

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry**



**Virtual Meeting of the
NCEH/ATSDR Board of Scientific Counselors
March 21, 2016**

Record of the Proceedings

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Agency for Toxic Substances and Disease Registry**

**NCEH/ATSDR BOARD OF SCIENTIFIC COUNSELORS
March 21, 2016**

Minutes of the Virtual 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 virtual meeting of the Board of Scientific Counselors (BSC). The proceedings were held on March 21, 2016 beginning at 3:00 p.m. EST.

The BSC is a Federal Advisory Committee that is chartered to provide advice and guidance to the Secretary of HHS, Director of CDC, and Director of NCEH/ATSDR regarding program goals, objectives, strategies and priorities in fulfillment of the agencies' mission to protect and promote persons' health. The BSC provides advice and guidance to assist NCEH/ATSDR in ensuring the scientific quality, timeliness, utility and dissemination of results. The BSC also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents to fulfill its mission to protect America's health.

Information for the public to attend the virtual BSC meeting via teleconference was published in the *Federal Register* in accordance with Federal Advisory Committee Act regulations. All sessions of the meeting were open to the public (*Attachment 1: Participants' Directory*).

Opening Session: Welcome, Introductions and Review of Conflict of Interest Topics

William Cibulas, Jr., PhD, MS

Deputy Associate Director for Science, NCEH/ATSDR
BSC Designated Federal Official

Dr. Cibulas called the proceedings to order at 3:00 p.m. EST and welcomed the participants to the virtual BSC meeting. He announced that BSC meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded the BSC members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters.

Dr. Cibulas conducted a roll call. None of the BSC voting members publicly disclosed conflicts of interest for any of the items on the March 21, 2016 published agenda. However, he announced that the 10 voting members and *ex-officio* members in attendance did not constitute a quorum for the BSC to conduct its business on March 21, 2016.

Adjournment of the BSC Meeting

No formal business was brought before the BSC due to the absence of a quorum. Dr. Cibulas adjourned the meeting at 3:22 p.m. EST.

Dr. Patrick Breyse, Director of NCEH/ATSDR, announced that the teleconference bridge line would remain open while NCEH/ATSDR staff located another BSC member to complete the quorum.

Recall to Order of the BSC Meeting

William Cibulas, Jr., PhD, MS

Deputy Associate Director for Science, NCEH/ATSDR
BSC Designated Federal Official

Dr. Cibulas announced that Dr. Robert Wright, a voting BSC member, had joined the virtual meeting. Dr. Wright declared no conflicts of interest for any of the items on the March 21, 2016 published agenda. Dr. Cibulas recalled the virtual meeting to order at 3:33 p.m. EST and

confirmed that the BSC was now operating with a quorum to formally vote on matters or conduct any other official business.

Update by the NCEH/ATSDR Office of the Director (OD)

Donna Knutson, PhD

Acting Deputy Director, NCEH/ATSDR
Centers for Disease Control and Prevention

Dr. Knutson reported that NCEH/ATSDR became involved in the Flint response on January 11, 2016 to provide federal leadership of the scientific and communication activities. CDC declared the Flint water crisis as a Level 3 emergency on February 1, 2016 and activated its agency-wide Emergency Operations Center (EOC) to broaden the scope and magnitude of resources for the response. Because the Level 3 emergency activation was terminated in the EOC on March 11, 2016, NCEH/ATSDR programs have resumed leadership of the Flint response for CDC.

CDC has designated nearly 100 employees to provide scientific, technical and programmatic leadership of the Flint response, including 12 active deployments and four pending deployments to the field. CDC will continue to staff the Federal Unified Coordination Group (UCG) and also will deploy two additional nurse case managers until May 1, 2016. Moreover, CDC is continuing to collect data from the state of Michigan to address ~5 epidemiologic questions.

The NCEH/ATSDR Assessment of Chemical Exposure (ACE) Team is expected to complete its activities in Flint on March 25, 2016. A major focus of these efforts has been to identify a potential association between lead in the Flint water system and the unusually high number of rashes reported. To date, the ACE Team has contacted 232 of 287 Flint residents who reported rashes and is collecting data from three different sources.

- A survey to determine whether the individual meets the criteria established for a case definition
- Water quality samples from the individual's home
- Findings from the individual's visit to a dermatologist

The ACE Team will analyze these data to assess whether the Flint water system is associated with reported rashes. CDC's infectious disease experts have not found a correlation based on their preliminary review of the data.

Targeted, random and organizational approaches are being implemented to collect water samples in the Flint community. Water sampling by the federal agencies is targeted. CDC's geospatial experts are collecting data from the city of Flint to map blood lead levels (BLLs) of children and

other health effects in relation to existing lead lines. EPA is replacing water lines based on targeted water sampling, households with reported rashes, and sentinel water testing at selected sites throughout the city of Flint.

Water sampling by Flint residents is random. The Michigan Department of Environmental Quality (MDEQ) provided households with containers, collection instructions and directions to centralized locations to leave the containers. Water sampling by Virginia Tech and another research organization is being conducted in the field to determine whether lead levels have decreased in the water systems of individual homes.

CDC's agency-wide activities have directly reached nearly 1,600 community members to date, including its five site-specific recommendations that were submitted to health departments in the city of Flint and the state of Michigan. Since the virtual LPPS meeting on February 23, 2016, CDC has made the most progress in or encountered the most significant challenges with recommendations 2 and 5.

- *Recommendation 2-Provide recent blood lead testing to children <6 years of age:* At this time, ~4,500 children of the total estimated population of 9,000 children have been “recently” tested (defined as the period from October 1, 2015-April 1, 2016). To date, 88% of families with children with elevated BLLs (EBLLs) have been contacted and offered case management. However, efforts are continuing to resolve the community’s mistrust of state and local government and increase the case management enrollment rate.
- *Recommendation 5-Implement a uniform communication plan:* CDC and its federal partners on the UCG (e.g., U.S. Environmental Protection Agency (EPA) and U.S. Department of Agriculture) have disseminated >170 different communication materials and harmonized messages on a variety of topics to the Flint community, such as safe washing of vegetables prior to cooking. However, CDC was challenged in addressing the tremendous lack of communication, coordination and collaboration between the Michigan Department of Health and Human Services (MDHHS) at the state level and the Genesee County Health Department at the local level. Moreover, morale is extremely low because MDHHS leadership is being sued as both state employees and private citizens. CDC deployed its senior risk communicators to Flint to conduct training workshops with state and local health department staff, but the delivery of standardized messaging has been difficult.

In terms of legislative activities, the UCG has provided 11 Congressional briefings to date. Most notably, the briefing to a 26-member delegation of Congressional appropriators and authorizers in Flint provided the UCG with an opportunity to describe recent site-specific activities conducted by the federal agencies. The Congressional delegation also visited a church to obtain feedback on the Flint response directly from community members.

Over the past 18 weeks, CDC has been participating in weekly conference calls with Congressional representatives from Michigan in both the House and Senate to provide regular updates. CDC has responded to >12 written requests for information and technical assistance from Congressional staff.

Dr. Breyse will represent CDC at a meeting that will be held in Flint on March 23, 2016 with other HHS agencies, state/local health departments, the local medical community and community members to discuss long-term surveillance and/or registry activities. The HHS Office of the National Coordinator for Health Information Technology has responsibility for creating electronic health records through the Affordable Care Act and also will attend the meeting.

The UCG has made strong efforts to maintain a systematic, organized and harmonized approach in the city of Flint and throughout the state of Michigan, but the presence of external research companies in the field has been confusing to the community. For example, three research companies are conducting studies to achieve specific outcomes: (1) detect and mitigate microbes in the Flint water system and *Legionella* in individual household water systems and (2) analyze water samples to determine a potential association between chlorine residue and rashes or other reported health effects. However, these efforts are resulting in messages to the community that are inconsistent with those of the federal partners on the UCG.

Dr. Knutson concluded her update by confirming that CDC's recommendations to health departments in the city of Flint and the state of Michigan as well as the BSC's recommendations to NCEH/ATSDR will play an instrumental role in improving CDC's environmental public health programs, particularly the Childhood Lead Poisoning Prevention Program and Clean Water for Health Program. She also noted that this guidance will serve as an excellent model to address lead-contaminated water systems in jurisdictions other than Flint, Michigan.

Patrick Breyse, PhD, CIH

Director, NCEH/ATSDR
Centers for Disease Control and Prevention

Dr. Breyse reiterated that the Flint water crisis continues to serve as a top priority for NCEH/ATSDR. Although NCEH/ATSDR's involvement in the Flint response officially began in January 2016, its communications with the CDC Clean Water for Health Program on the association between lead in the Flint water system and children's EBLs in the community have been ongoing since July 2015. NCEH/ATSDR's leadership at the federal level now includes the provision of expertise, technical assistance and guidance related to medical monitoring, surveillance, communications and follow-up to the city of Flint and the state of Michigan.

Dr. Breyse informed the BSC of NCEH/ATSDR's major challenge in its community outreach and engagement efforts in Flint. On the one hand, Flint residents have trusted and the federal partners have vetted the scientific validity of lead in water studies conducted by external experts, such as

Dr. Marc Edwards (Virginia Tech) and Dr. Mona Hanna-Attisha (Michigan State University, College of Human Medicine).

On the other hand, self-proclaimed “experts” recently were featured on a national talk show and advised Flint residents against showering or bathing due to the ability of lead to pierce the skin and the transmission of Legionnaires’ disease as a result of *Legionella* in the water system. Moreover, Water Defense is a non-profit organization that is widely promoting its proprietary technology for water sampling, but this methodology has no scientific rigor or supporting data.

Dr. Breyse noted that NCEH/ATSDR is making strong efforts to disseminate evidence-based information to combat the delivery of inaccurate messaging. For example, children’s BLLs ≥ 5 $\mu\text{g/dL}$ were 1.5-2 times higher during the switch between the Detroit water system and the Flint River (with the highest BLL reported at ≥ 35 $\mu\text{g/dL}$). Although EBLLs have been reported, the most recent EPA data show that the Flint water system has no lead hazards and is safe for bathing and showering.

Moreover, “lead poisoning” has not been detected at a level that will cause harmful or adverse effects to children in the future (e.g., poor educational performance or violent behavior). However, NCEH/ATSDR is continuing to deliver its overarching message that no level of lead in the blood is safe. NCEH/ATSDR and its federal partners will continue to promote the HHS approach of implementing interventions in the Flint community to help compensate for population-level deficits that have occurred as a result of lead in the water system.

Dr. Breyse concluded his update by thanking the LPPS for drafting excellent recommendations in an effective and efficient manner to respond to all six components of its complex charge related to the Flint water supply. He reiterated Dr. Knutson’s remarks regarding the tremendous value of the BSC’s guidance to NCEH/ATSDR in improving the site-specific activities and resolving challenges in Flint.

BSC DISCUSSION: NCEH/ATSDR OD UPDATES

Dr. Dietrich made several overarching comments before Dr. Perry opened the floor for the BSC’s discussion on the NCEH/ATSDR OD updates. Similar to CDC and its federal partners, he also has been deeply concerned about the delivery of inaccurate information. For example, the media has inaccurately characterized problems in the Flint water system as a “lead poisoning” issue. Moreover, guests on a national program recently were featured as “medical experts” and inaccurately recommended vitamin C as a chelating agent.

Dr. Dietrich advised CDC to refine its communication plan with much stronger messages to emphasize that higher BLLs detected in the Flint community are not associated with long-term health consequences. The community also should be educated on the critical need to mitigate more important sources of lead. For example, BLLs are the result of an integrated index of exposure to lead from multiple sources in the community, such as water (small contributor) and

lead-based paint residue (major contributor). Ongoing leadership and messaging by CDC, as a trusted and respected federal agency, will help to reduce anxiety in the Flint community and combat inaccurate information distributed by self-proclaimed “experts.”

Dr. Dietrich expressed his general endorsement of the draft LPPS recommendations, but he was concerned that the guidance does not consider exposure to lead from sources other than the Flint water system. Historical records show that much of the old, poorly deteriorated housing stock in Flint was built in the 1940s. Moreover, recent studies have clearly demonstrated that lead in paint residue in the Flint housing stock is a much greater contributor to children’s EBLs than the water system.

Other BSC members provided additional comments and suggestions in response to the NCEH/ATSDR OD updates.

- CDC’s recommendations to health departments in the city of Flint and the state of Michigan as well as the BSC’s recommendations to NCEH/ATSDR ideally will result in the replacement of lead-based pipes in the Flint water system. This effort likely will cost millions of dollars, but its impact on reducing children’s EBLs will be minimal if lead-based paint in the old, deteriorated housing stock is not removed. Although the LPPS’s current charge is to address the Flint water crisis only, this opportunity must be used to also highlight lead-based paint in housing stocks as a much larger contributor to EBLs in communities across the country.
- CDC should re-brand and promote the Flint water crisis as a clean, safe water issue rather than a lead poisoning issue.

Dr. Knutson appreciated the candor by Dr. Dietrich and other BSC members in expressing their concerns. She confirmed that additional services will be performed in the Flint community to reduce non-water lead sources, such as household lead abatement through window replacements. She also acknowledged the lead expertise of the BSC/LPPS members and their extensive knowledge of non-water sources of lead. However, she emphasized that lead in the water system continues to be the predominant concern in the Flint community. For example, data have been distributed to demonstrate the safety of the water based on current EPA standards, but the vast majority of the Flint community still refuses to drink the water unless the pipes are replaced.

Dr. Brown wholeheartedly agreed with the BSC’s comments and Dr. Knutson’s follow-up remarks. Because no homes were built in Flint after 1978, lead paint hazards have been detected in virtually all homes inspected to date. Despite scientific evidence that clearly identifies housing as a major source of lead, the community’s only interest at this time is for the government to immediately correct the lead-contaminated water system in Flint. The community is angry and distrustful and blames state and local government for causing a completely avoidable problem. Collaboration

involving community health workers, the local pediatric community and parents is underway to reestablish trust in Flint.

Dr. Breysse added that in its community outreach efforts, NCEH/ATSDR has continually highlighted problems in the Flint water system to emphasize the need for new CDC funding to support national lead and clean water programs in all 50 states. NCEH/ATSDR also is performing modeling and statistical analyses to pinpoint locations of children with EBLLs during the contamination period, identify lead lines in specific geographic areas, and use corresponding water measurement data to help predict the likelihood of a child having an EBLL.

Review of the Draft LPPS Recommendations to the BSC

Melissa Perry, ScD, MHS, BSC Chair

Chair, Department of Environmental and Occupational Health
George Washington University School of Public Health and Health Services

Dr. Perry reminded the BSC of its unanimous vote to approve the establishment of the LPPS during an interim virtual meeting in August 2014. For the members who were appointed after this time, she clarified that LPPS's first order of business was to help CDC provide technical assistance and public health guidance to MDHHS and the Genesee County Health Department due to the urgency of problems with the Flint water system. The LPPS fulfilled its initial six-part charge by drafting and submitting recommendations to the BSC Chair. However, the LPPS was not established to solely focus on the Flint response.

Matthew Strickland, PhD, MPH, MA, LPPS Chair

Associate Professor, University of Nevada, Reno
School of Community Health Sciences

Dr. Strickland reiterated Dr. Perry's introductory remarks. He informed the BSC that the LPPS was charged with and drafted recommendations to address lead in the Flint water supply because CDC designated this issue as a public health emergency. After this initial task is completed, he explained that the BSC is welcome to expand the charge for the LPPS to address sources of lead exposure other than water in communities other than Flint.

Dr. Strickland reported that the LPPS convened two virtual meetings in February 2016 to address its six-part charge related to lead contamination in the Flint water system. To guide the development of the draft recommendations, CDC presented updates on site-specific activities in the Flint community. The LPPS engaged in extensive e-mail communications to revise and refine the language. Dr. Strickland e-mailed a letter to Dr. Perry on March 7, 2016 with the draft LPPS recommendations for distribution to the entire BSC.

Dr. Strickland informed the BSC of some of the perspectives and insights of the LPPS members that are not reflected in the draft recommendations.

- Current BLLs in the Flint community do not reflect the full extent of exposures that occurred in 2014-2015.
- BLLs are an integrated measure that includes exposure to lead from both water and non-water sources.
- The LPPS only focused on fulfilling its six-part charge to rapidly provide assistance and services to an adversely affected community. However, the LPPS is well aware of the need for future research to fill data gaps.

Dr. Strickland summarized the draft LPPS recommendations for the BSC's review, discussion and formal approval.

RECOMMENDATION 1

The members of the Lead Poisoning Prevention Subcommittee recommend to the Board that CDC pursue a prevalence study of blood lead levels among children age 0-6 years of age in Flint, Michigan. Although present-day blood lead levels do not reflect the full extent of the lead poisoning experienced by Flint residents during 2014 and 2015, these data are nevertheless important to establish a baseline for surveillance and program evaluation moving forward. We recommend that blood lead screening be made available to all children age 0-6 years in the community and that efforts be made to assemble a dataset of historical blood lead measurements from previous years. Given that mitigation of the negative effects of lead exposure requires timely identification of affected children, the Subcommittee recommends that CDC move forward with this work as quickly as possible.

RECOMMENDATION 2

The members of the Lead Poisoning Prevention Subcommittee recommend to the Board that CDC scientists develop a set of guidelines and methods that state partners can apply when examining their local blood lead surveillance data. A systematic, standardized approach that is widely adopted by state partners participating in the NCEH blood lead surveillance program has the potential enhance the value of the data on a local and national level. The Subcommittee recommends that CDC collaborate with state partners during the development of these guidelines and methods to ensure they are feasible, appropriate, and that there is buy-in at the local level.

RECOMMENDATION 3

The members of the Lead Poisoning Prevention Subcommittee recommend that the Board encourage CDC to investigate important questions regarding the public health consequences of the Flint, Michigan water system lead contamination. We recommend

that CDC work collaboratively with other federal and non-federal scientists who may also be working on these issues. Examples of topics that CDC could contribute resources and scientific expertise include (but are not limited to):

- Historical models of lead concentrations in the water distribution system
- Biomarkers of past lead exposure (e.g., sample collection protocols, laboratory analyses, methods development/improvement)
- Biokinetic models of lead in children
- Statistical models and epidemiologic approaches for estimating the causal effect of the water system lead contamination on public health

BSC DISCUSSION: DRAFT LPPS RECOMMENDATIONS

Recommendation 1

- No approaches are described to make blood lead screening available to all children 0-6 years of age in the Flint community who are and are not enrolled in Medicaid. States are required to provide Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services to all Medicaid-enrolled children <21 years of age, including blood lead screening, but current data show that only 40% of clinics provide EPSDT services to eligible children.
- The language should be modified as follows: "...lead exposure experienced by Flint residents during 2014 and 2015...".

Recommendation 3

- Continued monitoring of changes that will be made to the Flint water system over time will be extremely useful, comforting and important to the community in terms of the safety of water and BLLs of their children. Ongoing monitoring over the next 1-2 years should be emphasized as a key recommendation.
- The recommendation calls for CDC to provide scientific expertise and allocate resources to biokinetic models of lead in children. However, the tremendous lead literature has resulted in a strong understanding of the biokinetics of lead in children, pregnant women and the general adult population. The recommendation should be revised to advise CDC to allocate funds to monitoring children <6 years of age in Flint and similarly impacted communities.

General Comments

- The recommendations do not focus on primary prevention. Even if the BSC formally approves the draft recommendations, efforts should continue on providing additional guidance regarding CDC's role in preventing a "Flint-like" crisis in other communities in the future.

NCEH/ATSDR provided several remarks in follow-up to the BSC's discussion on the draft recommendations.

Recommendation 1

- CDC is aggressively outreaching to healthcare providers (HCPs) in the Flint community to provide blood lead testing to the population of children identified in recommendation 1. Of all children ≤ 6 years of age in Flint, 94% are Medicaid recipients. CDC is comparing the state Medicaid database to other datasets in Michigan, such as the Michigan Care Improvement Registry, to identify children who have and have not been tested. The Centers for Medicare & Medicaid Services will pay for case management and other wraparound services to all Medicaid-enrolled children < 21 years of age, such as lead inspections and lead paint abatement in homes of children with BLLs ≥ 5 $\mu\text{g}/\text{dL}$. The abatements will serve as secondary prevention to index cases, but will serve as primary prevention to other children who may reside in the same remediated homes in the future.
- Federally Qualified Health Centers will provide blood lead screening to children in undocumented families in Flint. Moreover, CDC has established a close partnership with two community-based organizations to ensure the health needs of undocumented families are met.

Primary Prevention

- CDC includes a clear primary prevention message in all of its materials that have been disseminated to the Flint community. However, CDC welcomes additional guidance from the BSC in the future related to primary prevention of lead exposure. Alternatively, the BSC is free to include primary prevention language in the current draft recommendations. In the interim, CDC-funded lead programs at state and local levels would greatly benefit from a strong position statement by the BSC. For example, "Primary prevention continues to be the most important focus of lead exposure to children and is the only strategy to make progress in this area."
- CDC and MDHHS have initiated primary prevention activities in the state of Michigan. In its inspections of water systems to comply with the EPA Lead and Copper Rule, MDEQ historically has not informed MDHHS of violations or excessive lead levels. However, CDC has learned that this communication gap is not limited to the state of Michigan. As a result, CDC will collaborate with environmental health agencies in all states across the country to ensure that violations of the Lead and Copper Rule are immediately reported to state/local health departments. Rapid reporting of excessive lead levels in water systems will help health departments to identify and continuously monitor problems in specific geographic areas and take preventive measures before BLLs in children become elevated.
- CDC intends to propose guidance to EPA when the public comment period is opened for revisions to the Lead and Copper Rule. CDC's major comment will be to emphasize the importance of testing for corrosiveness to protect the mineral scale when water companies change the water chemistry or source.

Chair's call for a vote	Motion properly made by Dr. Matthew Strickland for the BSC to formally approve the Lead Poisoning Prevention Subcommittee's three draft recommendations as modified by the BSC Motion seconded by Dr. Sharron LaFollette
Outcome of vote	Motion unanimously passed by 9 BSC voting members
Next steps	<ul style="list-style-type: none"> • Dr. Perry will finalize the draft recommendations with the BSC's modification of recommendation 1. • Dr. Perry will include the final recommendations in a letter to Dr. Thomas Frieden, Director of CDC, and Dr. Patrick Breyse, Director of NCEH/ATSDR. • The LPPS will focus on drafting primary prevention recommendations in its next teleconference in accordance with the BSC's guidance.

Public Comment Session

Michael J. Kosnett, MD, MPH
Associate Clinical Professor
University of Colorado School of Medicine
Lead Poisoning Prevention Subcommittee Member

Dr. Kosnett expressed strong concerns regarding the unorthodox and scientifically unsound advice the Flint community has been receiving from self-proclaimed “experts.” He was particularly troubled by the potential for children to undergo unnecessary chelation as a result of this guidance. CDC’s longstanding policy does not recommend chelation for children unless BLLs exceed 45 µg/dL.

Dr. Kosnett pointed out that CDC has gathered substantial evidence to support its guidance. For example, CDC and the American College of Medical Toxicology co-hosted a seminar in 2012, “The Use and Misuse of Chelation Therapy.” He raised the possibility of CDC convening a half-day seminar with HCPs in the Flint community on the management of low to moderate elevations in BLLs. He anecdotally reported that in his recent discussions, HCPs in Michigan have been advocating for chelation of cases in which therapy would be contraindicated.

Dr. Kosnett also provided comments regarding the CDC blood lead reference value (BLRV). Current messaging of “no safe level of lead exists” should be replaced with “no level of lead has been shown to be without deleterious effects.” The terminology of “safe” is used for risk management rather than hazard identification.

Overview of the CDC Blood Lead Reference Value

Sharunda Buchanan, PhD

Director, NCEH Division of Emergency and Environmental Health Services
Centers for Disease Control and Prevention

Dr. Buchanan reported that prior to 2012, CDC recommended the “blood lead level of concern” at ≥ 10 $\mu\text{g}/\text{dL}$. The former Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) made recommendations to CDC to replace the blood lead level of concern with the BLRV to more effectively identify children who have been exposed to lead and require case management. CDC accepted ACCLPP’s recommendations because the shift to primary prevention would eliminate or reduce dangerous lead sources in children’s environments prior to exposure. Moreover, use of the BLRV would serve as a sound approach to identify children with BLLs that are much higher than concentrations of most other children.

CDC uses National Health and Nutrition Examination Survey (NHANES) data to calculate the BLRV and determine the 97.5 percentile of blood lead distributions in children. The current BLRV of ≥ 5 $\mu\text{g}/\text{dL}$ is based on the 2007-2008 and 2009-2010 NHANES datasets. CDC will review and analyze NHANES data every four years to calculate the 95th percentile of lead in children. Based on the calculations, CDC will determine whether the BLRV should be changed and adopted. CDC released the most recent NHANES data in 2016 and currently is analyzing the 2011-2012 and 2013-2014 NHANES datasets.

Mary Jean Brown, ScD, RN

Chief, NCEH Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Dr. Brown reported that CDC is exploring various strategies in its ongoing analysis of the BLRV, such as utilizing other available data in addition to NHANES. This approach will allow CDC to determine whether the national goal of eliminating EBLLs in children by 2020 is being met and decide if primary prevention strategies to identify, control and eliminate lead sources before children are exposed continue to be successful.

Dr. Brown announced that the federal government established an interagency workgroup to address issues related to lead exposure. In its analysis of the BLRV, CDC will solicit guidance from the federal workgroup, BSC and LPPS. During the June 2016 BSC meeting, for example, CDC will request input from the BSC based on four key questions and sub-questions.

1. What are the implications of establishing a new BLRV that is lower than 5 $\mu\text{g}/\text{dL}$?

- Are data available at this time to quantify the economic benefits of preventing BLLs <5 µg/dL?
 - Should the BLRV be adopted as a case definition?
 - Should the BLRV instead be used as a benchmark to monitor progress toward reaching the national goal of eliminating EBLs in children by 2020?
2. Should the BLRV be used as a combined case definition/benchmark?
 - If the BLRV is not used as a case definition, what is the best approach to communicate this public health decision?
 - If a decision is made for the case definition and benchmark to be the same, what is the best approach to communicate to HCPs and parents that CDC will change the BLRV every four years?
 - What strategies should be implemented to better interpret the implications of a point-in-time BLRV while analyzing, developing and communicating both regulations and guidance? Federal, state and local regulatory agencies will have a difficult time implementing and enforcing lead exposure standards based on a BLRV that changes every four years. Regulatory agencies also will be extremely challenged and burdened by this complex process.
 - If a point-in-time BLRV is not an appropriate target, what are sensible criteria for rule-making in light of the fact that a safe BLL for children has not been identified?
 3. Are other metrics available that might be useful to help measure progress toward reaching the national goal of eliminating EBLs in children by 2020, particularly in communities with the highest lead exposures? For example, the BLRV could be replaced with measures that will improve knowledge of differences in risk across various U.S. communities and subpopulations (e.g., geographic disparities, environmental justice areas or small-area prevalence studies).
 4. Can state and local surveillance data that provide smaller estimates than national data be modeled and used as surrogates of population-based estimates generated by NHANES?

Dr. Brown described CDC's action items and next steps to prepare the BSC and LPPS to provide input on the BLRV analysis.

- The BSC and LPPS members will be provided with the four key questions and sub-questions in writing, tables and summaries of the major findings from the most recent NHANES datasets at least two weeks before the next in-person BSC meeting on June 28-29, 2016.
- Another LPPS teleconference will be scheduled before the June 2016 BSC meeting if needed.
- Based on the date of the next federal workgroup meeting, the BSC and LPPS members will be invited to attend. The BSC is chartered to provide advice and guidance to HHS,

CDC and NCEH/ATSDR leadership, but participation by the members in upcoming federal workgroup meetings will be important. Most notably, the federal workgroup members, particularly EPA, the U.S Food and Drug Administration and the U.S. Department of Housing and Urban Development, historically have developed or revised their lead exposure standards and guidelines based on CDC policy.

- The BSC and LPPS members are welcome to e-mail Dr. Brown (mjb5@cdc.gov) with additional questions or issues for CDC to consider in the BLRV analysis.

Dr. Dietrich noted that the broader community of lead experts has not made progress in clearly communicating the purpose and intent of the BLRV to the public over the past four years. He suggested the development and delivery of simple messages in this regard, e.g., “The BLRV protects as many individuals as possible, but a number over this value does not necessarily mean an individual is lead poisoned.”

Closing Session

Dr. Perry thanked the BSC members for reorganizing their schedules to attend the interim virtual meeting and address the time-sensitive public health emergency in Flint. She also commended the LPPS members for their excellence and expertise in fulfilling a complex charge and providing the BSC with robust, thoughtful and insightful recommendations.

With no further discussion or business brought before the BSC, Dr. Cibulas adjourned the virtual meeting at 4:01 p.m. EST.

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

Date

Melissa Perry, ScD, MHS
Chair, NCEH/ATSDR Board of Scientific Counselors



Attachment 1: Participants' Directory

NCEH/ATSDR BSC Members

Dr. Melissa Perry, Chair
George Washington University

Dr. Hillary Carpenter
Retired Toxicologist

Dr. Deborah Cory-Slechta
University of Rochester School of Medicine

Dr. Kim Dietrich
University of Cincinnati College of Medicine

Dr. Sharron LaFollette
University of Illinois at Springfield

Dr. Matthew Strickland¹
University of Nevada, Reno

Dr. Phillip Williams
University of Georgia

Ms. Nsedu Witherspoon
Children's Environmental Health Network

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¹Dr. Strickland is Chair of the Lead Poisoning Prevention Subcommittee.



Attachment 2: Glossary of Acronyms

ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
ACE	Assessment of Chemical Exposure
BLLs; EBLLS	Blood Lead Levels; Elevated Blood Lead Levels
BLRV	Blood Lead Reference Value
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
EOC	Emergency Operations Center
EPA	U.S. Environmental Protection Agency
EPSDT	Early and Periodic Screening, Diagnostic and Treatment
HCPs	Healthcare Providers
HHS	U.S. Department of Health and Human Services
LPPS	Lead Poisoning Prevention Subcommittee
MDEQ	Michigan Department of Environmental Quality
MDHHS	Michigan Department of Health and Human Services
NCEH/ATSDR	National Center for Environmental Health/Agency for Toxic Substances and Disease Registry
NHANES	National Health and Nutrition Examination Survey
UCG	Unified Coordination Group