testing. All participants agreed that the document would, however, be very well-suited to an audience comprised of laboratory directors and supervisors. For example, the document could serve as a competency document to prepare these individuals to demonstrate that they possessed an overview of laboratory processes and procedures in an inspection.
- Include more communication with the NBS testing community to vet the content of the recommendations.

“I would have liked to have seen a little bit more in the way of ability for feedback before this document got to the point where, when I first saw it, it was pretty much a done deal. The newborn screening community should have the opportunity to review this because they need to know what is being put out there and what may eventually affect them personally.”

- Include participants from other sizes of laboratories; participants stated the composition of this discussion group may not be representative of all types of feedback from NBS laboratory practitioners; maybe can get others involved by forming a committee with representatives from around the country, by using a similar process to the CLSI feedback process, or by visiting some NBS laboratories in person to discuss the recommendations.

“I would really like to see... smaller laboratories have more opportunities and...have the ability to provide feedback.”

c) Additional improvements include:

- Provide recommendations for NBS processes that do not involve taking a sample from a patient, such as pulse oximetry, hearing screening and possibly other bedside screening.³
- Provide guidance for how to interact with the public and the media. Participants discussed at length their concerns about privacy and about the negative impact of hyperbolic media coverage on parental worries about privacy. They wanted specific guidance on how to address such concerns and still provide informative, effective screening procedures. Participants suggested that a statement within the recommendations that laboratories currently work to ensure the privacy of infants would be helpful and would carry credibility among lay audiences.

³ The NBS and BGT recommendations are not intended to address bedside testing, and thus these tests are outside the scope of this document.

“Clearly this document tries to address [privacy concerns] a little bit by saying everyone should follow their HIPAA and also their state laws on privacy. ...the capacity to address something about privacy, and the protection of privacy, might not necessarily help the laboratory because I think they’re doing a great job anyways, but it may also serve to address some of the public criticisms that are unfounded.”

- Include more guidance on day-to-day challenges associated with newborn screening, such as how to improve transparency in states’ rates of false positives; how to reduce inconsistency in state performance reporting; and how to address limited capacity to standardize performance from laboratory to laboratory.

Major Findings from the BGT Discussion Group

1. Awareness of the MMWR document

All group participants were aware of the document prior to receiving the invitation to participate in the discussion group. Participants said that they learned about the MMWR document in one of three ways:

- By email from CDC’s MMWR updates, close to the time of publication;
- At a professional meeting/conference, also close to the time of publication; or
- Through their own or a colleague’s participation in the process of developing the recommendations.

A few participants reported first learning of the document a few years ago when they were consulted about laboratory practices relating to the recommendations.

When asked about whether they were aware that staff members can use the document for earning CE credits, the discussion group participants collectively responded that they were unaware of such opportunities, but will use it for training in the future.

2. Knowledge and understanding of the recommended practices

Participants commonly said that the document was a good overview of BGT laboratory processes, and that most of the recommendations were already customary laboratory practice in these settings. Most participants stated that while little information contained in the document was new to them, they considered it to be a good aggregation of information that was rarely available elsewhere.

One participant expressed appreciation of the set of recommendations regarding factors to consider when introducing new biochemical genetic tests and establishment of test performance specifications, stating that it was helpful for addressing all the steps needed prior to bringing new tests to patient testing.

Participants also commented that because BGT is different from clinical chemistry, having these recommendations is very important. Also, the recommendations help standardize the interpretation of test results so one can compare from laboratory to laboratory.

Nevertheless, several recommendations relating to test reports, reflex testing and samples to be considered for establishment of test performance were confusing or may have been misinterpreted. These are further discussed in #5 “Concerns, barriers and perceived problems” below.

3. Use and implementation of the CDC recommendations

- a) Current use of the recommendations: Nearly all participants said that their laboratories were already following many of the recommendations prior to the release of the MMWR document. Participants stated that there were no practices in the document (other than the reflex testing guidelines noted earlier) that they did not plan to implement in their facilities.
- b) Areas of the recommendations that are most useful: Participants said the recommendations are most useful in the following ways:
1. Good overview of quality systems and quality practices, and was therefore helpful to orient fellows⁴ and new laboratory employees.
 2. Good information on considerations before introducing new tests:
“...it tells you that you have to put many things into consideration before bringing out the test and how you bring out the test...”
 3. Good information on test performance establishment and verification:
“...when you’re validating the test and putting out the test or launching a new test, the things you need to consider in your coding, your trainings, implementing and how you come back to validate, verify your performance, and your technical staff competency and those listings, I think this is kind of an overview guiding you through the process.”
 4. Useful for meeting personnel competency requirements.
 5. Useful to justify resource allocation: one participant noted that the recommendations would be useful in situations in which the laboratory administration requires justification for why a new hire needs to be board certified for a certain position or for when investment is needed in new equipment and personnel.
 6. Good to improve and reinforce quality improvement plan as well as for reference and information.

⁴The term “fellow” in this context refers to an individual with an MD or a PhD who is formally undergoing advanced training.

4. Comments on MMWR format/presentation of the recommendations

Some participants expressed concern that the document was dense and difficult to read. However, participants felt that the document presents a useful overview of quality practices, and in general felt that it is helpful to have the recommended practices for NBS combined with the recommendations for BGT.

5. Concerns, barriers and perceived problems

The participants agreed that in general there were no barriers preventing their facilities from using the document. When pressed to identify barriers (beyond redundancy with other guidelines), some participants said the lack of specificity in the MMWR document limited its direct application in their laboratories.

Some recommendations were confusing or may have been misinterpreted by participants:

- Reporting of test results, particularly the portions regarding reporting tests related to family history or reporting tests previously done on the patient;⁵
- Use of reflex testing (automatically re-testing when a certain value is obtained). These participants agreed that every test requires a written order by the referring physician before completing the test, but commented that the MMWR document did not reflect this requirement. They noted that this recommendation was more applicable to NBS laboratories and not BGT laboratories.⁶
- The MMWR document was not understood to be useful in competency documentation, as it provided instruction for individual laboratory practice but did not make provisions for laboratory supervisors to monitor and document staff members' skills.⁷

"I don't think it could be used for competency documentation because... this is teaching them how to practice, not monitoring their practice."
- While the MMWR document did provide clarifications for applicable CLIA requirements, participants did not think it helped them meet CLIA regulations. When preparing for a CLIA or CAP inspection, they were more likely to use the CLIA requirements or CAP checklist versus the MMWR recommendations as reference materials;

⁵ The recommendations state that test results in reference to information on family members (e.g., information regarding abnormalities previously detected in a relative used for the selection of the test method) when appropriate and necessary to ensure appropriate interpretation of the test results and understanding of their implications.

- If applicable, an indication that other biochemical genetic tests have been performed for the patient, or, when available, results of other relevant tests that the laboratory performed for the patient

⁶ Following is the actual recommendation, which states that laboratories should have procedures in place to address the unique issues for BGT including when reflex testing is needed (so that if a written order is needed it should be in place or addressed): **Biochemical Genetic Testing** Laboratories that perform biochemical genetic testing **should have procedures in place** to address the following postanalytic or interpretive issues, which often are unique to biochemical genetic testing: Reflex testing (i.e., follow-up testing that is automatically initiated when certain test results are observed in the laboratory) might be needed when useful and appropriate to clarify or expand primary or initial test results.

⁷ CLIA regulations require laboratories to have policies and procedures for competency assessment of all employees. See § 493.1235 Standard: Personnel competency assessment policies: As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

- Inclusion of a sufficient number of both positive and normal samples in test performance establishment was confusing, since the suggested recommendation might not be appropriate to rare diseases.⁸

6. Further dissemination and ways of using the recommendations

Several participants said that they shared the MMWR document with members of the clinical community, which included supervisors within their facility, other biochemical geneticists, and in one instance, a colleague who was transitioning the laboratory from compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements to CAP. One participant said that a colleague had shared the document with them.

Many participants said that they made the MMWR document available to their staff and others at their facilities. Specifically, participants mentioned sharing the document in the following ways:

- Posting a hard copy of the document in the laboratory.
- Saving a PDF copy of the document on a laboratory computer.
- Providing quality managers and fellows who rotate through laboratory with copies.
- Sharing (either in hard copy or electronically) with management level staff and directors within the facility.

Several participants shared useful information about how to use the document in their facilities. Two participants noted that, as a result of the group discussion, they would forward the document to their fellows, laboratory managers, and supervisors. In addition, all participants said they were unaware that the document could be used for continuing education.

“When this came out I did distribute it [the document] to our directors, and I honestly don’t know if they just filed it or if they pored over it...as a result of this discussion, I am rethinking about making sure the lab manager and supervisor are familiar with it.”

⁸ The relevant recommendations are as following: **Samples for Establishment of Test Performance**

In general, test performance specifications should be established with an adequate number, type, and variety of samples to ensure that test results can be interpreted in the context of specific patient conditions and that the limitations of the testing and test results are known. The number and type of both positive and normal samples should be considered when selecting and determining samples needed.

The numbers of both positive and normal samples should be adequate for determining the performance specifications of the assay being established. Both disease prevalence and sample characteristics might influence sample availability, thus the availability of samples and reference materials also should be considered. For example, a large number of positive samples (and in certain circumstances, normal samples) might not be available for rare conditions; unstable samples or samples that need to be collected invasively (such as cerebrospinal fluid or muscle biopsy samples) might be limited. **Laboratories should consider these factors and define test performance specifications and limitations based on the samples that are available and included in the performance establishment.**

7. Current measurement of impact

None of the participants reported using any metrics or indicators to measure the impact of the recommended practices in the MMWR document, though several participants mentioned that they use metrics and indicators to measure the success of their processes as a whole.

“We all have metrics for looking at the changes of our processes, but I’m not sure that any of those come from here [the MMWR document].”

“Because we have already implemented pretty much everything, the impact of these [recommendations] on our practice is not big; except for now, we have a document that’s educational, that’s good, that gives you a general overview, a big picture and everything you need to have in place.”

Participants commonly said that the recommendations had no impact on their quality improvement plans, which were already mature and comprehensive.

Regarding the impact on preparing for a laboratory inspection, one participant said CAP already has a BGT checklist, using some of the criteria in this document.

8. Participant suggestions for improvement

a) Ways to improve user-friendliness of the recommendations:

Nothing was suggested in this area.

b) Ways to further disseminate the recommendations:

- Translate into other languages, as it would be very useful in other countries too.
- Educate CLIA and CAP inspectors about the processes of the BGT laboratories.

“... a clinical chemist... could get a copy of this to read through prior to the inspection so they could get a better grasp of how the biochemical genetics laboratories differ from a chemistry laboratory...”

- Include laboratories not represented in the discussion group: participants said it would be interesting to hear from other types of laboratories, and especially smaller laboratories who may not have a full time QA department.

c) Additional improvements:

- Add more information about proficiency testing, determination of test specificity and detection rates, test validation and QC practices for rare disease testing

Participant A: *“[I would like to see] recommendations on how to handle those analytes which are not available.”⁹*

⁹This comment refers to the unavailability of certain analytes in existing proficiency testing programs.

Participant B: *“Yes, that’s what I was going to say as well. That’s an issue when there’s not a standard and there are no positive control samples.¹⁰ How do you handle that?”*

- Include how to use disclaimers (meaning statements about any limitations of testing) on biochemical genetic tests. Participants discussed how using inappropriate language on reports could cause legal issues for their facilities, and that the issue of disclaimers in general warranted improved standardization. Participants suggested that disclaimers, including method description and sensitivity and specificity, could be given either on a written report or on the laboratory’s website.
- Clarify recommendations about reporting other applicable tests on previous tests on the patient or on family members, including conforming with HIPAA requirements.¹¹

“...including family members’ results in the report, or disseminating other family members’ results; that would be a HIPAA violation.”

- Clarify reflex testing and reflex test ordering, reporting and validation.

“I think [the recommendation for reflex testing] is unclear. ... [it is] just lab practice that most of the people in this room would just [do].”

¹⁰ This comment refers to samples for testing of rare diseases.

¹¹ There is a provision within HIPAA regulations permitting using and disclosing protected health information for healthcare purposes: 45 CFR §164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) Standard: Permitted uses and disclosures. Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(c) Implementation specifications: Treatment, payment, or health care operations.

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is: (i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or (ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

In addition, HHS provided clarifications for these provisions among the HIPAA frequent questions available at HHS HIPAA FAQs

Question: Does the HIPAA Privacy Rule permit doctors, nurses, and other health care providers to share patient health information for treatment purposes without the patient’s authorization?

Answer: Yes. The Privacy Rule allows those doctors, nurses, hospitals, laboratory technicians, and other health care providers that are covered entities to use or disclose protected health information, such as X-rays, laboratory and pathology reports, diagnoses, and other medical information for treatment purposes without the patient’s authorization. This includes sharing the information to consult with other providers, including providers who are not covered entities, to treat a different patient, or to refer the patient. See 45 CFR 164.506.

- Provide more detailed descriptions of QC practices for multianalyte testing, including specific examples.
- Provide more detailed information about informed consent procedures.
- Describe samples to be considered for establishing test performance specifications, especially for assays performed for cerebrospinal fluid samples.¹²

“I think maybe we can have more clarification on the [reference] test intervals; we have our own protocol that we follow, but...because these are the disorders that are very rare so getting the positive samples is really a challenge for us. So, if we have some recommendation on that it would be helpful.”

- Consider providing proficiency samples in order to aid the standardization of diagnosis.

Ideas for Communicating CDC Recommendations to the Laboratory and Clinical Community

Participants in both the newborn screening and biochemical testing groups provided suggestions for communicating CDC recommendations to the laboratory and clinical community, which are presented in Table 4 below.

Table 4: Suggestions for Communicating the Recommendations to Laboratory and Clinical Community

| Target Audience(s) | Dissemination Approach |
|--|--|
| <p>Laboratory directors; pediatricians; general science communities; any interested party</p> | <p>Publication of recommendations in a peer-reviewed journal: Nearly all participants agreed that there is a greater likelihood that the clinical community will read and use recommendations if they are published in a peer-reviewed journal. Participants strongly encouraged this approach in both sessions.</p> |

¹² The participant was requesting clarification for the following recommendations: “The numbers of both positive and normal samples should be adequate for determining the performance specifications of the assay being established. Both disease prevalence and sample characteristics might influence sample availability, thus the availability of samples and reference materials also should be considered. For example, a large number of positive samples (and in certain circumstances, normal samples) might not be available for rare conditions; unstable samples or samples that need to be collected invasively (such as cerebrospinal fluid or muscle biopsy samples) might be limited. Laboratories should consider these factors and define test performance specifications and limitations based on the samples that are available and included in the performance establishment. The types of samples should represent the types of patient specimens that are expected for the assay (e.g., whole blood, serum, urine, dried blood spot, fresh or frozen tissue, or prenatal specimens). For example, if the laboratory intends to perform amino acid analysis for urine, plasma, and cerebrospinal fluid specimens, test performance specifications need to be established for all three specimen types because each specimen type might be associated with a different total testing process as a result of differences in specimen collection and handling, specimen stability, interfering substances, analyte extraction, reference ranges, results interpretation and other preanalytic, analytic and postanalytic factors.”

| Target Audience(s) | Dissemination Approach |
|--|---|
| Meeting attendees; members of professional societies | Presentation about recommendations at annual professional meetings/conferences: Many participants first heard about the recommendations document in these settings. |
| Clients served by programs | Inclusion of mentions in laboratory or public health newsletter |
| NBS laboratory supervisors and directors; NBS laboratory staff; NBS follow-up testing groups | Sending emails to NBS email listservs: Several participants in this group had learned about the MMWR document via email notifications, and viewed this as an effective route for reaching audiences who do not regularly access MMWR. |
| NBS physicians | Development and provision of blurbs for inclusion in NBS program newsletters: Participants recommended this approach because they said that it was a good way to disseminate information to physicians, who are less likely to read the document in its entirety, due to its length and lack of immediate relevance. |
| Physicians; researchers; laboratory staff; general public | Placement of document on dedicated website(s): Several participants recommended this approach as an efficient way to reach a broad audience. |
| Program directors; ABMG diplomats and those involved with Maintenance of Certification; Clinical Chemistry program directors/ members; quality assurance officers of institutions | <p>Issuance of statements in collaboration with professional associations, including:</p> <ul style="list-style-type: none"> • the American Board of Medical Genetics (ABMG); • the American Association for Clinical Chemistry (AACC); • the American College of Medical Genetics (ACMG); and • CAP/CLIA. <p>Participants recommended this approach as a way to establish credibility and to demonstrate that the entities that oversee NBS and BGT laboratories recognize this document and the recommendations included within the document.</p> |

DISCUSSION

Awareness and Perceptions of the MMWR document

Most participants learned about the MMWR document either via email (as an MMWR update from CDC, or from a professional association email listserv) or at a conference or professional meeting. Several participants in the BGT group had contributed to the development of the document, and none expressed concerns over the development of the document. Some participants also mentioned that MMWR is not a well-known resource for the BGT and NBS communities. While MMWR is a widely used and well-respected resource in the infectious disease and chronic disease areas, it may require more effective communication to bring this resource to the BGT and NBS communities.

There was concern in the NBS group that there had been insufficient opportunity for members of this community to review and vet the recommendations prior to publication. This may need future clarification because indeed there was repeated review by various groups: the 2010 CLIAC recommendations were the basis for the document and were shared with the broad NBS community, followed by CDC collaboration from 2010-2012 with multiple federal agencies, two additional federal advisory committees, key stakeholder organizations and NBS laboratories to incorporate additional input and ensure adequate vetting. Several rounds of review and comment were conducted during this period after the CLIAC recommendations were done.

Participants stated that this lack of vetting was particularly problematic in a context where they believed that “recommendations...become mandates” and laboratories already face challenging compliance requirements. This may need future clarification, because the BGT and NBS recommendations are voluntary.

Participants in both groups mentioned that while the BGT and NBS recommendations were a good summary of good laboratory practices, the dense format of the information made the document challenging to read. One solution to this challenge would be to offer training on specific areas of the recommendations and outline the key aspects.

In both groups, participants reported that the CDC recommendations did not differ significantly from other available resources, including CAP, CLIA and CLSI guidelines. In both groups, participants shared that all of the discussion group participants came from large or medium-sized, well-supported, rigorously run laboratories, and said that the document might be more useful for laboratories that do similar testing but do not follow the guidelines as closely, whether for capacity or resource reasons. Participants in both groups mentioned that the criteria listed for qualifications of laboratory personnel was helpful; one member of the NBS group stated that their institution’s HR department had used the document to make changes for their hiring scheme.

In the NBS group, the participants stated they had already implemented the recommendations by using other existing regulations and guidance documents. The BGT group shared this perception. Since the document was provided as a guide and resource

to clarify essential quality practices and help laboratories achieve continuous quality improvement, laboratories are encouraged to review their existing practices. If a laboratory already has the recommended practices in place, then it has already implemented the good laboratory practices and is expected to use the NBS and BGT recommendations as a reference to maintain quality practices and personnel competency.

The BGT group also perceived several specific problematic recommendations (those involving reporting previous test results on the patient and family members and conducting reflex testing) and a lack of specificity in the MMWR document as limiting factors.

In both groups, all participants said that they did not make any changes to their laboratory procedures or quality plans as a result of the recommendations, since they were already aligning their efforts with (similar) existing guidelines. For this reason, the MMWR document was not considered helpful in preparation for, or during, CAP or CLIA inspections. This may need further clarification, because CLIA surveyors are not generally expected to use the recommendations to evaluate regulatory compliance even though they have been provided with copies of the document.

In both groups participants noted that the document could be very useful to international audiences, particularly in Asia and Latin America, where there is less existing guidance for laboratories.

Dissemination of Recommendations by Participants

NBS participants suggested that the recommendations' redundancy with other sources limited their willingness to share the document with their staff. For this reason, most of the NBS group had not taken action to make the document available to their staff, although one had shared it with fellows in training. In contrast, participants in the BGT group felt the document as a global overview of good laboratory practice and used (or shared their intent to use) the document for training and education of a number of different stakeholders, and provided it to their staff through a number of different channels.

Participants in the NBS group expressed that the document was well-suited for competency documentation for supervisors and administrators, whereas the BGT group participants did not recognize this as a valuable use. Further training is needed to inform laboratory professionals about the usefulness of this document for competency testing.

Interestingly, members of the NBS group also reported that the document would be an excellent training tool for BGT laboratory staff and fellows to learn about how NBS laboratory procedures differ from biochemical diagnostic testing. In both groups, participants were unaware that CE credits were available for staff who read the document.

Participants in the BGT group had shared the MMWR document with laboratory managers and BGT colleagues. In contrast, the NBS participants had generally not shared the document. NBS participants said that their role in relation to clinicians was to sort through laboratory-related information and only share the relevant portions. These participants did not perceive their partners at hospitals to be invested in improving laboratory procedures beyond collection of samples adequate for testing purposes.

Overall, the participants in both groups stated that the recommendations provided in the CDC document were scientifically and logistically sound, though they shared that the document was very dense with information and was therefore challenging to read.

There were several subject areas where the NBS and BGT groups had differing perceptions of the recommendations. These perceptions and the levels of use of the recommendations are outlined in Table 5.

Table 5. Contrasting Perceptions and Levels of Use for the NBS and BGT Groups

| Subject Area of Perception | NBS Group | BGT Group |
|---|---|--|
| Adequacy of review and vetting | Needed more opportunity to contribute to vetting | Some members participated in document development, vetting was adequate |
| Usefulness of information | Redundant with CLSI guidelines and CAP checklists | While redundant, valuable overview of good laboratory practices |
| Usefulness of BGT and NBS recommendations for competency testing | Useful for supervisors and administrators | Not recognized by group as useful |
| Usefulness of combining NBS and BGT in document | Knowing about NBS practices would be useful to BGT laboratorians, but BGT practices are not useful to NBS laboratorians | No need for BGT laboratorians to know anything about NBS practices |
| Distributed document to clinical community | No | Limited |
| Levels of use | No specific recommendations implemented and not widely distributed among laboratory and clinical staff | No specific recommendations implemented, distributed to managers, will use in the future |

Areas of Recommendations Identified as Most Helpful

Both the BGT and NBS discussion groups identified several areas or aspects of the good laboratory practice recommendations as helpful for their practice or the laboratory community in general, including:

- Overview of all aspects of good laboratory practices for NBS and BGT
- Factors to consider when introducing new tests or new technology
- Test performance establishment/validation protocols for new tests
- An outline of qualifications of laboratory personnel for hiring and promotion
- Reinforcement of the use of Quality Improvement Plan
- Potential usefulness internationally

Areas of Recommendations or Regulatory Oversight That Need Clarification or Improved Understanding

Participants of the discussion groups suggested that several areas of the good laboratory practice recommendations would need improvement or clarification for better understanding. Their suggestions included:

- Provide examples of validating multianalyte tests, test limitation statements for patient reports and validate tests for rare conditions
- Provide clarifications regarding reflex testing, requesting second specimens and including information on other relevant testing in test reports to improve understanding of these recommendations
- Provide more detailed recommendations about informed consent procedures

In addition, the discussion also revealed that several areas of federal regulatory standards need improved understanding, including:

- CLIA requirements for laboratories to have policies and procedures for competency assessment of all employees (§493.1235).
- HIPAA regulations permitting the use and disclosure of protected health information with care providers for healthcare purposes (45 CFR §164.506).

Lack of Awareness of Continuing Education Activities

CDC provides a free-of-charge CE activity for the 2012 MMWR publication at <http://www2a.cdc.gov/TCEOnline/>. As of April 2014, 459 health professionals registered for this CE activity and 320 have earned CE credits in their desired categories including CEU, CME, continuing nursing education (CNE) and continuing education contact hours (CECH). While CE participants may only represent a fraction of individuals who read or planned to use the recommendations, their general comments conveyed that the document was informative, helpful and provided a great learning experience. Most participants expressed that the document addressed a need or a gap in their knowledge or skills, and that they could apply the knowledge gained when possible. However, participants in both the BGT and NBS discussion groups were unaware of the CE activity and the different categories of CE credits available. On the other hand, both groups expressed that they would be interested in using this resource in the future. Therefore, future dissemination and outreach efforts will be

critical to improve laboratory professionals' awareness of the CDC recommendations as a resource for improving understanding of recommended quality practices. Additional training and education activities also should be developed to specifically address the learning needs of laboratory and healthcare professionals and to facilitate their competency documentation needs.

Limitations

While use of discussion groups is a valuable tool for exploring participants' awareness, knowledge, attitudes, beliefs and behaviors (7), discussion group methodology has some limitations. Discussion groups are qualitative; they are designed to develop insight and depth of understanding, not quantitative estimates. Discussion groups rely on purposive sampling to identify groups of people with characteristics that are relevant to the study purpose and outcomes. Findings from discussion group dialogues are not generalizable to the population as a whole; discussion group methodology does not use the rigorous sampling methodology that would be necessary to draw wide-ranging conclusions (7, 8). For example, the laboratory professionals from large state public health laboratories who participated in the discussion groups may not have the same experiences or be reflective of individuals from very small laboratories in cities and rural areas throughout the country. Also, all participants consented to participate in the discussion groups; it is not known how, or if, these participants differed from those who declined to participate, due to schedule conflicts or other reasons. In addition, laboratory supervisors or quality managers may have had different opinions due to their different roles in the laboratory.

IMPLICATIONS FOR NEXT STEPS

Lessons Learned

The feedback provided by the discussion groups revealed very helpful insights about the current status of awareness, understanding and utilization of the recommended practices. Following are among the lessons learned that could be used to guide the next steps of this projects as well as development of future recommendations:

- Identifying areas of misunderstanding that need clarification is important to improving understanding of the recommendations,
- Clearly defining the purpose of the recommendations is important to their acceptance,
- 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 feedback to members of the NBS and BGT laboratory communities will increase use of recommendations,
- Providing training on the recommendations is necessary to increase their understanding and use,

- Awareness does not equal understanding — although most of the 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. Therefore to facilitate use of the recommendations in practice we need to take steps to help our target users improve understanding of the recommended practices and how to apply them.
- The MMWR document provides quality management principles for many complex areas of laboratory practices. As a comprehensive guide, it is also time-demanding to read through and not sufficiently user-friendly for many laboratory professionals' busy schedules. Therefore efforts that facilitate understanding and use of the recommendations, such as supporting materials, dividing the whole document into sections with clarifications and examples and interactive training activities, are essential for sustained implementation of the recommended practices.
- Training/education activities should be tailored to different audience groups, use practical examples and be delivered in user-friendly ways to facilitate learning.

Major Next Steps

Based on the input from the discussion groups, major next steps of the project will include (also see Appendix C):

1. Convene a NBS and BGT taskforce, with members included from large, medium and small laboratories and with job titles of director, supervisor and quality assurance manager. Explore areas to have the NBS and BGT groups work together.

The taskforces will have the following activities:

- a) Improve understanding of the good laboratory practice recommendations by key audience communities.
 - Review a potential supplemental tool based on the MMWR recommendations, which is a crosswalk of CLIA requirements and the MMWR good laboratory practice recommendations and give feedback regarding its usability.
 - Contribute to the content of a training needs assessment which will identify areas of focus for developing education tools, training activities and/or supporting materials of the MMWR good laboratory practice recommendations.
- b) Assist in identifying formats, platforms and facility for training events.
- c) Offer recommendations for how to market the training/education tools and to what audience.
- d) Provide advice for developing systems to track and measure the impact of the MMWR good laboratory practice recommendations, training products and education tools.
- e) Pilot test the nationally-representative survey which will focus on the training and marketing results of the products (not implementation of recommendations).

- f) Explore options for other supplemental information to assist users in using the MMWR good laboratory practice recommendations.

2. Conduct case studies by following up with selected discussion group participants, to obtain additional clarification and in-depth information on how the recommendations had been used in their specific setting, which areas of the recommendations were utilized by which laboratory personnel and which laboratory activities had been influenced.

The outcomes of these case studies are expected to lead to information on the impact of the recommended practices in specific but representative laboratory settings, which will serve to not only provide critical information to the systematic evaluation and complement the suggestions from the taskforces regarding further training needs.

3. Develop 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. Major areas of the recommendations to cover include:

- a) Preanalytic practices and responsibilities of NBS and BGT laboratories, including providing information on the tests performed by the laboratory and instructions for specimen collection, submission and transport. The education activities will emphasize the laboratory responsibilities for preanalytic systems assessment, to help laboratories monitor the effectiveness of their preanalytic procedures, identify areas needing improvement and take corrective and preventive actions.
- b) Application of the quality management system approach in NBS and BGT laboratory environments to improve laboratory services and operations.
- c) Analytic practices, including recommended QC practices and participation in proficiency testing/external quality assessment programs.
- d) Postanalytic practices, including the recommended reporting practices and postanalytic quality systems assessment.
- e) Compliance issues, to address the common issues and questions reflected from laboratory inspection processes.

4. Develop evaluation tools to assess the improvements in understanding of the recommended practices and improved use of the recommendations in practice.

5. Marketing the CDC Recommendations in the MMWR Document

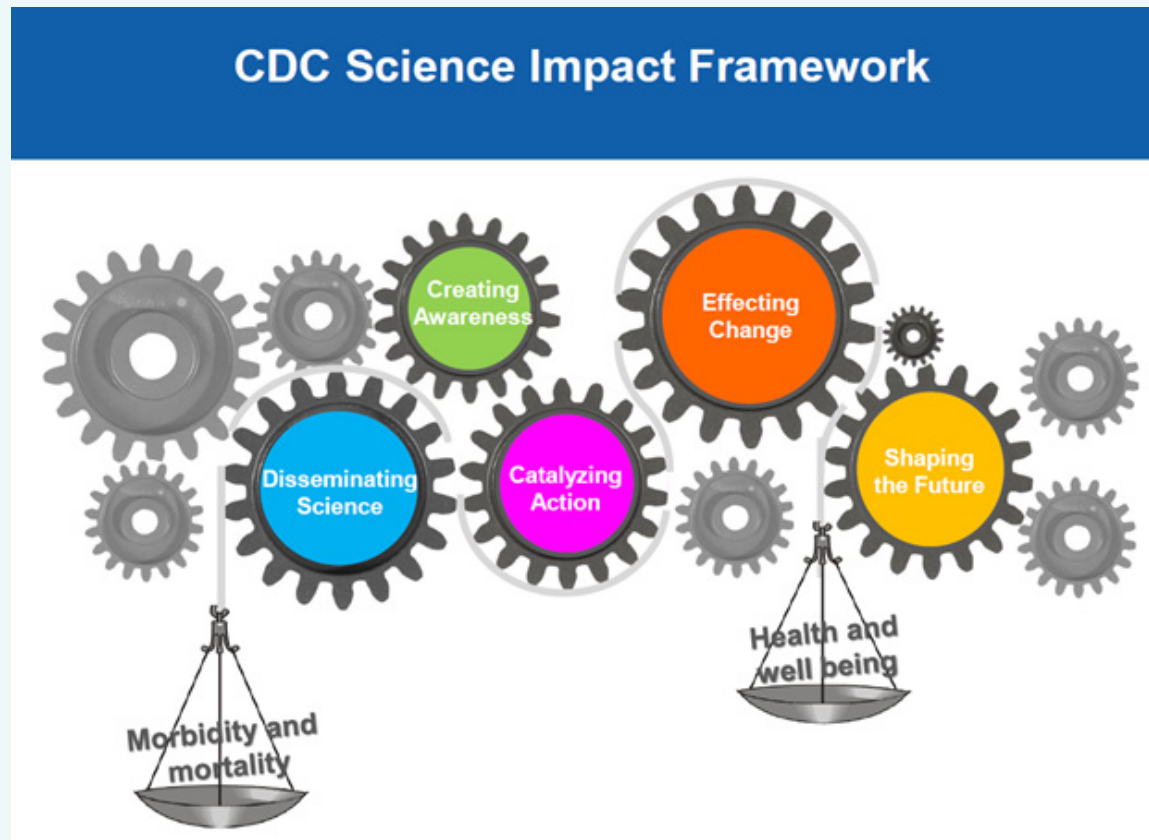
- a) Define the intended audiences and uses for the document.
 - Nearly all participants said that it is critical that CDC make it clear at the start of the document that it is intended to provide an overview of good laboratory practice, not to provide required guidelines and to direct readers to sources where more specific guidelines can be found.

- b) Explicitly state why the level of specificity was selected.
 - Participants who expressed a desire for more specific guidance in the document were countered by other group members who shared their perception that the intent of the document was to simply provide an overview. They agreed that CDC should make clear why the level of specificity in the document was selected.
- c) Continue to work with public health listservs to disseminate the document, including provision of a permanent URL.
 - Many participants in both groups learned of the document via curated listservs, and suggested that it is a good way to ensure that the MMWR document is broadly shared in the scientific community.
- d) Utilize email listservs with credibility outside the public health arena.
 - While all discussion group participants were familiar with MMWR, none considered it a primary reference source, and most stated that the report was not well-known to individuals outside the realm of public health.
 - Nearly all participants agreed that CDC should disseminate the recommended practices on email listservs that are used and credible beyond the public health arena, such as national conferences or as in peer-reviewed journals. Many participants said that professional conferences were an efficient, credible channel to disseminate the MMWR document to a wide range of clinical and scientific professionals.
- e) Highlight portions of the document addressing current field controversies.
 - Many participants lamented the lack of consistency in terminology in genetic testing, spoke about the need for guidance in privacy issues, and discussed controversy over the implementation of reflex testing recommendations.
 - Since the guidelines provided may have long-term impact for laboratories, the portions of the recommendations that speak to controversial topics should be carefully vetted by a range of stakeholders prior to publication/release. Once consensus is reached, however, these sections should be widely disseminated to bring standardization and clarity to the field.
- f) Emphasize the availability of CEUs.
 - Most of the discussion group participants were unaware of using the document for CEUs. Even discussion group participants who had played a role in development of the document were unaware of this opportunity. Participants frequently said that the document provided a good overview of their field, but that it was so dense that they hesitated to pass it along to staff. Promotion of the availability of CEUs may incentivize use of the document.
- g) Promote the use of the document in international settings.
 - All participants (in both groups) agreed that the recommendations were similar to existing guidelines in the US (and Europe); however, many laboratories operate in countries and regions where there is less regulatory infrastructure. Participants suggested that laboratories outside the US and Europe (particularly in Asia and Latin America) can benefit from the guidance in this document.

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APPENDIX A: CDC SCIENCE IMPACT FRAMEWORK¹



¹ CDC Science Impact Framework. CDC Science Impact Framework.

Five Levels of Influence by Scientific Products:

DISSEMINATING SCIENCE: Disseminating science may include publication of findings in peer review journals or other venues, presentation at conferences, or through other media channels.

CREATING AWARENESS: Receiving recognition may include awards, general awareness, or acceptance of a concept or findings by scientific community or policy makers, generating new discussion.

CATALYZING ACTION: Catalyzing action may include partnerships and collaborations, technology creation, congressional hearings or bills, or introduction in practice.

EFFECTING CHANGE: Effecting change may include building public health capacity, legal/policy change, cultural/social/behavioral change, or economic change.

SHAPING THE FUTURE: Shaping the future may include new hypothesis or strategies, implementation of new programs/initiatives, or quality improvement.

APPENDIX B: DISCUSSION GUIDE

Biochemical Genetic Testing and Newborn Screening Discussion Groups

Write on newsprint before people enter the discussion group room:

- **Name of Discussion Group** – Biochemical Genetic Testing (1 group)
- **Name of Discussion Group** - Newborn Screening Discussion (1 group)
- **Group Goals for both separate discussion groups:**
 - Discuss how the recommendations in “Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders” published by CDC in April 2012 are being used by laboratory scientists.
 - Seek clarification on topics and questions that are anticipated for inclusion in a nationwide survey regarding the use of the recommended practices from the document.

FOR MODERATOR: The goal of the discussion groups is to assess the use and impact of CDC recommendations for laboratory practices published in an April 2012 MMWR. The recommendations offer guidance on quality practices in different types of laboratories to help laboratories improve quality of services, improve health outcomes of patients and families, and improve overall public health.

APHL and CDC have limited data on laboratories’ awareness of the MMWR recommendations and little knowledge about their incorporation into laboratory procedures and practices. These discussion groups will provide first hand preliminary information to APHL and CDC on awareness of the recommendations, how they are accepted and how they are being used in laboratories directed by discussion group participants.

As a reminder, the recommended practices in the MMWR document are recommendations rather than regulatory requirements!

INTRODUCTION TO GROUP PROCESSES AND PROCEDURES (10 MINUTES)

We would like to welcome you all to this group discussion. Thank you very much for agreeing to participate in this discussion group. My name is Ashani Johnson-Turbes and I will facilitate our discussion. I work for ICF Macro, a research and consulting firm in Atlanta, Georgia. We are conducting this discussion group on behalf of the Association of Public Health Laboratories (APHL) to discuss recommendations in the MMWR document titled “Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders,” which was published by the CDC in April 2012.

As you may recall from when you were contacted to participate in this group, we are conducting the group to gather information about your impressions of the MMWR document, obtain your feedback on the recommendations, and learn about how you are using the recommended practices in your laboratories. We will use the information gathered to develop

of a nationwide survey. **Please note that the purpose of this group is not to scrutinize the MMWR document. These discussions are not meant to be used for rewriting the recommendations, rather they will help APHL and CDC know your overall thoughts, how you use the recommendations in your laboratories, and if you think that there are any gaps in the recommendations.**

My role is to simply facilitate the discussion, make sure we stay on topic, raise questions, and make sure we stay within our 2-hour time limit. I am not here to push any particular agenda or point of view, but rather to hear your frank and honest opinions. There are no right or wrong answers, and nothing to be ashamed of. We all have our own likes and dislikes, our own thoughts and feelings. We just ask that you speak one at a time, say your first name only before your answers, so that we know who is speaking for our notes.

I want to remind everyone that the discussion here is private. We report findings in aggregate and do not report your comments by name. We ask that you respect one another's privacy in the same way. We don't expect you to tell us anything that you would be uncomfortable sharing with the group, but we do hope that you will be honest with your responses to the questions I ask.

NOTE: Participants will complete the Informed Consent Form prior to entering the discussion group room. The consent form requests permission for CDC and/or APHL to contact participants after the discussion group to gather additional information, if necessary.

Also remember that your participation in this group is voluntary. That means you can leave at any time. If you are uncomfortable with a question, or if you simply don't have a response, it is fine to pass. We don't need everyone to answer every question, but we are interested in all of your perspectives and really value what you have to say.

During this discussion, a lot of questions might come up that you would like me to answer. I am not a laboratory scientist, a health care professional or an expert in this area. I will not be able to answer your questions and I may even need you to clarify terms as we proceed. However, I do have a room full of scientists behind me that can answer questions if you want to talk to them at the end of our discussion. So please keep track of your questions and after we finish with our discussion, there will be someone available who can answer questions and provide you with additional information, if wanted.

Now I'm going to ask a series of questions, but mainly I want to hear from you. As I mentioned, my role is simply to guide the discussion. Sometimes we may really get going on one question, and I'll have to move you on to the next question so that we may cover everything. Please don't take it personally! We just need to hear from everyone about several topics.

As you can see there is a mirror behind me. It is a two-way mirror because we have observers and a note-taker viewing this group. The note-taker is from my company, ICF Macro. We also have APHL and CDC staff members observing this discussion group. Our observers are very interested in taking notes on potential topics and/or potential responses to use in the national survey on how the recommendations are being used.

FOR MODERATOR: Review ground rules.

There are also a few ground rules that I would like us to adopt for our discussion:

- Please use your first name only during the discussion.
- You have been asked here to offer your views and opinions.
 - Feel free to agree and/or disagree respectfully. I'm not looking for consensus. We want to give each of you equal "air time." Please speak loudly, clearly, and one at a time.
- Everyone's input is important. I may call on you if you are being quiet.
- Avoid side conversations.
- Let one person speak at a time.
- I may need to cut a discussion short to get through the whole discussion.
- Please turn off all cell phones!
- There are no right or wrong answers
- All answers are confidential, so feel free to speak your mind.
- Respect one another at all times.
- It's okay to disagree.

Most important, please try to speak up, speak clearly, and one at a time. We are audiotaping the discussion so that we can have an accurate record of the discussion.

Do you have any questions before we get started?

FOR MODERATOR: Answer any questions that you can and get started!

PARTICIPANT INTRODUCTIONS AND WARM-UP EXERCISE (2-5 MINUTES)

So we can get to know each other a little, let's go around the room and introduce ourselves. Please tell us your name, your position and the type of laboratory you work in.

Thank you. Now, let's get started with our discussion.

DISCUSSION QUESTIONS

1. How and when did you first know about the MMWR document?
2. Which recommendations in this document are new information to you or your facility?
 - a. Among the recommendations that were new to you or your facility, which have you implemented (or incorporated into policies and procedures)
 - i. How have the recommendations been implemented?

- b. Are there any other new recommendations that you are considering or hoping to implement?
 - i. How do you plan to implement them and what general timeframe are you considering?
 - c. Are there any new recommendations that you do not plan to implement?
 - i. If yes, why?
 - d. What benefits or challenges have you experienced as a result of implementing any changes?
3. With the recommendations your facility has implemented, have any changes in the facility's testing services occurred?
- a. Have you used any metrics or indicators to measure the impact those recommendations have had on your facility?
 - i. If yes, how did the metric results or how will the metric results be used to inform work processes in your practice?
 - ii. List some examples, such as shortening turn-around time, fewer unsatisfactory samples submitted, or verbal feedback from clinical users.
 - b. What impact have the recommendations had on your quality improvement plan?
4. How is the document made available and accessible to staff members or others at your facility?
- a. Are you aware that staff members can use the document for earning continuing education credit? Has that opportunity been used by you or your staff?
 - b. Do staff members use the document for training and/or continuing education purposes?
5. Have the recommendations been useful in other areas, such as competency documentation, new employee training, etc.?
6. Have the recommendations been used to justify resource allocation (e.g., personnel hiring, training, space, and new equipment or laboratory protocols) to your administration or leadership?
7. Do any of the recommendations provide you with clarifications or options that help you meet CLIA requirements?
- a. If yes, which ones?
 - b. Have you had an inspection (CAP, CLIA or other) since implementing any changes that reflect the recommendations in the document?

- i. If yes, did implementing the recommendations in the document have any impact on the inspection? Why or why not?
 - c. Assuming that your laboratory was already meeting the CLIA requirements, did the recommendations help you explain to the surveyors how your processes meet CLIA requirements?
8. Did you share and/or communicate any of the recommendations with the clinical community (for example, test requestors, sample submitters, other healthcare professionals)?
 - a. If yes, which recommendations were shared?
 - b. What benefits or challenges have you encountered as a result of communicating these recommendations? For example, did they help open lines of communication between parties in the clinical community?
9. What factors are preventing you or your facility from using and implementing the recommendations?
10. Are there any gaps in the recommendations that you would like to see addressed?
 - a. How would you like to see these gaps addressed?
 - b. What kind of training and/or tools would be helpful?
11. Are there any recommendations that you find confusing or need further clarification on?
 - a. For those recommendations you find confusing, what information would be helpful for clarification?
12. Is there any additional information you would like to share with the panel?

FALSE CLOSE: (15 MINUTES DEPENDING ON HOW MUCH FOLLOW-UP WE NEED)

I have one more activity for you to do today. Please take about 5 minutes and reflect on how to communicate any of the recommendations in the MMWR with the clinical or laboratory community (e.g., test requestors, referring laboratories, sample submitters, other healthcare professionals).

Please write down on the note pad in front of you 3 best or promising methods to communicate information about the recommendations to the clinical or laboratory community, which community and why you think it is a best/promising approach to share this information.

| Promising communication/ dissemination approach | To which audience | Why you think it is promising approach to communicate/ disseminate information to clinical or laboratory community |
|--|---|---|
| EXAMPLE 1: Quarterly email blasts to newborn screening (or inherited metabolic disease) listserv | 1. Laboratory directors and supervisors | 1. This approach ensures that laboratory directors and supervisors are aware of and knowledgeable about recommended practices. They are the key people to share this information with since they are tasked with getting information to their laboratory staff. |
| Example 2: Quarterly email blasts to pediatricians in my institution | 2. These pediatricians submit biochemical genetic test requests to my laboratory. | 1. This approach helps pediatricians know what information is provided by my laboratory on our tests and help them select appropriate tests for their patients. It also helps them understand what information is needed by my laboratory in order to perform the tests they requested. |

You do not need to write your name on your paper. While you do this, I'm going to step out for a moment to check in with our in-person observers to see if there is anything that they want me to follow up on or that I forgot to ask you. I will be right back.

FOR MODERATOR: Check in with observers. Ask participants any last questions recommended by observers.

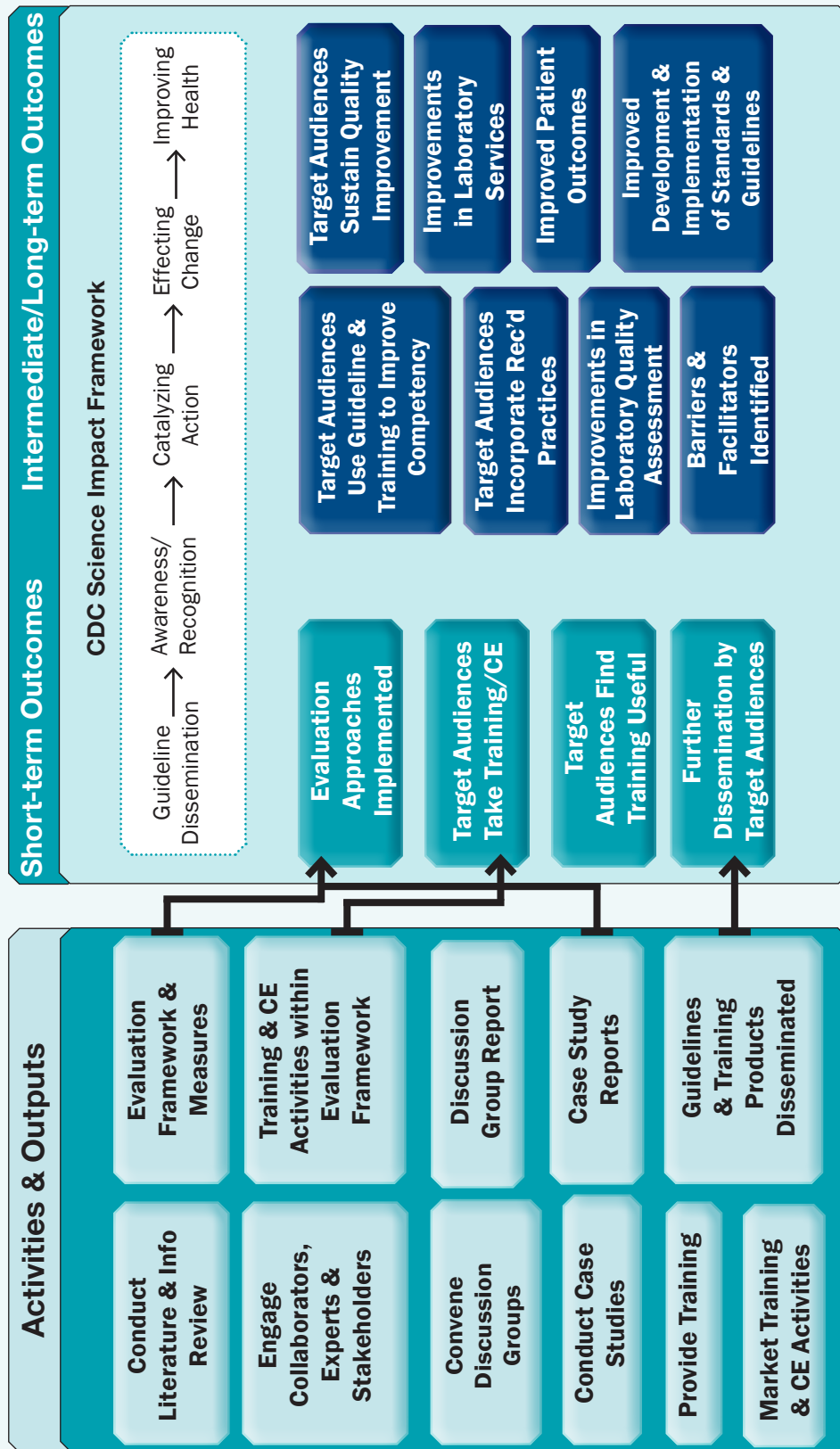
WRAP-UP (2-5 MINUTES)

This covers all of our questions. We really appreciate your time and attention, you've been terrific and your feedback will be helpful to APHL and CDC in determining the best ways to use the MMWR document. Our time is up, but I would be happy to answer any questions that any of you have.

Do you have any questions?

FOR MODERATOR: Answer any questions that participants may have OR request that CDC/ APHL scientists enter the room to answer any questions.

APPENDIX C. NEXT STEPS AND LOGIC MODEL





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