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Minutes of the Teleconference Meeting

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a teleconference meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) Laboratory Workgroup (LWG). The proceedings were held on July 25, 2013 from 2:00 P.M. to 4:30 P.M. EST.

The purpose of the teleconference meeting was for ACCLPP to review, discuss and formally vote on LWG's draft report, *Guidelines for Measuring Lead in Blood Using Point of Care Instruments.*

**Opening Session**

**Barbara Ellis, PhD, MS**
Acting Associate Director for Science, NCEH/ATSDR
ACCLPP Designated Federal Official and Acting Chair

Dr. Ellis conducted a roll call to determine the ACCLPP voting members, *ex-officio* members and liaison representatives who were in attendance. She announced that the members constituted a quorum for ACCLPP to conduct its business on July 26, 2013 and called the teleconference meeting to order. None of the ACCLPP voting members disclosed any conflicts of interest for the public record.

Dr. Ellis welcomed all of the participants to the teleconference meeting and extended an apology on behalf of Dr. Robin Ikeda, Acting Director of NCEH/ATSDR, who was unable to participate. She emphasized Dr. Ikeda's ongoing appreciation for the tremendous service the ACCLPP members continue to provide to the federal government.

Dr. Ellis announced that she would serve as both the ACCLPP Chair and Designated Federal Official for the teleconference meeting because a permanent chair has not been appointed at this time.
Mary Jean Brown, ScD  
Lead Scientist, Healthy Homes/Lead Poisoning Prevention Program  
Centers for Disease Control and Prevention

Dr. Brown announced that because the use of point-of-care (POC) instruments has dramatically increased over the past five years, ACCLPP was asked to evaluate this technology in terms of its reliability, validity, quality assurance (QA) and reporting requirements. Most notably, a number of clinical offices across the country currently use POC instruments for blood lead testing. In addition to requests from practitioners in the field, the NCEH/ATSDR Board of Scientific Counselors also supported ACCLPP’s involvement in this effort. ACCLPP formally established and charged LWG with this task in November 2011.

Dr. Brown announced that based on ACCLPP’s formal adoption of the LWG report, CDC would review the report and concur with, agree in principle, or would not concur with the guidelines. CDC hoped to include the LWG report as part of the second printing of the ACCLPP 2002 report, Managing Elevated Blood Lead Levels Among Young Children.

Patrick Parsons, PhD  
Chief, Laboratory of Inorganic and Nuclear Chemistry  
New York State Department of Health  
ACCLPP Member & Laboratory Workgroup Chair

Dr. Parsons presented an update on LWG’s activities to guide ACCLPP’s deliberations and formal vote on the draft report. In its second charge from ACCLPP, LWG addressed the need for recommended standards of practice for users of POC blood lead testing. During its October 2012 teleconference, LWG discussed the need for revised practice standards as a result of ACCLPP’s formal adoption of the reference value blood lead level >5 µg/dL (RVBLL). LWG then began drafting and revising the report.

The LWG guidelines are based on blood lead practice standards developed by the New York State Department of Health's Clinical Laboratory Evaluation Program. Because these practice standards were outdated and focused on screening tests only, LWG expanded its guidelines to serve as a resource in updating practice standards across the country. The LWG report is divided into a statement of guidelines and guidance in interpretation.

Dr. Parsons highlighted key sections of the draft report. Guidelines 1a, 1b, 2, 3 and 4 focus on “contamination control.” The LWG report defines “contamination” as an amount of lead that would change the observed blood lead level (BLL) by >1 µg/dL. Guidelines 1a and 1b address universal precautions in the work area, such as the use of personal protective equipment when handling blood and proper disposal of materials contaminated with blood.

Guideline 2 addresses contamination control in the work area, such as designation of a clean work area and procedures to minimize contamination from airborne lead during the collection and analysis of specimens. Guideline 3 addresses materials and specimen collection, such as preparation of the skin collection site prior to capillary skin puncture and the use of supplies that
are certified for blood lead testing. Guideline 4 addresses sample processing, such as minimizing contamination by not reusing specimens for lead and other tests.

Guideline 5 focuses on the “use of capillary blood from a fingerstick” to ensure that no air gaps are present in the capillary. The guideline clarifies that fingerstick samples of capillary blood are appropriate for screening purposes only and typically are used with a POC device. The guideline advises users of a POC device to consult the manufacturer’s directions.

Guideline 6 focuses on the “use of venous blood” to ensure the quality of the blood specimen. The guideline clarifies that venous blood is preferred for blood lead testing purposes. Only venous blood that has been preserved with ethylene diamine tetraacetic acid or heparin should be used as anticoagulants. Other issues covered in this guideline include the appropriate fill volume, the need for mixing prior to aliquoting, and the need to monitor for blood clots. The guideline recommends rejecting blood specimens with visible clots.

Guidelines 7-11 focus on “reemphasis of the manufacturer’s directions” in the following areas: storage requirements, operating requirements, power source considerations based on the use of POC analyzers in CDC field studies, the use of test kit components, and instrument calibration.

Guideline 12 focuses on “analysis of quality control (QC) materials.” LWG’s “ideal” guidance is for two clinically significant levels to be run each time the analysis is run. LWG’s “minimum” guidance is for two clinically significant levels to be run with each new test kit lot, with each new shipment, with each new operator (e.g., every 2 weeks), or when problems are suspected or identified. The guideline clarifies that the frequency of QC should reflect the volume of testing.

Guideline 13 focuses on “repeat testing of the original specimen.” The guideline states that if the initial result is >5 µg/dL (i.e., at or above the current RVBLL), the original specimen should be reanalyzed if volume permits. The purpose of the guideline is for laboratories to rule out bench contamination errors and resolve discrepancies. If the specimen has insufficient volume, such as from a capillary specimen, the guideline recommends reporting the initial result and referring the patient for confirmatory testing.

Laboratories are advised to resolve large discrepancies if possible with either additional analyses or reporting of test results as inconclusive with the following comments: “The specimen was insufficient to repeat the analysis. The patient was referred for confirmatory testing.” The guideline clarifies “acceptable” differences in repeat testing: a discrepancy of >3 µg/dL for the concentration range of 5-20 µg/dL; a discrepancy of >4 µg/dL for the concentration range of 21-40 µg/dL; and a discrepancy in 10% of samples for the concentration range of >40 µg/dL.

If discrepancies are identified, obvious outliers should be discarded and the average of the 2 remaining values should be reported. The patient should be referred for confirmatory testing for any result exceeding 5 µg/dL or if the validity of the test is uncertain.

Guideline 14 focuses on “confirmatory testing.” The guideline states that if the BLL is >5 µg/dL, the laboratory must refer either the patient or the venous blood sample for confirmatory testing.
The guideline clarifies that the BLL of 5 µg/dL was selected to maximize identification of children with BLLs above the RVBLL.

If the patient is referred, preliminary results may be released with the following comments: “The initial test result is for screening purposes only. Confirmatory test results are pending.” If the venous blood sample is referred, a laboratory certified by the Clinical Laboratory Improvement Amendments (CLIA) should perform confirmatory testing with a method that is categorized by CLIA as “high complexity” (e.g., atomic absorption spectrometry or inductively coupled plasma mass spectrometry). Preliminary results may be released with a comment that “results of confirmatory testing are pending.” Unopened venous specimens are preferable.

Dr. Parsons noted that ACCLPP would need to give particular attention to Guideline 15 during its deliberations. The previous Guideline 15 focused on “reporting 5-10 µg/dL on patient reports.” The guideline stated that reference ranges must indicate BLLs 5-9 µg/dL have been associated with adverse health effects in children ≤6 years of age. The guideline clarified that reports should not indicate BLLs <10 µg/dL are “normal.” Based on ACCLPP’s formal adoption of the RVBLL ≥5 µg/dL, LWG’s position was that the guideline was redundant and should be deleted.

The current Guideline 15 is “reporting POC results to clinical healthcare providers.” The guideline states that BLLs at or above the RVBLL ≥5 µg/dL for 2012-2016 established by CDC require further investigation. The following comment is recommended to include on laboratory test reports to clinical healthcare providers:

“For children 5 years old and younger, blood lead levels ≥5 µg/dl indicate that they may have been exposed to lead at levels higher than most children. The blood lead level should be confirmed using a venous blood sample and a CLIA-certified high-complexity analytic method according the recommendations of the Advisory Committee on Childhood Lead Poisoning Prevention.”

Guideline 16 is “reporting requirements” to ensure that all blood lead results are reported to the proper state or federal agency. The guideline clarifies that reporting is essential for proper follow-up and public health surveillance. However, reporting requirements may vary by state due to different data, time frames or mechanisms.

Guideline 17 is “reporting potential contamination” to indicate potential false-positive results when the specimen is received in a container not known to be lead-free. The guideline clarifies that a footnote in the report is not needed for containers cleared through in-house lot-testing.

Specimens that are received in tubes from non-tested lots still should be tested. Results that are below the RVBLL 5 µg/dL should be reported. Results that are above the RVBLL 5 µg/dL should be reported with the following comment: “This specimen was from a lot of tubes not known to be lead tested.” The use of tubes that have been specifically certified for lead is preferable. These tubes can be obtained from laboratories or purchased from manufacturers.

Guideline 18 is “method comparison” to ensure that POC BLLs are periodically compared with confirmatory testing. The guidance clarifies “acceptable” differences between the screening and confirmatory results: a discrepancy of >3 µg/dL for the concentration range of 5-20 µg/dL; a
discrepancy of >4 µg/dL for the concentration range of 21-40 µg/dL; and a discrepancy in 10% of samples for the concentration range of >40 µg/dL. Personnel competency and the performance of quality control and proficiency testing (PT) should be periodically reviewed to determine the root cause of discrepancies.

Guideline 19 is “external QA” to emphasize that PT participation provides a valuable assessment of analytical performance. The guideline clarifies that no federal requirement exists for PT of CLIA-waived devices, but PT is highly recommended. Some states (e.g., California and Wisconsin) require regular participation in PT programs to receive reimbursement for test costs.

After LWG finalizes the draft report, the members will address the three remaining charges. For “alternate matrices to assess lead exposure,” ACCLPP charged LWG with investigating and reporting its findings on the efficacy, reliability and validity of measuring lead in saliva as an index of lead exposure. To a lesser extent, ACCLPP also charged LWG with investigating and reporting its findings on the reliability and validity of measuring lead in other non-traditional matrices (e.g., sweat, hair, nails and packed red cells) as indices of lead exposure.

For “environmental lead analytical issues,” ACCLPP charged LWG with investigating and reporting its findings on the reliability of current technologies for assessing the lead content of paint, plastics and other environmental samples as well as laboratory capacity for handling these samples. LWG’s literature review and analysis will include the use of handheld X-ray fluorescence analyzers in assessing lead in consumer products and the use of area concentrations versus mass fractions in assessing risks for lead exposure.

For “reference intervals for adult lead exposure,” ACCLPP charged LWG with investigating and reporting its findings on strategies for clinical laboratories to report the reference interval for adult lead exposure. LWG is aware that many laboratories currently report <30 µg/dL or <20 µg/dL as “normal” for adult BLLs.

Dr. Parsons concluded his overview by thanking the LWG members for their outstanding efforts and expertise in drafting and revising the report: Drs. Valerie Charlton, Leland McClure, Megan Sandel, Donald Simmons and Mr. Noel Stanton. He also thanked the CDC subject-matter experts for providing LWG with strong support and technical assistance throughout the entire process: Drs. Walter Alarcon, Mary Jean Brown, Robert Jones and Mr. Jeffrey Jarrett.

Dr. Ellis and Brown moderated ACCLPP’s deliberations on the draft report. Due to time constraints, Dr. Ellis confirmed that ACCLPP would still have an opportunity to submit written comments to Dr. Parsons with a copy to Dr. Brown (mjb5@cdc.gov) no later than August 8, 2013.

ACCLPP made a number of comments and suggestions for LWG to consider in finalizing the draft report.
• Page 6, Introduction: The section should be expanded with more emphasis on long-term and lifetime exposure to and problems from lead, particularly in children. The report states: “Human exposure to lead is estimated to account for 143,000 deaths and 0.6% of the global burden of disease every year.” If juvenile delinquency, social issues, neurobehavioral issues and other problems related to lead exposure in children were described, the global burden of lead exposure would be greater than 0.6%.

• Page 6, Introduction: The section should reference Dr. Bruce Lanphear’s published paper that provided an actual societal cost of lead exposure compared to other environmental problems.

• Page 6, Introduction: The section states: “Childhood lead exposure is estimated to contribute to about 600,000 new cases of children with intellectual disabilities every year.” Because the report will be a CDC product, emphasis should be placed on the number of children above the RVBLL 5 µg/dL in the United States with adverse subclinical effects in cognitive function as a result of lead exposure. The sentence should be replaced with language from the ACCLPP Report, Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention (<10 Document), as well as language from the report the Educational Intervention Workgroup (EIWG) currently is drafting.

• Page 6, Introduction: The language should be revised as follows: “Laboratory investigations are the most definitive way to diagnose lead-exposed individuals...”.

• Page 8, Guideline 1b: The language should be revised to clarify that the work area should be decontaminated with a “1:10 dilution of a standard bleach-type solution.”

• Page 8, Guideline 2: The language should be revised as follows: “Designate a clean work area by minimizing contamination from ambient airborne and surface lead during specimen collection and analysis.”

• Page 8, Guideline 2: The language should be revised as follows: “Clean area refers to space that is dedicated to testing for blood lead and is typically cleaned on a daily basis or when contamination occurs by wet wiping flat surfaces.”

• Page 11, Guideline 12: The report should provide clear guidance to laboratories on recordkeeping and documentation because QC is recommended on each new test kit, on each new shipment, by each new operator, or when problems are suspected or identified. Due to variations in recordkeeping requirements across jurisdictions, the new language should be generic rather than specific. Proposed language: “Ideally, records should be kept for 2 years unless otherwise dictated by other agencies.”

• Page 11, Guideline 12: The word “ideally” should be deleted from the guideline. The new language should be: “Two clinically significant levels of quality control should be analyzed each time the instrument is set up for an analytical run.”

• Page 11, Guideline 13: “Large discrepancies” should be clearly defined. Proposed language: “Use the average of the two consecutive test results to determine whether the discrepancy is large enough to require a third analysis.”

• Page 12, Guideline 16: The term “when feasible” should be deleted from the guideline and replaced with “as required.” The current language is ambiguous and indicates that laboratories have a choice in complying with reporting laws mandated by states. The
revised guideline should be definitively stated with no qualifiers: “Report all blood lead test results to the appropriate state or local agency as required.”

- Page 12, Guideline 17: The guideline should be revised to advise laboratories to reject any specimen upfront that was not collected in a certified blood collection container.
- Consideration should be given to drafting model language to assist laboratories in flagging BLLs above the RVBLL ≥5 µg/dL. This approach would be extremely useful in standardizing laboratory reporting of blood lead test results.

Drs. Brown and Parsons made several remarks in response to ACCLPP’s deliberations.

- Guideline 12: Because the LeadCare II instrument is CLIA-waived, no oversight or regulatory mechanism exists for laboratory recordkeeping except in jurisdictions that require PT at the local level (e.g., California and Wisconsin). However, Dr. Brown confirmed that Dr. Robert Jones, Chief of the CDC Inorganic and Radiation Analytical Toxicology Branch, would identify a reference to Good Laboratory Practices to address this issue.
- Guideline 12: A guideline for routine QC measures would not be feasible or realistic for laboratories that do not have daily operations, such as a facility with weekend hours only. A guideline that is overly prescriptive would be burdensome to many POC testing settings. However, Dr. Brown pointed out that the guideline recommends analyzing two QC samples each time the instrument is set up for an analytical run. This language assures that QC will be performed on a daily basis.
- Guideline 17: The guideline should not be revised because the likelihood is small of contamination from the collection of specimens in non-certified containers and generation of false-positive results. Laboratories should have strong confidence in reporting test results of venous samples that were collected in non-certified containers and are below the RVBLL ≥5 µg/dL.
- Magellan Diagnostics is now incorporating the table from the <10 Document in materials that are provided to its laboratory clients.

At the conclusion of the deliberations, Dr. Ellis entertained a motion for ACCLPP to formally approve the draft LWG report with the understanding that the document would be revised based on the input provided during the teleconference meeting.

A motion was properly placed on the floor and seconded by Drs. Megan Sandel and Kim Dietrich, respectively, for ACCLPP to adopt LWG’s draft report, *Guidelines for Measuring Lead in Blood Using Point of Care Instruments*, with the changes noted for the record. **The motion passed by a majority vote of 8 members in favor and 1 abstention** (Mr. Perry Gottesfeld).

In terms of next steps, Dr. Brown announced that the document would be finalized, formally submitted to the HHS Secretary and CDC Director, and posted on the CDC.gov website. Based on its review of the report, CDC would concur with, agree in principle, or would not concur with the guidelines. CDC would “agree in principle” if a particular guideline was outside of its control or resources were not sufficient for CDC to implement the guideline. CDC plans to engage other agencies in dialogue, such as the Centers for Medicare and Medicaid Services, that also would be impacted by the POC testing guidelines.
Dr. Brown reiterated that CDC hopes to include the LWG report and the upcoming EIWG report in the second printing of the ACCLPP 2002 report, *Managing Elevated Blood Lead Levels Among Young Children*. However, introductions of these reports will be extensively revised during this editorial process.

Dr. Brown noted that individual ACCLPP and LWG members have expressed a strong interest in LWG focusing on environmental lead analytical issues and alternate matrices to assess lead exposure. She asked the ACCLPP and LWG members to inform her by e-mail of their opinions on which of the two issues should be the higher priority.

Dr. Parsons recalled that a laboratory appendix was developed for a previous ACCLPP report. He planned to quickly review and update the appendix for inclusion in the current draft report. In terms of prioritization of LWG’s three remaining charges, he was in favor of focusing on “reference intervals for adult lead exposure” first. This topic would be the easiest issue for LWG to address in a relatively short period of time. LWG would utilize the *ACCLPP Guideline for the Identification and Management of Lead Exposure in Pregnant and Lactating Women* as a basis for establishing reference intervals for adult lead exposure.

Dr. Parsons explained that LWG’s next focus area should be alternate matrices to assess lead exposure because environmental lead analytical issues will require extensive effort and resources.

Dr. Walter Alarcon, ex-officio member for the National Institute for Occupational Safety and Health (NIOSH), announced that the Laboratory Workgroup from the Adult Blood Lead Epidemiology and Surveillance Program (ABLES) developed Management Guidelines for Blood Lead Levels in Adults. These guidelines contain reference intervals and management recommendations for lead-exposed adults. NIOSH is developing a NIOSH Alert that will adapt these guidelines and will engage LWG in this effort.

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**Public Comment Session**

**Carolyn Grossman**  
Mirepoix LLC

Ms. Grossman commended LWG for recognizing the important role of the blood lead screening test and formulating the guidelines to account for real-world costs and other practical issues associated with POC testing. In terms of guideline 13, she questioned LWG’s rationale for not providing guidance on the appropriate time frame for confirmatory testing. Providers frequently confuse follow-up and confirmatory testing. She also requested information on the availability of the two-event, low-cost QA version of PT. This methodology is extremely important for public health because the ability to meet the costs associated with a full CLIA PT is challenging.

Dr. Parsons responded that the draft report does not include guidance on the appropriate length of time to confirm an elevated blood lead test result because this issue is much broader than the POC testing community. However, the previous laboratory guidance document might be
updated to include this information if needed. In the interim, the <10 Document includes a table with appropriate intervals for confirmatory laboratory testing of blood lead test results.

Jane Malone  
Policy Director, National Center for Healthy Housing  
ACCLPP Liaison Representative

Ms. Malone reported that the National Center for Healthy Housing (NCHH) administered a survey to the Childhood Lead Poisoning Prevention Programs (CLPPPs). Due to the loss of their CDC funding, more than 50% of CLPPP positions have been eliminated. These positions included those that were assigned to mission-critical activities (e.g., primary prevention, lead risk assessment, enforcement of state and local laws, outreach and education, and tracking of at-risk children).

State and local CLPPPs that are competing for alternative sources of funding and reimbursement for these services are achieving varying degrees of success. Medicaid reimbursement for eligible case management and follow-up services is inconsistent and inadequate in most states and localities. Ms. Malone confirmed that a report of the survey findings would be posted on the NCHH.org website, but she also would share the report with ACLPPP.

Closing Session

The participants joined Dr. Ellis in thanking Dr. Parsons for his outstanding leadership as the LWG Chair and the LWG members for their excellent work in producing a high-quality report.

With no further discussion or business brought before ACCLPP, Dr. Ellis adjourned the teleconference meeting with a formal motion from ACCLPP.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

_________________________ Barbara Ellis, PhD, MS  
Acting Chair & Designated Federal Official  
Advisory Committee on Childhood Lead Poisoning Prevention
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Dr. Patrick Parsons
Dr. Megan Sandel

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Joshua Glasser
Department of State

Dr. Kristina Hatlelid
U.S. Consumer Product Safety Commission

Ms. Jacqueline Mosby
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Dr. Donald Simmons
Association of Public Health Laboratories

Designated Federal Official
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Acting Associate Director for Science, NCEH/ATSDR

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Jay Dempsey
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Demetria Gardner
Jeffrey Jarrett
Robert Jones
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Julie Racine  
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Robb Morse  
Magellan Diagnostics  

Noel Stanton  
Wisconsin State Laboratory of Hygiene  

Nicole Thompson  
Public Health-Seattle & King County
## Glossary of Acronyms

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<tr>
<td>ACCLPP</td>
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