

**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**



**Meeting of the Lead Poisoning Prevention Subcommittee of the
NCEH/ATSDR Board of Scientific Counselors
September 19, 2016
Atlanta, Georgia**

Record of the Proceedings

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**LEAD POISONING PREVENTION SUBCOMMITTEE OF THE
NCEH/ATSDR BOARD OF SCIENTIFIC COUNSELORS
September 19, 2016
Atlanta, Georgia**

Minutes of the Meeting¹

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 meeting of the Lead Poisoning Prevention Subcommittee (LPPS) of the NCEH/ATSDR Board of Scientific Counselors (BSC). The proceedings were held on September 19, 2016 at the CDC Chamblee Campus in Atlanta, Georgia (Building 106, Conference Room 1A).

NCEH/ATSDR established the LPPS in March 2015 with the following charge: (1) provide expertise on public health policies and practices relevant to lead poisoning prevention (LPP) and (2) conduct preparatory research, analysis and other developmental activities requiring a more detailed focus that cannot be practically accomplished by the full BSC.

Information for the public to attend the LPPS meeting in person or participate remotely via teleconference was published in the *Federal Register* in accordance with Federal Advisory

¹*Editor's note:* The final minutes reflect post-meeting comments by the LPPS members to clarify specific issues and topics that were discussed during the meeting.

Committee Act (FACA) regulations. All sessions of the meeting were open to the public (*Attachment 1: Participants' Directory*).

**Opening Session: Welcome, Introductions,
Confirmation of Quorum and Conflict of Interest**

William Cibulas, Jr., PhD, MS

Deputy Associate Director for Science, NCEH/ATSDR
LPPS Designated Federal Official (DFO)

Dr. Cibulas clarified that subcommittees are required to adhere to the same FACA rules and regulations as their parent committees. As a result, LPPS meetings include the same organizational components as BSC meetings: advance notice of the meeting to the public published in the *Federal Register*, a quorum of the LPPS membership during all sessions of the meeting, conflict of interest disclosures by the voting members, and a public comment period.

Dr. Cibulas opened the floor for introductions and confirmed that the nine members in attendance constituted a quorum for the LPPS to conduct its business on September 19, 2016. He called the proceedings to order at 8:33 a.m. and welcomed the participants to the LPPS meeting.

Dr. Cibulas announced that LPPS meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded the LPPS 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. John Belt announced that he would recuse himself from participating in discussions or voting on any issues related to CDC's funding of LPP activities. None of the other LPPS members publicly disclosed conflicts of interest for any of the items on the September 19, 2016 published agenda.

Matthew Strickland, PhD, MPH, MA, LPPS Chair

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

Dr. Strickland was pleased that all nine LPPS members were able to attend the meeting either in person or remotely via teleconference. He confirmed that the participation of each member would be particularly important when the LPPS drafts its formal recommendations to the BSC later during the meeting. He thanked the LPPS members for continuing to contribute their time and expertise to help NCEH/ATSDR in its ongoing efforts to reduce lead poisoning cases in the nation.

Donna Knutson, PhD

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

Dr. Knutson reported that several exciting developments are underway at NCEH/ATSDR at this time. Official government paperwork has been submitted to support the merger of the NCEH Division of Emergency and Environmental Health Services (EEHS) and Division of Environmental Hazards and Health Effects (EHHE). The NCEH/ATSDR Office of the Director (OD) is now focusing on competing positions for the newly consolidated EEHS/EHHE division. The new organizational structure has been stressful for some staff, but the merger also will generate additional opportunities and benefits.

FY2016 will end on September 30, 2016, but the actions that Congress will take in terms of a continuing resolution are still uncertain at this time. NCEH/ATSDR is continuing to develop a transition booklet to clarify its role in environmental public health (EPH) to the new administration that will take office in January 2017.

Major changes in NCEH/ATSDR's leadership include the retirement of Dr. Mary Jean Brown, former Chief of the LPP Program, on August 31, 2016. As one of CDC's leading subject-matter experts in lead, her retirement has resulted in a tremendous loss for both NCEH/ATSDR and the LPP Program. However, the transition to new leadership and new Congressional proposals will provide opportunities to strengthen the LPP Program.

Ms. Sandra Malcom also retired from NCEH/ATSDR on August 31, 2016. She has served as the Committee Management Specialist for the BSC for several years and also has provided outstanding support to the LPPS since its establishment in March 2015. NCEH/ATSDR currently is identifying a replacement for Ms. Malcom to ensure that the logistical, administrative and other needs of the BSC and LPPS members continue to be met with no interruption in high-quality service.

NCEH/ATSDR recently participated in a community event in Flint, Michigan that was sponsored by the U.S. Environmental Protection Agency (EPA) on September 17, 2016, but its site-specific activities are nearly complete. EPA is continuing to conduct sequential testing to identify homes with higher than expected lead levels. EPA's testing to date found fixtures to be the primary source of lead in water rather than lead service lines. However, more recent testing showed that the city of Flint failed EPA's Lead and Copper Rule standards.

EPA currently is identifying 7% of all Flint households that failed testing. The state of Michigan will be required to bear the cost of completely replacing lead service lines in these homes. NCEH/ATSDR extensively consulted with HHS and provided a wealth of data regarding the advantages and disadvantages of full versus partial replacement of lead service lines. Michigan is the only state at this time that meets the requirements of the Stafford Disaster Relief and Emergency Assistance Act. As a result, Michigan is eligible to receive new federal funding in FY2017 to address lead-contaminated water.

NCEH/ATSDR designed a rash study for the Flint community with extensive community input from small-group discussions and the provision of filters to prevent lead from migrating into homes. NCEH/ATSDR released a report of the rash study findings in August 2016. Dr. Patrick Breyse, Director of NCEH/ATSDR, contributed technical expertise to the media during the press release. The comprehensive, ~120-page report concluded that the current Flint water supply does not contain any elements with the ability to start or worsen rashes. However, the report also found that previous fluctuations in some water quality parameters likely would have contributed to rashes at a previous time when the Flint River was still the water source.

NCEH/ATSDR designed its Community Assessment for Public Health Emergency Response (CASPER) as a double statistical analysis of 10 different cells with interviews of 30 persons within each cell. CASPER results are generalized to the general population to project statistical results for an entire community. The CASPER for the Flint community included questions on behavioral health/mental health issues associated with the water crisis; rent, utilities and other financial issues; and safety issues.

Key findings of the CASPER based on family members ≤ 18 years of age who were interviewed in 282 Flint households are highlighted below.

- Flint is a stable community with 60% of residents living in the city for >12 years on average.
- Water filters were promoted as the intervention, but the majority of residents do not trust filters in their households and still prefer to use bottled water.
- Most residents believe that the switch to the Flint River as the water source played a role in their mental and physical health effects.
- Many residents believe that additional resources, support and assistance should be provided to Flint to identify persons in the community who have ongoing behavioral health issues and need services.
- A large number of residents believe that their services are sufficient at this time.
- Several residents do not trust the government and rely on family members/friends and news outlets as the primary sources of their information. Health departments serve as a source of information for a much lower percentage of residents.
- Most residents emphasized the need for the community's concerns to be heard.
- NCEH/ATSDR's discussions with HHS showed that Head Start enrollment and other community services need to be increased.

NCEH/ATSDR plans to finalize and release the CASPER report within the next three weeks. Regular updates of the report will be posted on the Michigan.gov website.

Dr. Knutson concluded her remarks by thanking the LPPS members for participating on the previous teleconferences and attending the current in-person meeting to provide NCEH/ATSDR with their excellent subject-matter expertise in the LPP field. She confirmed that OD looks forward to the presentation of LPPS's bold and thoughtful recommendations during the next BSC meeting. She was confident that LPPS's guidance would play a critical role in helping NCEH/ATSDR to achieve its future EPH goals.

Pamela Protzel Berman, PhD, MPH

Associate Director for Policy, NCEH/ATSDR
Centers for Disease Control and Prevention

Dr. Protzel Berman made several legislative announcements that are relevant to the NCEH/ATSDR LPP Program. Congress is attempting to reach agreement on the continuing resolution. After the ongoing procedural votes are completed, the continuing resolution is expected to fund the government through December 9, 2016. However, resources for public health emergencies, such as the Zika virus and the catastrophic Louisiana flood in August, will have an impact on funding for the LPP Program.

The Senate passed the Water Resources Development Act (WRDA) of 2016 on September 15, 2016 with an overwhelming vote of 95 to 3. The WRDA will provide more resources to states to pay for complete replacement of lead service lines in 7% of households in Flint and other affected communities that failed the EPA Lead and Copper Rule standards.

HHS and NCEH/ATSDR provided technical assistance and education on the WRDA to Congressional staff. NCEH/ATSDR used this opportunity to inform Congressional staff of the critical need for a more robust LPP Program with stronger surveillance that is national in scope. The passage of the WRDA by Congress will allow NCEH/ATSDR to expand and improve the LPP Program in the future. Most notably, the WRDA includes the Stabenow Amendment that calls for a \$10 million increase in funding to the LPP Program over a two-year period. For example, aid to address lead-contaminated water in Flint would cover infrastructure issues, replacement of lead service lines to remove contamination and testing.

Other parts of the Stabenow Amendment address EPA and state primacy issues, such as the establishment of EPA water programs across the country. Because the proposed funding is mandatory, additional Congressional language would not be required. If the bill is passed with the current language, the LPP Program budget will be increased by \$10 million.

The Stabenow Amendment also includes language that authorizes the establishment of voluntary registries in cities with lead-contaminated water problems. The registries would be designed to

follow children who reside in Flint and similar communities, capture their developmental issues, and maintain data on the health outcomes of this population over time. Although CDC is not specifically named in the bill, the HHS Secretary would provide NCEH/ATSDR with oversight of the registries.

The current Senate markup for the FY2017 budget calls for a \$2.5 million appropriation to CDC to establish a new Lead Advisory Committee. Senate representatives proposed this language due to their recognition of the need for external professionals in the field to provide subject-matter expertise and guidance to the HHS Secretary and the CDC Director on LPP efforts. However, the House has not yet approved any of the provisions the Senate has passed for new funding to the LPP Program and the establishment of a new Lead Advisory Committee. The House might not pass any of these bills until after the Presidential election in November 2016.

Reconsideration of the Strategy for the NCEH Lead Surveillance Program

Sharunda Buchanan, PhD, MS

Director, NCEH Division of Emergency and Environmental Health Services
Acting Chief, Lead Poisoning Prevention Program
Centers for Disease Control and Prevention

Dr. Buchanan described issues that CDC currently is considering to modify or improve the existing strategy for the Lead Surveillance Program. The Lead Contamination Control Act of 1988 authorized CDC to implement a comprehensive Childhood Lead Poisoning Prevention Program (CLPPP) with a focus on three major activities.

- Develop programs and policies to prevent childhood lead poisoning (CLP) and other housing-related health hazards.
- Educate the public and healthcare providers about CLP and other housing-related health hazards.
- Provide funding to state and local health departments to determine the extent of CLP poisoning by (1) screening children for elevated blood lead levels (EBLLs); (2) helping to ensure that lead-poisoned infants and children receive medical and environmental follow-up; and (3) developing neighborhood-based efforts to prevent CLP.

The key milestones of the CDC CLPPP are summarized as follows. In the 1980s-2010, full funding was allocated to CDC to conduct a comprehensive program with >40 grantees that focused on universal screening of high-risk children ≤ 6 years of age and case management for those with EBLLs. Individual awards to states ranged from ~\$400,000--~\$1 million. CDC established the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) to provide external expertise and guidance on conducting the CLPPP. In 2010, level funding was

allocated and the shift was made to targeted screening of high-risk children in communities based on local epidemiologic data.

In 2012, funding was decreased by 93% (or from \$35 million to \$2 million) and led to the loss of extramural programs and the termination of ACCLPP. In 2014, a portion of the CLPPP funding was restored for grantees to conduct surveillance, target community-based strategies to high-risk children, and strengthen partnerships. In 2015-2016, the Flint water crisis occurred and caused CDC to reconsider its existing lead surveillance capacity for 2017 and beyond to address and prevent similar events from occurring in the future.

The 35 grantees awarded under the 2014-2016 Funding Opportunity Announcement (FOA) include 29 states, 5 cities and the District of Columbia. The grantees are funded to eliminate CLP by creatively targeting resources and implementing program initiatives in three key areas.

- Build and strengthen lead surveillance systems to identify neighborhoods and populations of children who are disproportionately affected by high BLLs.
- Educate parents and clinical providers in target areas about the importance of blood lead testing for children <6 years of age.
- Collaborate with institutional and community-based partners to initiate, promote and evaluate CLP prevention activities.

CDC is focusing on five major areas in its ongoing development of the new FOA that will begin in 2017.

First, an automated syndromic surveillance system with an electronic alert would allow CDC to review blood lead test data in real time before an incident occurs in communities. CDC would notify the state or locality to conduct an investigation when a blood lead alert is triggered in the syndromic surveillance system. CDC has been using Flint as a case study to develop the model and plans to deploy the system to states and localities after the system is pilot tested, evaluated and refined.

Second, enhanced lead surveillance will increase screening rates of high-risk children and allow states and localities to eliminate lead sources prior to exposure. CDC is exploring the possibility of including “enhanced surveillance” language in the new lead FOA. CDC also will provide grantees with guidance on conducting small-area prevalence studies with a uniform approach.

Third, CDC will continue its cross-sector collaborations with federal, state and local partners, including EPA, U.S. Department of Housing and Urban Development (HUD), American Water Works Association, state/local water utilities, and state/local departments of environmental quality. CDC and its partners have identified several issues that will play an important role in advancing existing lead surveillance capacity, such as health-based changes to the EPA Lead

and Copper Rule, health department notifications, changes in water sources or water chemistry, and exceedances of the 15 ppb standard for lead in water.

Fourth, enhanced data reporting will require improvements in several areas.

<i>Program Component</i>	<i>Improvements Needed</i>
Laboratory limit of detection (LOD) capacity	Increased epidemiological technical support Increased information technology support to improve state reporting systems, including the shift from paper based to electronic systems
Laboratory timeliness	<ul style="list-style-type: none">• System modifications to report near real-time data
State/local program timeliness	<ul style="list-style-type: none">• Capacity to report near real-time data
Requirements	<ul style="list-style-type: none">• More uniform reporting requirements

Fifth, secondary and tertiary prevention will help to identify and implement policies, systems and environmental changes to minimize lasting effects of lead exposure in children through case management, social services and educational interventions.

Overall, CDC is striving to scale up the CLPPP as a national program in all 50 states to achieve the Healthy People 2020 goal of eliminating CLP. Dr. Buchanan confirmed that CDC welcomes input from the LPPS on issues to consider while the new FOA is being developed.

LPPS DISCUSSION: CDC'S LEAD SURVEILLANCE STRATEGY

Dr. Buchanan provided additional details on CDC's proposed strategy to enhance lead surveillance capacity in response to the BSC's specific questions.

- Establishment of criteria by CDC or its grantees to identify and prioritize localities for the small-area prevalence studies of children with EBLLs.
- CDC's official policy or plans to scale up the CLPPP as a national program in all 50 states to ensure the severe budget cut in 2012 is not repeated in the future.
- CDC's intention for states and localities to use surveillance data gathered under the new FOA and place much more emphasis on primary prevention.

In response to Dr. Kosnett's questions, Dr. Buchanan reminded the LPPS of Dr. Breyse's comments during the June 2016 BSC meeting. CDC leadership supports budgetary allocations to reestablish a Lead Advisory Committee similar to the ACCLPP that was disbanded in 2012. CDC leadership also supports budgetary allocations to fund the CLPPP and extramural grants to states at levels comparable to those prior to 2013.

Dr. Parsons asked CDC to provide information on specific laboratory issues: (1) the proportion of blood lead testing in the United States that is performed with LeadCare II devices in physician's offices and other non-laboratory settings; (2) the extent to which states report non-laboratory blood lead data to CDC; and (3) ongoing strategies to enhance reporting of blood lead testing data.

Drs. Buchanan and Robert Jones, Chief of the NCEH Inorganic and Radiation Analytical Toxicology Branch, responded to Dr. Parson's questions as follows. CDC administered a survey to its 35 grantees regarding their current use of laboratory methodologies for blood lead testing, but only ~20 states responded. The use of point-of-care instruments greatly varied across states at a range of 10%--57%. Efforts are underway to improve the LeadCare II device to allow for better detection at lower blood lead levels (BLLs). Similar to graphite furnace atomic absorption spectrometry (GFAAS) and inductively coupled plasma mass spectrometry (ICP-MS), the LeadCare Ultra device is intended for moderately complex laboratories and has the capability to report data to computer systems.

LPPS GUIDANCE

- The LPPS should formulate two key recommendations to CDC regarding the future direction of the Lead Surveillance Program.
 - CDC should advise CMS to require physicians to report blood lead testing results to their state registries as a condition of receiving Medicaid reimbursement.
 - CDC should issue a clear and unequivocal recommendation for federal, state and local public health partners in the United States to devise a primary prevention plan and invest resources to eliminate sources of lead poisoning throughout the country. CDC's recommendation should emphasize that lead-based paint is the primary source of BLLs ≥ 5 $\mu\text{g}/\text{dL}$ among ~500,000 children in the United States. CDC should partner with EPA and HUD to develop a white paper on creating a national primary prevention plan. The white paper should include cost projections to implement this initiative, but some estimates have shown that ~\$10 million would be needed to support a national primary prevention plan. The National Center for Healthy Housing (NCHH) and the National Safe and Healthy Housing Coalition have jointly launched "Find It, Fix It, Fund It: A Lead Elimination Action Drive" and could serve as key stakeholders in this effort. The two organizations are using their new initiative to build political will, create key public investments and policies to eliminate lead-based paint hazards, and generate a roadmap for Congress to take action.
- In general, the LPPS expressed strong support for CDC's proposed strategy for the 2017 FOA and recognized the tremendous value of the Lead Surveillance Program. In particular, individual members provided diverse perspectives on CDC's proposed approach.
 - On the one hand, CDC should reconsider the proposed strategy of strengthening its focus and targeting more resources to lead surveillance in the 2017 FOA. For example, health departments in New York City and New York State (NYC/NYS)

- already have collected a wealth of surveillance data on communities with children who have the highest BLLs, such as the City of Newburgh. Instead of conducting additional surveillance, more emphasis should be placed on implementing effective interventions to address lead problems in inner-cities or underprivileged areas, such as abatement programs to remediate lead-based paint; improved nutritional programs to reduce children's absorption of lead; and enhanced Head Start programs to address lead-related cognitive deficits or developmental delays in children.
- On the other hand, CDC should pursue the strategy for the Lead Surveillance Program that is being proposed for 2017 and beyond. For example, the automated syndromic surveillance system will allow CDC to benefit from real-time rather than retrospective data and analyses. Small-area prevalence studies will strengthen lead research and generate important outcomes related to lead in smaller geographic areas rather than in larger municipalities. However, CDC should continue to deploy its existing Healthy Homes and Lead Poisoning Prevention Surveillance System. This valuable resource has provided ongoing assistance to states, particularly those with no surveillance systems, in submitting their lead data to CDC.
 - CDC and its grantees should collaborate in a joint effort to establish criteria for the small-area prevalence studies. For example, CDC's role would be to provide each grantee with state-specific housing characteristics and relevant information from other datasets. The grantee's role would be to consult with CDC regarding site-specific information on high-risk areas that support their targeted screening plans.
 - CDC should contact Dr. Peter Grevatt, Director of the EPA Office of Ground Water and Drinking Water. He currently is reviewing potential changes to the Lead and Copper Rule that would be more responsive to lowering BLLs.
 - CDC leadership should ask EPA to invite the LPPS to review elements of any revisions of the Lead and Copper Rule that would establish or consider health-based criteria for standards governing lead in water.
 - CDC should encourage its grantees to consider factors other than BLLs (e.g., race, income, educational status and housing/construction histories of properties) in their future efforts to enhance surveillance and increase screening rates.
 - CDC should use the 2017 FOA to reiterate the importance of primary prevention to its grantees. For example, grantees should design their lead screening questionnaires for providers to ask patients about the presence or use of lead in their homes, occupations and hobbies. Providers should initiate these conversations during prenatal visits with pregnant women and hospital visits with parents of newborns. More detailed and in-depth screening questionnaires would prompt providers to perform capillary or venous blood lead testing.
 - CDC should collaborate with federal, state and local partners and community groups to model the reduction or elimination of lead hazards in children's environments in the most impacted communities. The partners should target resources to enhancing surveillance and conducting interventions that improve education, nutrition and social/intellectual development of children who are exposed to lead.

- CDC should take caution in completely switching from universal screening to a targeted prevalence study approach in the 2017 FOA. For example, universal screening has been invaluable in NYS due to the requirement for providers to perform blood lead testing of Medicaid children 1-2 years of age and administer a screening questionnaire to pregnant women. NYC and other jurisdictions in the state also require universal screening of all pregnant women with a BLL. CDC should be mindful of the fact that universal screening is still a much better approach than a prevalence study or targeted screening with a questionnaire in multiple localities throughout the country.
- CDC should use the 2017 FOA as an opportunity to collect more qualitative data from primary prevention programs, such as their activities, barriers and efforts to create change (e.g., improvements in laboratory methodologies, refinements in data reporting and better code enforcement at the local level).
- CDC should collaborate with the Centers for Medicaid & Medicare Services (CMS) and/or manufacturers to capture data from blood lead tests performed in physician's offices and other non-laboratory settings with instruments that have a Clinical Laboratory Improvement Amendments (CLIA) waived permit.
- CDC has acknowledged the need for more uniform reporting requirements to enhance data reporting. To support this effort and improve the quality of lead data, CDC also should require its grantees to collect and report information on the specific methods that are used to measure BLLs. CDC does not require its grantees to capture this data element at this time.

Public Comment Session

Dr. Cibulas read a written comment into the public record that was submitted for the LPPS to consider. The public comment was submitted by Mr. Robb Morse, Clinical Diagnostics Marketing Director of Magellan Diagnostics.

Reportable Range of LeadCare II

Magellan Diagnostics' LeadCare systems for the determination of lead in blood at the point-of-care were born out of the CDC's recognition of a need to screen more children for lead poisoning. In the intervening 20 years, the exposure of children to lead, as evidenced by surveys of blood lead levels such as NHANES, has fallen dramatically. The results of the two most recent surveys, and the concomitant lowering of the CDC's Blood Reference Value for Lead demonstrate the success of this partnership.

The second generation "LeadCare II Blood Lead Test System" was cleared in 2006 by the FDA, which dictated a reportable range of 3.3 to 65 µg/dL when granting the system's CLIA-waiver status. With the Reference Value for pediatric lead exposure at 3.5 µg/dL, we

believe the FDA's 2006 decision to limit the reportable range of LeadCare II to 3.3 µg/dL will compromise the ability of pediatricians to assess the exposure levels of the majority of their patients.

For example, according to the most recent NHANES data, a pediatrician with 100 patients might see the following blood lead levels:

BLL	Number of patients	Identifiable with LeadCare II today?
>5 µg/dL	1	Yes
3.3 – 5 µg/dL	2	Yes
2 – 3.3 µg/dL	8	No (“<3.3”)
<2 µg/dL	89	No (“<3.3”)

Pediatricians experienced in monitoring blood lead levels have told Magellan that they want to be able to distinguish between their patients with BLLs near the 3.5 reference value from those below 2 µg/dL (the lower limit reported by the majority of reference labs), so they can respond appropriately to concerned parents. Given the NHANES data, today pediatricians using LeadCare II will have a quantitative result for ~3% of their patients (3 of 100, above). With a lower limit of 2, they would have a quantitative result for 11% of their patients.

Accordingly, we are planning the studies needed to demonstrate the performance of LeadCare II below the 3.5 µg/dL reference level with the intent of submitting documentation to the FDA to gain their agreement to reduce the lower limit of the system's reportable range. Based on our in-house studies, and on the other recently FDA-cleared LeadCare technologies (LeadCare Ultra and Plus), we expect this to be ~2 µg/dL.

Does the LPP Subcommittee agree that, given changes in the BLL reference value, pursuing a lower reporting limit for the LeadCare II system would be helpful to clinicians and lead poisoning prevention programs in their efforts to reduce lead exposure?

LPPS DISCUSSION: PUBLIC COMMENTS

- Dr. Kosnett expressed support of the studies that Magellan Diagnostics plans to conduct to examine the accuracy and precision of the LeadCare II device in measuring BLLs less than 3.5 µg/dL.
- Dr. Parsons urged the LPPS to table any formal recommendations at this time in response to the question posed by Magellan Diagnostics. He explained that the ability of the LeadCare II instrument to measure lower BLLs is still associated with a high level of uncertainty. Before the LPPS is in a position to make an informed judgment on this issue,

he emphasized that additional data would be needed from Magellan's laboratory and from field-based studies in which the device is used by doctors' office personnel.

Modern Analytical Techniques to Measure Lead in Blood

Patrick Parsons, PhD, LPPS Member

Chief, Laboratory of Inorganic and Nuclear Chemistry
Wadsworth Center, New York State Department of Health

Advice Requested from the LPPS by Dr. Parsons:

1. Can current blood lead analytical methods support reporting data to within ± 0.1 $\mu\text{g}/\text{dL}$ with sufficient accuracy and precision based on a single measurement?
2. What is the typical expanded uncertainty in blood lead measurements, calculated according to the *Guide to the Expression of Uncertainty in Measurement (GUM)*, by method?
3. Are current limits of detection (LODs)/methods (e.g., ICP-MS, GFAAS, or LeadCare II/ LeadCare Plus/ LeadCare Ultra) adequate to support a blood lead reference value (BLRV) of 3.5 $\mu\text{g}/\text{dL}$?

Dr. Parsons presented a two-part overview to inform the development of LPPS's formal recommendations on whether current technologies have the capability to support accurate, quality measurements of lower BLLs at 3.5 $\mu\text{g}/\text{dL}$.

Part 1: Background Information on Modern Analytical Techniques

The International Union of Pure and Applied Chemistry (IUPAC) issued harmonized guidelines in 2002 for single laboratories to validate their analysis methods. In its definition of "LOD," IUPAC emphasized the important need for laboratories to account for the specific method used to calculate the LOD, including the sample matrix. For example, the lead LOD in water is lower (i.e., better) than would be possible in a blood matrix. However, measurements at the LOD are quite uncertain overall and might easily be in error by a factor of 2. Most notably, EPA recommends using a limit of quantitation (LOQ), but other laboratories view the LOQ as an arbitrary measure and some use a 10% relative standard deviation instead.

Analytical techniques that laboratories currently use to measure blood lead are described below.

- GFAAS is a well-established technique with a track record of over 30 years. GFAAS involves the atomization of lead from a sample of 12 μL of diluted blood. GFAAS can be used as a reference method when calibrated with primary calibration standards and is directly traceable to système international (SI) units.

- ICP-MS was developed in the 1980s as an isotope-specific technique that has been refined over time and currently is used by high-end laboratories. ICP-MS can be used as a reference method when calibrated with primary calibration standards and directly traceable to SI units.
- Sector field ICP-MS has a high level of sensitivity and requires an extensive level of expertise to eliminate background contamination when measuring lower BLLs. Most clinical laboratories do not have the capacity or resources to use sector field ICP-MS.
- Anodic stripping voltammetry (ASV) primarily is implemented with disposable screen-printed technologies. Blood is mixed with a reagent that de-complexes lead bound to proteins and allows “free” lead in its +2 oxidation state to bind to the working electrode. Magellan’s original LeadCare instrument is no longer on the market, but upgrades of the ASV disposable sensor technology (LeadCare II and LeadCare Plus) are available.

The following table compares the key features and components of the current methods that laboratories use to measure blood lead.

Method	LOD	LOQ	CLIA Definition	FDA Definition	Cost & Type	Throughput
GFAAS	~1 µg/dL	~2-3 µg/dL	High complexity	Laboratory developed test	\$30,000-\$50,000 Automated	120-300 samples/day
ICP-MS	0.05-0.20 µg/dL	0.30-0.70 µg/dL	High complexity	Laboratory developed test	\$180,000-\$250,000 Automated	80-90 samples/day
Sector Field ICP-MS	~0.016 µg/dL	~0.055 µg/dL	Very, very high complexity	Isotope ratios	≥\$500,000 Automated	
Magellan ASV Sensor: LeadCare	~2 µg/dL		Moderate complexity		Non-automated	
Magellan ASV Sensor: LeadCare II	3.3-65 µg/dL		Waived		~\$3,000 (~\$6/test) No automated connectivity	

Method	LOD	LOQ	CLIA Definition	FDA Definition	Cost & Type	Throughput
Magellan ASV Sensor: LeadCare Plus	1.9-65 µg/dL		Moderate complexity		\$3,495 (~\$7.55/test) \$900 data management system (optional) Optional HL7 2.5.1 for connectivity	15-20 samples/hour
Magellan ASV Sensor: LeadCare Ultra	1.9-65 µg/dL		Moderate complexity		\$25,200 (~\$5.52/test) HL7 2.5.1 for connectivity	~90 samples/hour

Part 2: Capacity of Current Analytical Methods to Quantify Lower BLLs

CDC has issued five guidance documents on *Preventing Lead Poisoning in Young Children* to date and released the most recent set of recommendations in 2005. CDC has made significant policy changes over time by decreasing the BLL of concern in the United States from 60 µg/dL in 1965 to a BLRV of ≥ 5 µg/dL in 2012.

CDC is now exploring the feasibility of lowering the current BLRV from 5 to 3.5 µg/dL and determining whether modern technologies have the capacity to support this policy change. The CLIA regulation was originally implemented in 1991 and is now being reviewed to determine whether a more stringent blood lead proficiency testing (PT) standard than ± 4 µg/dL or $\pm 10\%$ should be required.

The NYS Blood Lead Laboratory conducted an evaluation and found that the vast majority of laboratories could achieve and sustain an acceptable performance of $\geq 80\%$ with a more rigid blood lead PT standard of ± 2 µg/dL or $\pm 20\%$. However, the evaluation showed that the level of laboratory performance would decrease to $< 80\%$ with an even more stringent standard of ± 1 µg/dL. The findings by the NYS Blood Lead Laboratory were consistent with recommendations issued by the Clinical and Laboratory Standards Institute (2001) and ACCLPP (2009) to tighten the acceptable criteria for blood lead laboratory performance to ± 2 µg/dL or $\pm 20\%$.

The College of American Pathologists reported more recent data based on its collection of blood lead data from 295 laboratories in 2016. Of the participating laboratories, ~47% used a LeadCare device, 34% used GFAAS and 19% used ICP-MS. The assessment showed that 69% of laboratories do not report results at a BLL of ~ 1 µg/dL and 10% of laboratories do not report results at a BLL of 3 µg/dL. These data emphasize the need to strengthen the LOD by improving

current technologies, particularly since contamination becomes much more problematic when laboratories measure lower BLLs.

Overall, the former ACCLPP extensively addressed LeadCare point-of-care practice standards in its previous deliberations. Because CMS never updated or implemented the CLIA PT standard from ± 4 to ± 2 $\mu\text{g}/\text{dL}$, the acceptable range for laboratories to report BLLs at this time would be 1.5-5.5 $\mu\text{g}/\text{dL}$ at a BLRV of 3.5 $\mu\text{g}/\text{dL}$.

Dr. Parsons's personal opinion was that only a few states have implemented CDC's 2012 policy change from the BLL of concern of 10 $\mu\text{g}/\text{dL}$ to the current BLRV of 5 $\mu\text{g}/\text{dL}$ in their public health practices. He concluded his overview by summarizing the capabilities of current technologies to support accurate, quality measurements of lower BLLs.

- Both ICP-MS and GFAAS are solid high-complexity reference methods that are capable of accurately measuring BLLs at 1 $\mu\text{g}/\text{dL}$.
- ICP-MS is adequate at this time to support a BLRV of 3.5 $\mu\text{g}/\text{dL}$ so long as appropriate expertise and sufficient capacity to control for pre-analytical contamination are available.
- GFAAS has the potential to support a BLRV of 3.5 $\mu\text{g}/\text{dL}$, but additional refinements are needed to improve this method.
- LeadCare II is a well-established instrument for point-of-care blood lead screening, but its ability to support a BLRV of 3.5 $\mu\text{g}/\text{dL}$ is uncertain at this time.
- The capacity of LeadCare Plus and LeadCare Ultra to support a BLRV of 3.5 $\mu\text{g}/\text{dL}$ will be determined by data collected from Magellan's upcoming laboratory studies and outcomes from studies that investigate the use of these devices under field conditions.

Dr. Breyse noted that clinical measurements for other conditions (e.g., elevated cholesterol and vitamin D deficiency) have much larger relative standard deviations than impacts from lead. He encouraged the LPPS to consider broader clinical measurements that routinely are found to be acceptable in other areas of clinical laboratory medicine.

Dr. Breyse pointed out that policy has the ability to protect health, drive technology and improve methods. He advised the LPPS to continue its efforts to use policy in this manner to establish standards to measure lower BLLs.

LPPS DISCUSSION: MODERN ANALYTICAL TECHNIQUES TO MEASURE LOWER BLLS

- The LPPS members thanked Dr. Parsons for his extremely informative presentation to guide the deliberations on whether CDC should lower the current BLRV from 5 to 3.5 $\mu\text{g}/\text{dL}$ and if current analytical techniques have the capacity to support this policy change.
- Several LPPS members expressed their support for lowering the BLRV to 3.5 $\mu\text{g}/\text{dL}$ because the policy change would generate more public health benefits to children.
- As the LPPS member who represents parents of children with EBLs, Ms. Colón emphasized the importance of articulating clear messages and providing the general

public (e.g., parents, pediatricians and case workers) with evidence-based information regarding the public health implications of and differences between a BLRV of 5 versus 3.5 µg/dL.

Dr. Kosnett suggested that CDC advise CMS to require the reporting of point-of-care blood lead test results to state blood lead registries as a condition for Medicaid reimbursement for the test.

Dr. Buchanan noted that CDC is continuing to gather information from states regarding the proportion of blood lead surveillance data collected by LeadCare II instruments. Based on incomplete information, LeadCare II usage from state-to-state widely ranges from 10%-56%.

CDC's Blood Lead Reference Value

Helen Schurz Rogers, PhD

Associate Director for Science

NCEH Division of Emergency and Environmental Health Services

Centers for Disease Control and Prevention

Advice Requested from the LPPS by NCEH/EEHS:

1. What are the implications of establishing a new BLRV that is lower than 5 µg/dL?
2. Should the BLRV be used as a combined case definition/benchmark?
3. Are other metrics available that might be useful to help measure progress toward reaching the national goal of eliminating EBLLs in children by 2020, particularly in communities with the highest lead exposures?
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 the National Health and Nutrition Examination Survey (NHANES)?

Dr. Rogers informed the LPPS that CDC is continuing to discuss the possibility of lowering the current BLRV from 5 to 3.5 µg/dL. She presented an overview of the data that CDC is reviewing to inform its decision-making process.

The former ACCLPP voted to approve two recommendations to CDC in 2012. First, eliminate and replace the terminology of "blood lead level of concern" (i.e., ≥ 10 µg/dL) with a reference value based on the 97.5th percentile of the distribution of BLLs in children 1-5 years of age as measured by NHANES. Second, reevaluate the BLRV every four years. CDC concurred or concurred in principle with ACCLPP's recommendations.

NHANES is a continuous, cross-sectional representative survey of the non-institutionalized U.S. civilian population. NHANES is conducted in two-year cycles with a complex, multi-stage

probability design. During each NHANES cycle from 1999-2010, ~10,000 participants, including ~1,240 children 1-5 years of age, were interviewed and physically examined. Blood specimens were collected from 850 (or ~69%) young children.

The CDC Elemental Analysis Laboratory uses ICP-MS to measure BLLs. The LODs of BLLs in the NHANES cycles were 0.25 µg/dL (2011-2012) and 0.1 µg/dL (2013-2014). The CDC laboratory calculated the distribution of BLLs for children 1-5 years of age to determine the 97.5th percentile, geometric mean BLLs, and 95% confidence intervals. Pairwise t-tests were conducted to identify significant differences between geometric mean BLLs. Subgroups of the sample with well-known historical disparities were analyzed by age, gender, race/ethnicity, poverty-to-income ratio and household income.

Of 1,531 children 1-5 years of age who were tested in the 2011-2014 NHANES cycles, 1,486 had BLLs <3.5 µg/dL and only 45 had BLLs ≥3.5 µg/dL. Of the 45 children with BLLs ≥3.5 µg/dL, the estimated prevalence was 2.41% and the breakdown by gender was equal. However, the small sample size resulted in a relative standard error of ≥30. NHANES estimates and 95% confidence intervals at or above the BLRV of 5 µg/dL showed steady decreases in the prevalence of BLLs: 8.65% (1999-2002 cycles), 4.11% (2003-2006 cycles), 2.64% (2007-2010 cycles), and 1.2% (2011-2014 cycles). However, the prevalence of BLLs in the 2011-2014 NHANES cycles would have been higher at 2.41% if the lower BLRV of 3.5 µg/dL had been used.

CDC conducted analyses to determine geometric mean BLLs in children 1-5 years of age based on specific characteristics. By race/ethnicity, geometric mean BLLs were approximately equal between non-Hispanic white and Mexican American children. The higher geometric mean BLL of 1.14 µg/dL in non-Hispanic black children was statistically significant. A significant relationship was observed between a lower household income of <\$20,000 and a higher geometric mean BLL of 1.8 µg/dL versus a higher household income of ≥\$20,000 and a lower geometric mean BLL of 0.8 µg/dL.

NHANES estimates and 95% confidence intervals showed steady declines in geometric mean BLLs: 1.94 µg/dL (1999-2002 cycles), 1.61 µg/dL (2003-2006 cycles), 1.33 µg/dL (2007-2010 cycles), and 0.86 µg/dL (2011-2014 cycles). Decreases in geometric mean BLLs from the 1999-2002 to the 2011-2014 cycles were significant. By race, non-Hispanic black children had the highest geometric mean BLLs. However, the 95% confidence intervals are now overlapping with those of non-Hispanic white and Mexican American children.

LPPS DISCUSSION: CDC'S BLRV

- Dr. Parsons reminded the LPPS members of the feedback he provided during the June 2016 BSC meeting. NHANES is a controlled study that provides accurate and excellent data for the nation. As a result, CDC's high level of expertise, skilled laboratorians, state-of-the-art equipment and extraordinary measures to eliminate contamination do not reflect "real world" laboratory practices in the field. He reiterated that the actual capacity of

laboratories in the field must be considered in the decision-making process of lowering the BLRV from 5 to 3.5 µg/dL.

- Dr. Kosnett announced that he is leading a small workgroup that includes representation by LPPS members, BSC members and CDC subject-matter experts. The workgroup's overarching charge is two-fold. First, data will be collected and reviewed to address the public health implications of lowering the BLRV from 5 to 3.5 µg/dL, particularly related to the positive and negative predictive value of blood lead surveillance data regarding the prevalence of children with EBLLs. Second, a determination will be made on whether current technologies are sufficient to support this policy change. After the full LPPS membership formally approves the workgroup's findings, the draft recommendations will be submitted to the BSC. Dr. Kosnett anticipated that the workgroup likely would fulfill its charge and submit its initial findings to the LPPS Chair within the next six months.
- The LPPS members extensively discussed and provided diverse perspectives on whether the terminology of "elevated BLLs" should continue to be used in education, outreach and messaging/communications if CDC implements a new BLRV of 3.5 µg/dL. On the one hand, Dr. Lowry believed that 3.5 µg/dL simply provides a number for a low level of lead in an individual's blood. Because blood lead at this low level does not necessarily reflect an "elevated" BLL, the use of this terminology should be discontinued. On the other hand, Dr. Maddaloni believed that "elevated BLLs" is easy to communicate and would still be appropriate terminology to use at lower levels. If 97.5% of children have BLLs <3.5 µg/dL, for example, the remainder of children with BLLs ≥3.5 µg/dL would indeed be "elevated."

Dr. Mary Mortensen, of the NCEH Division of Laboratory Services (DLS) noted that at lower LODs, the relative contribution of lead contamination present in blood lead collection tubes to the analytical result increases. DLS increasingly has been rejecting tubes that are not adequately free of contamination for its highly sensitive laboratory measurements.

Dr. Kosnett raised the possibility of encouraging or requiring clinical laboratories to report uncertainties associated with blood lead results. With this approach, laboratories could provide 95% confidence intervals around their reported values. He also suggested that laboratories be advised of the need to only accept high-quality trace metal tubes for blood lead surveillance.

Dr. Breyse informed the LPPS that he would be unable to attend the afternoon session of the meeting due to prior commitments. He made two key comments for the LPPS to consider in its formulation of recommendations to CDC on emerging lead topics.

First, the former ACCLPP members are to be commended for their outstanding guidance to CDC to eliminate the BLL of concern and periodically redefine the BLRV as new data become available over time. ACCLPP's recommended approach has played a critical role in the public health success of lowering children's BLLs in communities across the country. In the absence of an established health threshold for lead, Dr. Breyse's position was that ACCLPP's advice on this issue was brilliant.

Second, retaining the current BLRV of 5 µg/dL or lowering the BLRV to 3.5 µg/dL will be the most significant EPH decision that CDC makes in 2016. As a result, CDC is heavily relying on the subject-matter expertise of the LPPS to offer clear, accurate and evidence-based guidance to diverse stakeholders in this regard.

Dr. Breyse noted that the capacity of epidemiology studies to assess the impact of very low blood lead concentrations (e.g., 1 or 2 µg/dL) on IQ will depend on the use of sensitive and precise clinical laboratory methods. He thanked the LPPS members for their continued commitment to this effort.

LPPS's Formal Recommendations to the BSC

Matthew Strickland, PhD, MPH, MA, LPPS Chair

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

Dr. Strickland announced that the LPPS would devote the entire afternoon session to continuing its discussions, prioritizing emerging lead topics presented by the speakers over the course of the meeting, and drafting formal recommendations for submission to the BSC.

The LPPS members extensively discussed and identified six issues that potentially could be developed as formal recommendations to the BSC.

- Revision of existing lead standards and guidelines
- Primary prevention
- Reestablishment of a high-level CDC Lead Advisory Committee to the HHS Secretary
- Revision of Occupational Safety and Health Administration (OSHA) lead standards
- Development of a standardized template for clinical laboratories to uniformly interpret blood lead test results
- CMS's implementation of more rigorous blood lead PT criteria

Based on its deliberations, the LPPS drafted and formally voted on six recommendations that would be submitted to the BSC for a vote and forwarded to CDC for action.

RECOMMENDATION 1

The Lead Poisoning Prevention Subcommittee recommends that CDC call on the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Housing and Urban Development (HUD) to revise their standards and guidelines concerning the actionable

content of lead in paint, soil, dust and water to be consistent with the goal of maintaining the impacted population's blood lead level equal to or less than CDC's reference value.

Chair's call for a vote	Dr. Matthew Strickland properly placed a motion on the floor for the LPPS to submit Recommendation 1 to the BSC for discussion, consideration and formal approval. Dr. Jennifer Lowry seconded the motion.
Outcome of vote	The 9 LPPS voting members unanimously passed the motion.

RECOMMENDATION 2

The Lead Poisoning Prevention Subcommittee recommends that CDC work with partner agencies and stakeholders to develop a Strategic Plan to implement primary prevention to include reduction of lead hazards in the home (including, but not limited to, lead-based paint, dust, soil, water and take-home exposures) and education to healthcare providers (including, but not limited to, obstetricians and pediatricians).

Chair's call for a vote	Dr. Matthew Strickland properly placed a motion on the floor for the LPPS to submit Recommendation 2 to the BSC for discussion, consideration and formal approval. Dr. Jennifer Lowry seconded the motion.
Outcome of vote	The 9 LPPS voting members unanimously passed the motion.

RECOMMENDATION 3

The Lead Poisoning Prevention Subcommittee, which is presently a subcommittee to the NCEH/ATSDR BSC, would have the potential for greater impact and visibility if reconstituted at a higher level within HHS. Such a committee would more easily engage representatives across key federal agencies and stakeholders.

Chair's call for a vote	Dr. Matthew Strickland properly placed a motion on the floor for the LPPS to submit Recommendation 3 to the BSC for discussion, consideration and formal approval. Dr. Jennifer Lowry seconded the motion.
Outcome of vote	The 9 LPPS voting members unanimously passed the motion.

RECOMMENDATION 4

Current OSHA standards for lead in general industry and construction provide inadequate protection for the health of workers. The Lead Poisoning Prevention Subcommittee (LPPS) recommends that CDC support the scientific rationale for revision of OSHA lead standards at the federal level. The LPPS recommends that CDC specifically provide comments to OSHA in support of its Advanced Notice of Proposed Rulemaking on occupational lead standards that will be issued in November 2016.

Chair's call for a vote	Dr. Matthew Strickland properly placed a motion on the floor for the LPPS to submit Recommendation 4 to the BSC for discussion, consideration and formal approval. Dr. Jennifer Lowry seconded the motion.
Outcome of vote	The 9 LPPS voting members unanimously passed the motion.

RECOMMENDATION 5

The Lead Poisoning Prevention Subcommittee recommends that CDC develop a standardized template for clinical interpretation of blood lead results for use by clinical laboratories nationwide on their test reports. This interpretative guidance would identify the Reference Value and delineate risk-based intervals that represent escalating priorities for public health and medical intervention. In developing this template, CDC should examine recent guidelines, such as those developed by the Pediatric Environmental Health Specialty Unit program.

Chair's call for a vote	Dr. Matthew Strickland properly placed a motion on the floor for the LPPS to submit Recommendation 5 to the BSC for discussion, consideration and formal approval. Dr. Jennifer Lowry seconded the motion.
Outcome of vote	The 9 LPPS voting members unanimously passed the motion.

RECOMMENDATION 6

The Lead Poisoning Prevention Subcommittee recommends that CDC communicate to HHS Secretary Sylvia Burwell the need for the Centers for Medicaid & Medicare Services (CMS) to implement recommendations to tighten guidelines for blood lead proficiency testing criteria to $\pm 2 \mu\text{g/dL}$, $\pm 10\%$ under the Clinical Laboratory Improvement Amendments of 1988. In its communications with the HHS Secretary, CDC should note that it has been six years since the former Advisory Committee on Childhood Lead Poisoning Prevention made this recommendation to former HHS Secretary Kathleen Sebelius.

Chair's call for a vote	Dr. Matthew Strickland properly placed a motion on the floor for the LPPS to submit Recommendation 6 to the BSC for discussion, consideration and formal approval. Dr. Jennifer Lowry seconded the motion.
Outcome of vote	The 9 LPPS voting members unanimously passed the motion.
Next Steps	<ul style="list-style-type: none"> • Dr. Strickland will compile all six of LPPS's unanimously approved recommendations in a letter to Dr. Melissa Perry, the BSC Chair. If the BSC votes to approve the LPPS recommendations during its next meeting, the guidance will be forwarded to NCEH/ATSDR OD to take action. • If the BSC votes to approve Recommendation 6, Dr. Strickland will ask Dr. Perry to take action on a suggestion by Dr. Parsons. ACCLPP's 2010 letter to former HHS Secretary Sebelius and Secretary Sebelius's response to ACCLPP should be included in LPPS's recommendations that are submitted to NCEH/ATSDR OD.

Summary, Next Steps and Closing Session

The action items that were raised over the course of the meeting are set forth in the table below.

ACTION ITEMS	
Responsibility	Action Step
Dr. Knutson	Provide the DFO with a summary of the Flint CASPER report for distribution to the LPPS members.
Dr. Protzel Berman	Provide the DFO with Senate language to distribute to the LPPS members that calls for a \$10 million increase to the LPP Program budget and \$2.5 million for CDC to establish a new Lead Advisory Committee.
Dr. Cibulas	Distribute EPA's draft Lead and Copper Rule for the LPPS members to submit comments on health-based issues.
Dr. Cibulas	Explore the possibility of offering video conferencing at future LPPS meetings for members who are unable to attend in person.
Dr. Cibulas	Provide Magellan Diagnostics's written public comment to the LPPS members who were unable to attend the meeting in person.

Dr. Cibulas responded to questions by several members regarding the next steps for the six recommendations that the LPPS unanimously approved during the current meeting. The BSC meeting in December 2016 might need to be postponed until January 2017 because HHS must first officially appoint nine new members. Although Dr. Strickland will compile and submit the LPPS recommendations in a letter to Dr. Perry prior to the next BSC meeting, he also will be placed on the agenda to present the guidance to the full BSC membership.

In terms of dissemination, Dr. Cibulas confirmed that the formal recommendations will be captured in both sets of minutes for the current LPPS meeting and the next BSC meeting. The guidance also will be available on both the BSC and LPPS webpages.

Dr. Kosnett thanked the NCEH/ATSDR staff for expanding the LPPS webpage to include its membership roster, charter and meeting minutes. Dr. Strickland thanked the LPPS members for drafting six solid recommendations to submit to the BSC for a formal vote.

With no further discussion or business brought before the LPPS, Dr. Cibulas adjourned the meeting at 3:03 p.m. on September 19, 2016.

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

Date

Matthew Strickland, PhD, MPH, MA
Chair, Lead Poisoning Prevention
Subcommittee



Participants' Directory

Lead Poisoning Prevention Subcommittee Members

Dr. Matthew Strickland¹, Chair
University of Nevada, Reno

Mr. John G. Belt
Ohio Department of Health

Ms. Elizabeth A. Colón
Childhood Lead Action Project

Dr. Kim Dietrich¹
University of Cincinnati College of Medicine

Dr. Nathan Graber
New York State Department of Health

Dr. Michael J. Kosnett
University of Colorado School of Medicine &
Colorado School of Public Health

Dr. Jennifer A. Lowry
Children's Mercy Hospital

Dr. Mark A. Maddaloni
U.S. Environmental Protection Agency

Dr. Patrick Parsons
New York State Department of Health

Board of Scientific Counselors Member

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

NCEH/ATSDR Designated Federal Official

Dr. William Cibulas, Jr.
Deputy Associate Director for Science

NCEH/ATSDR Director

Dr. Patrick Breyse

CDC/NCEH/ATSDR Representatives

Dr. Walter Alacorn
Ms. Christine Anube
Dr. Sharunda Buchanan
Dr. Kathy Caldwell
Dr. Po-Yung Cheng
Mr. Bennett Conner
Ms. Kristin Day
Dr. John Decker
Mr. Ed Dieser
Ms. Alisha Etheredge
Ms. Cheryl Everhart
Ms. Demetria Gardner
Mr. James Hodge
Mr. Jeff Jarrett
Ms. Laurie Johnson

Dr. Robert Jones
Dr. Donna Knutson
Ms. Shirley Little
Ms. Elise Lockamy
Ms. Amanda Malasky
Dr. Josephine Malilay
Dr. Jacquelyn Mason
Dr. Mary Mortensen
Ms. Christina Newby
Dr. Pamela Protzel Berman
Dr. Helen Schurz Rogers
Mr. Christian Sheel

Dr. Jerry Thomas

Members of the Public

Ms. Catherine Lufkin
Magellan Diagnostics

Robb Morse
Magellan Diagnostics

Dr. Andy Rooney
National Toxicology Program

¹Lead Poisoning Prevention Subcommittee members who also serve as NCEH/ATSDR Board of Scientific Counselors members



Glossary of Acronyms

ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
ASV	Anodic Stripping Voltammetry
BLLs; EBLLS	Blood Lead Levels; Elevated Blood Lead Levels
BLRV	Blood Lead Reference Value
BSC	Board of Scientific Counselors
CASPER	Community Assessment for Public Health Emergency Response
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
CLP; CLPPP	Childhood Lead Poisoning; Childhood Lead Poisoning Prevention Program
CMS	Centers for Medicaid & Medicare Services
DFO	Designated Federal Official
DLS	Division of Laboratory Sciences
EEHS	Division of Emergency and Environmental Health Services
EHHE	Division of Environmental Hazards and Health Effects
EPA	U.S. Environmental Protection Agency
EPH	Environmental Public Health
FACA	Federal Advisory Committee Act
FOA	Funding Opportunity Announcement
GFAAS	Graphite Furnace Atomic Absorption Spectrometry
GUM	<i>Guide to the Expression of Uncertainty in Measurement</i>
HHS	U.S. Department of Health and Human Services
HUD	U.S. Department of Housing and Urban Development
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IUPAC	International Union of Pure and Applied Chemistry
LOD	Limit of Detection
LOQ	Limit of Quantitation
LPP	Lead Poisoning Prevention
LPPS	Lead Poisoning Prevention Subcommittee

NCEH/ATSDR	National Center for Environmental Health/Agency for Toxic Substances and Disease Registry
NCHH	National Center for Healthy Housing
NHANES	National Health and Nutrition Examination Survey
NYC; NYS	New York City; New York State
OD	Office of the Director
OSHA	Occupational Safety and Health Administration
PT	Proficiency Testing
SI	Système International
WRDA	Water Resources Development Act

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