DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION National Center for Environmental Health

Division of Emergency and Environmental Health Services Healthy Homes/Lead Poisoning Prevention Branch





CENTERS FOR DISEASE CONTROL AND PREVENTION

Advisory Committee on Childhood Lead Poisoning Prevention November 16-18, 2010 Atlanta, Georgia

Record of the Proceedings

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ATTACHMENT 1

List of Participants

(*Note:* The Designated Federal Official opened the floor for introductions on November 16, 17, and 18, 2010 and confirmed the presence of a quorum with the ACCLPP voting members and non-voting *ex-officio* members on all three days of the meeting.)

ACCLPP Members

Dr. George Rhoads, Chair Dr. Deborah Cory-Slechta Dr. Sher Lynn Gardner Mr. Perry Gottesfeld Dr. Kimberly Hansen Dr. Michael Kosnett Mr. David McCormick Dr. Brenda Reyes Dr. Megan Sandel Mr. Dana Williams, Sr.

Ex-Officio Members

- Dr. Walter Alarcon (National Institute for Occupational Safety and Health)
- Dr. Kristina Hatlelid (U.S. Consumer Product Safety Commission)
- Ms. Janet Hawkins (Alternate, U.S. Department of Housing and Urban Development)
- Ms. Jacqueline Mosby (U.S. Environmental Protection Agency)
- Dr. Walter Rogan (National Institute of Environmental Health)

Designated Federal Official

Dr. Mary Jean Brown, Chief Healthy Homes/Lead Poisoning Prevention Branch, CDC

Liaison Members

- Dr. Helen Binns (American Academy of Pediatrics) Dr. Benjamin Gitterman
- (American Public Health Association) Mr. Steve Hays (American Industrial
- Hygiene Association)
- Dr. Ezatollah Keyvan-Larijani (Council of State and Territorial Epidemiologists) Ms. Jane Malone
 - (National Center for Healthy Housing)

- Ms. Ruth Ann Norton (National Coalition to End Childhood Lead Poisoning)
- Dr. George Rodgers, Jr. (American
- Association of Poison Control Centers)
- Dr. Donald Simmons (Association of Public Health Laboratories)
- Ms. Amy Warner (American Academy of Nurse Practitioners)

CDC Representatives

Dr. Christopher Portier, NCEH/ATSDR Director, CDC Dr. Thomas Sinks NCEH/ATSDR Deputy Director, CDC Dr. Sharunda Buchanan, **EEHS Director, CDC** Barry Brooks Bernadette Burden Sascha Chanev Dr. Ginger Chew Kimball Credle Jay Dempsey Carrie Dooyema Dr. Henry Falk Larry Franklin Joy Gulliksen Samantha Harrykisson Dr. Robin Ikeda Jeffrey Jarrett Dr. Robert Jones Claudine Johnson Deborah Millette Jeffrev Morelli Dr. Antonio Neri Rose Glass Pue Jamie Raymond **Barbara Rogers** Marissa Scalia Sucosky Jana Telfer **Connie Thomas** Lem Turner

Tiffany Turner Nikki Walker Margie Walling Will Wheeler Latoria Whitehead Joyce Witt

Guest Presenters and Members of the Public

Craig Boreiko (International Lead Zinc Research Organization) Michael Campisi (Magellan Biosciences) Thomas Carroll (New York State Department of Health) Hung Cheung (OEM Advisor, LLC) Dr. Maria Doa (U.S. Environmental Protection Agency) Karen Doran (U.S. Government Accountability Office) Dr. Marc Edwards (Virginia Tech) Doug Farguhar (National Conference of State Legislatures) Jon Gant (U.S. Department of Housing and Urban Development) Dr. Thomas Gilmore (Thomas Jefferson University Hospital) Carolyn Grossman (Magellan Biosciences)

Natalie Herzog (U.S. Government Accountability Office) Mike Kashtock (Food and Drug Administration) [via conference call] Dr. David Jacobs (National Center for Healthy Housing) Amy Leone (U.S. Government Accountability Office) Ronnie Levin (Member of the Public) Beth McKee-Huger (Greensboro Housing Coalition) Dr. Patrick Parsons (New York State Department of Health) Amanda Reddy (New York State Department of Health) Rebecca Renner (National Association of Science Writers) Chris Saranko (Environmental Planning Specialists) Michael Schock (U.S. Environmental Protection Agency) Meghan Schuck (Geosyntec Consultants, Inc.) Janet Simmons (U.S. Department of Housing and Urban Development) Anne Wengrowitz (ACCLPP Consultant)

ATTACHMENT 2

Glossary of Acronyms

AAP	American Academy of Pediatrics
ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
AHS	American Housing Survey
APHA	American Public Health Association
ASV	Anodic Stripping Voltammetry
BLLs	Blood Lead Levels
BOCA	Building Officials Code Administration
BSC	Board of Scientific Counselors
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CERHR	Center for Evaluation of Risks to Human Reproduction
CLIA	Clinical Laboratory Improvement Amendments
CLIAC	Clinical Laboratory Improvement Advisory Committee
CLPPPs	Childhood Lead Poisoning Prevention Programs
CMS	Centers for Medicare and Medicaid Services
CPSC	U.S. Consumer Product Safety Commission
CPWG	Lead in Consumer Products Workgroup
EBLLs	Elevated Blood Lead Levels
EEHS	Division of Emergency and Environmental Health Sciences
EIWG	Educational Intervention Workgroup
EPA	U.S. Environmental Protection Agency
EPH	Environmental Public Health
EQASs	External Quality Assessment Schemes
FDA	Food and Drug Administration
FELTP	Field Epidemiology Laboratory Training Program
FMOH	Federal Ministry of Health
FTC	Federal Trade Commission
GFAAS	Graphite Furnace Atomic Absorption Spectrometry
GHC	Greensboro Housing Coalition
HBC	Human Biomonitoring Commission
HHLPPB	Healthy Homes/Lead Poisoning Prevention Branch
HHS	Department of Health and Human Services
HNP	Healthy Neighborhoods Program
HUD	U.S. Department of Housing and Urban Development
ICC	International Code Council
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IDEA	Individual with Disabilities Education Act
IPMC	International Property Maintenance Code
LCR	Lead and Copper Rule
LPPP	Lead Poisoning Prevention Program
LSWP	Lead Safe Work Practices
LSWP	Lead-Safe Work Practices
LWG	Laboratory Methods Workgroup
MSF	Doctors Without Borders/Médecins Sans Frontières

NCECLP	National Coalition to End Childhood Lead Poisoning
NCEH/ATSDR	National Center for Environmental Health/
	Agency for Toxic Substances and Disease Registry
NCHH	National Center for Healthy Housing
NCSL	National Conference of State Legislatures
NFPA	National Fire Protection Association
NHANES	National Health and Nutritional Examination Survey
NIOSH	National Institute for Occupational Safety and Health
NLPPW	National Lead Poisoning Prevention Week
NOFA	Notice of Funds Availability
NSHHC	National Safe and Healthy Housing Coalition
NTP	National Toxicology Program
NYS	New York State
OMB	Office of Management and Budget
OSHA	U.S. Occupational Safety and Health Administration
PIR	Poverty-to-Income Ratio
PSAs	Public Service Announcements
PT	Proficiency Testing
RRP	Renovation, Repair and Painting
RUCO	Rental Unit Certificate of Occupancy
SAB	Science Advisory Board
SCE	Systematic Code Enforcement
SMOH	State Ministry of Health
WHO	World Health Organization
XRF	X-Ray Fluorescence

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION

National Center for Environmental Health Division of Emergency and Environmental Health Services Healthy Homes/Lead Poisoning Prevention Branch

ADVISORY COMMITTEE ON CHILDHOOD LEAD POISONING PREVENTION November 16-18, 2010 Atlanta, Georgia

DRAFT Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), Division of Emergency and Environmental Health Services (EEHS), Healthy Homes/Lead Poisoning Prevention Branch (HHLPPB) convened a meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The proceedings were held on November 16-18, 2010 at the Westin Atlanta Perimeter North Hotel in Atlanta, Georgia.

Opening Session: November 16, 2010

Dr. Mary Jean Brown is Chief of HHLPPB at CDC. She called the meeting to order at 9:05 a.m. on November 16, 2010 and welcomed the attendees to the proceedings. She reminded the ACCLPP voting members to recognize their potential conflicts of interest identified by the CDC Committee Management Office and recuse themselves from participating in discussions or voting on issues for which they have a real or perceived conflict of interest.

Dr. Brown opened the floor for introductions and confirmed that the ACCLPP voting members and non-voting *ex-officio* members in attendance constituted a quorum. The list of participants is appended to the ACCLPP minutes as <u>Attachment 1</u>.

Dr. Sharunda Buchanan is the Director of EEHS at CDC. She joined Dr. Brown in welcoming the participants to the ACCLPP meeting. She was pleased to announce that since the last ACCLPP meeting in October 2009, the CDC Lead Poisoning Prevention Branch has been officially renamed to the "Healthy Homes/Lead Poisoning Prevention Branch."

Dr. Buchanan concluded her opening remarks by thanking the ACCLPP members for their continued commitment and contributions to helping CDC strengthen its environmental health

portfolio. She emphasized that ACCLPP's outstanding guidance, technical expertise and solid recommendations over many years have been invaluable to CDC.

Overview of the New York State Healthy Neighborhoods Program

Thomas Carroll, Housing Hygiene Section Chief Bureau of Community Environmental Health & Food Protection Center for Environmental Health New York State Department of Health

Amanda Reddy, MS, Research Scientist Outreach and Education Group Center for Environmental Health New York State Department of Health

Mr. Carroll and Ms. Reddy presented an overview of and 2007-2009 evaluation data from the New York State (NYS) Healthy Neighborhoods Program (HNP). The 1985 NYS Rat Control Program eventually evolved to HNP due to the need to coordinate efforts in the field to address rat control, lead poisoning and housing problems throughout entire neighborhoods.

The key features of HNP include a combination of door-to-door canvassing/referrals to perform in-home assessments, deliver interventions, and address environmental health and safety hazards. Census and surveillance data also are used to target HNP activities to areas with high-risk factors (e.g., lead-poisoned children, residential fires, poverty and minority status).

HNP interventions include written and verbal education, referrals to local and state resources, and necessary products to alleviate environmental hazards in the home (e.g., cleaning supplies, smoke and carbon monoxide detectors, and items to promote residential safety). HNP staff includes sanitarians, health educators, nurses and other public health professionals with training in environmental health and housing.

HNP content areas focus on tobacco control, fire safety, lead poisoning prevention, asthma, indoor air quality (e.g., carbon monoxide, radon, ventilation and odors, and temperature and humidity), general conditions (e.g., cleaning and clutter, pests, structural issues, and mold, mildew and moisture), and other issues (e.g., injury prevention and social services). In terms of lead poisoning, NYS visually surveys each home built before 1978 and provides referrals if chipping or peeling paint is observed or if young children in high-risk homes have not been screened for lead poisoning.

Prior to 1985, NYS funded its expanded environmental health activities with categorical grants and Rat Control Program funds. From 1985-1997, NYS used federal block grants and funding from other federal sources to support additional environmental health focus areas (e.g., fire death prevention, fall prevention, lead hazard control, general sanitary conditions, carbon monoxide, asthma and other environmental health outcomes).

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In 2006, NYS used new Health Care Reform Act dollars to include tobacco control programs in HNP. NYS currently uses its General Fund to conduct HNP activities in ten counties with a budget of ~\$2 million. NYS counties compete for HNP funding. The current HNP grantees represent both urban and rural settings with tremendous variations in housing stock and population densities ranging from 79-71,506 persons per square mile.

In the competitive HNP grant process, applicants submit work plans that include a core framework. However, the work plans also are customized to meet local needs and capitalize on local resources and opportunities. Because HNP is not a case management program, applicants must document strong partnerships at state and local levels. Local grantees must submit quarterly reports to NYS outlining their progress in meeting the stated work plan objectives (e.g., follow-up visits to 25% of at-risk homes). NYS assesses the overall impact of HNP and sponsors annual meetings with all grantees to provide training and discuss issues related to funding, data collection or other concerns.

Outreach workers use two types of multi-page forms to collect HNP data. The "dwelling" form gathers information from the primary respondent on demographics, dwelling conditions based on a visual assessment and self-reported information, dwelling characteristics, and education, referrals or products delivered. The "asthma" form gathers information on the presence of triggers, asthma self-management, and asthma symptoms and morbidity. Personal identifiers are automatically removed and data are immediately entered into the state HNP system at the time when completed forms are faxed or scanned.

NYS performed a comprehensive evaluation of HNP using data submitted by 12 local grantees that were continuously funded from October 2007-December 2009. The evaluation was based on 13,165 initial visits, 2,904 revisited homes, and 3,603 homes with lead hazards. New York City was excluded from the evaluation due to its dramatically different processes of collecting data and delivering interventions.

The strengths and limitations of the HNP evaluation design are highlighted as follows. Subsets were included where appropriate (e.g., pre-1978 dwellings to determine lead hazards or the proportion of asthmatics who routinely sleep with pets). The percent of non-missing responses documented on forms was included.

"Improvement" was defined as either a total correction or removal of a hazard when the home was revisited. The McNemars test was used to make a statistical assessment of improvement based on the overall percent of homes with corrections or improvements of conditions at the revisit. The 95% confidence interval was calculated allowing for continuity corrections.

The large sample size resulted in the detection of small differences. The quality of data varied among counties, in-home assessments performed by individual outreach workers, and completed forms submitted by outreach workers. The results are subject to biases in the areas of selection, recall, social desirability and reporting.

HNP is a "real-world" program that aims to provide services rather than function as a research protocol. Although limitations in the evaluation design should be acknowledged and considered in interpreting the findings, the healthy homes approach is well documented and supported in the peer-reviewed literature.

The key findings and conclusions of the HNP evaluation are summarized as follows. Of 13,165 homes included in the evaluation, 61% were multi-unit dwellings, 68% were rental units, and 92% were built prior to 1978. Of all rental units, 29% received Section 8 or rental assistance. Of all pre-1978 housing, 63% were built before 1950.

In terms of the demographics of primary respondents, 52% were non-white, 16% were Latino, 51% received food stamps or public assistance, and 75% received a GED or higher educational degree. In terms of the demographics of individual residents, 59% were adults, 41% were children, 38% of adults were male, 13% of all residents had asthma, and 20% of children 3-6 years of age had never been screened for lead.

The conditions analysis showed that homes with lead hazards had more environmental health problems than homes without lead hazards. The vast majority of improvements between the initial visits and revisits were statistically significant, but the most substantial changes in five hazard categories were:

- 1. Fire safety: installed smoke detectors that are audible from sleeping areas (94.5%).
- 2. Lead: remediated indoor paint hazards (35.6%).
- 3. Tobacco control: took a smoke-free home pledge and discontinued smoking in the home (11.9%).
- 4. Indoor air quality: repaired or removed a malfunctioning appliance (67%).
- 5. General conditions: housekeeping-eliminated significant dust (42.1%); pests-eliminated rats (70.8%); mold and moisture-repaired plumbing leaks (68.7%); and other conditions-repaired structures (38.4%).

In addition to assessing specific hazards, NYS also developed a hazard score to determine multiple hazards in the home based on environmental health conditions described on the dwelling form. For each hazard, each dwelling was assigned "0" (no hazard present), "1" (one hazard present), or "0.5" (all or part of the information needed to determine the presence of a hazard was missing). The number of hazards per dwelling was counted at both the initial visit and revisit to calculate the mean change in the number of hazards between visits.

The total number of hazards in homes ranged from 0-23. Of 2,904 HNP homes, the mean hazard score decreased from 4.7-3.2 between the initial visit and revisit. Of 830 homes with lead hazards, the mean hazard score decreased from 6.7-4.6 between the initial visit and revisit. Of 1,017 homes with an asthmatic, the mean hazard score decreased from 5.2-3.3 between the initial visit and revisit. Between the initial visit and revisit, the percent of homes with 0 hazards increased from 1.5%-5.5%; the percent of homes with a hazard score \leq 1 increased from 7.1%-23.7%; and the percent of homes with a hazard score \leq 2 increased from 18.1%-46.2%.

The hazard score calculations confirmed that houses have multiple hazards and most dwellings are not "hazard-free" at the revisit despite significant improvements in individual hazards. The hazard score compliments the conditions analysis, but is not designed to estimate the severity of hazards.

NYS evaluated the data to determine the impact of HNP on individuals in addition to dwellings. In this analysis, NYS assumed the proportion of improved hazards among revisited dwellings would be the same in all dwellings that received an initial visit if improvements were measured among all dwellings.

For selected conditions, NYS computed the proportion of revisited residents who lived in a dwelling where the selected hazard was identified at the initial visit, but were absent from or improved by the revisit. NYS multiplied this proportion by the number of residents who lived in dwellings where the hazard was found at the initial visit. The analysis showed that HNP improvements had a positive impact on a significant number of adults and children for the vast majority of environmental hazards.

NYS used the evaluation data to perform a separate analysis of ~4,500 residents with asthma who received the HNP intervention. The design of the asthma assessment included data from the asthma form, a separation of asthma between adult and children, a focus on both asthma among all residents and "active asthma" in a smaller subgroup, triggers presented at the dwelling level, and self-management, knowledge and morbidity presented at the individual level. Despite the broad evaluation design, NYS acknowledged that other approaches might provide useful comparisons on the best strategies to target and deliver asthma services.

The assessment showed that HNP contributed to dramatic changes in three key areas. The reduction in asthma triggers was significant in terms of decreasing or eliminating smokers in the home, mold or mildew, and pets in sleeping areas. The decline in acute morbidity over the past three months was substantial with less days of worsening asthma and attacks; less days of daycare, school or work missed by individuals with asthma; and less days of daycare, school or work missed by others.

Improvements in self-management and knowledge of asthma were tremendous based on residents using rapid-relief medication <2 times per week; controlling their asthma; using peak flow meters; developing personal asthma action plans; recognizing early warning signs; and having knowledge of personal asthma triggers, avoidance or removal or triggers, and steps to take for worsening asthma. However, NYS acknowledges that longer-term morbidity findings are difficult to predict due to the overlap in the recall period of 3-6 months.

NYS has developed various mechanisms to deliver the HNP asthma interventions. Most notably, the Healthy Home Environments for New Yorkers with Asthma Program is a pilot initiative in Erie County that connects local HNPs with regional managed care plans. The goals of this activity are to improve targeting of resources; enhance integration of environmental management into routine asthma care; and improve coordination of existing services. The program has been found to be much more effective than the door-to-door HNP approach in

identifying the number of self-reported days with worsening asthma among both adults and children at the initial visit and revisit.

NYS plans to use the evaluation data to improve existing HNP services and develop new projects in the future after the existing analyses are refined. Other research questions with importance and relevance to HNP will be determined. Additional analyses will be performed to improve lead homes, the delivery of asthma and other interventions, and program cost-effectiveness. For example, the HNP evaluation cost was \$285 per unit (or a total of ~\$3.8 million).

NYS intends to broadly share key findings and lessons learned from the HNP evaluation and propose changes to inform training needs and decision-making for specific housing types. NYS is making strong efforts at this time to develop a publicly-available and interactive website to post the evaluation findings and other up-to-date information about HNP.

ACCLPP applauded Mr. Carroll and Ms. Reddy for presenting an extremely comprehensive and informative overview of HNP and the evaluation data from this activity. The ACCLPP members made several suggestions for NYS to consider in its future plans for HNP.

- NYS should solicit outside expertise to reach consensus on assigning different weights to a particular hazard in the hazard score based on its importance. For example, NYS should perform a factor analysis in which similar hazards are collated to more easily identify the strengths and weaknesses of a specific hazard. Dr. Megan Sandel is an ACCLPP member and offered her expertise to NYS in this effort.
- Because an HNP-specific website is not available at this time, NYS should develop a formal mechanism in the interim to broadly share the findings, lessons learned and best practices with health departments outside of NYS. NYS should particularly share cost-effectiveness and cost-benefit data to provide other states with a strong rationale to implement an "HNP-type" program. For example, a state could achieve substantial cost-savings over time with the reduction of only one emergency department visit for an asthmatic child or the prevention of only one carbon monoxide poisoning death.
- NYS should conduct an independent validity study to determine the capacity of outreach workers across all counties to accurately assess environmental health hazards in the home.
- NYS should take advantage of its two most significant assets (*i.e.*, a large HNP sample size and easy access to numerous schools of public health and other academic institutions) to conduct a formal randomized controlled trial of best practices of the HNP interventions. This innovative study would play an important role in contributing to the healthy homes literature and filling existing data gaps in this area.

Dr. Brown agreed with ACCLPP's suggestion for NYS to broadly share the HNP evaluation results with other state and local health departments. She announced that Mr. Larry Franklin is the CDC Project Officer for the NYS Lead Poisoning Prevention Program (LPPP). She confirmed that Mr. Franklin would contact Mr. Carroll and Ms. Reddy in the near future to explore strategies to widely publicize the HNP activities and evaluation outcomes.

CDC Healthy Homes/Lead Poisoning Prevention Branch Chief's Report

Mary Jean Brown, ScD, RN

Chief, Healthy Homes/Lead Poisoning Prevention Branch, NCEH, EEHS Centers for Disease Control and Prevention

Dr. Brown covered the following areas in her update. The November 2010 meeting marks the first time that ACCLPP has convened an annual three-day meeting rather than biannual two-day meetings. HHLPPB made this decision to achieve cost-savings from traveling ACCLPP members and guest speakers twice per year and reduce staff time in preparing for two meetings per year.

HHLPPB released numerous publications in 2010. A series of articles on the evidence base for housing interventions was published in the *Journal of Public Health Management and Practice*. The articles were based on findings from expert panel workshops sponsored by CDC and the National Center for Healthy Housing (NCHH). The full-length supplement is available at no charge at <u>http://journals.lww.com</u>.

American Public Health Association (APHA) Press published a new book, *Healthy & Safe Homes: Research, Practice and Policy*, in partnership with CDC, NCHH and the Home Safety Council. The book is a compilation of perspectives of noted scientists, public health experts, housing advocates and policy leaders who discuss substandard housing that plagues the United States and offer holistic, strategic and long-term solutions to correct these problems. The book is available for purchase at the online APHA Bookstore.

HHLPPB published several studies in peer-reviewed journals related to housing and allergens, the association between blood lead levels (BLLs) and wild game consumption, and lead poisoning among internationally displaced children in Kosovo. HHLPPB published Notes from the Field in the *Morbidity and Mortality Weekly Report* describing an outbreak of acute lead poisoning among children <5 years of age in Nigeria.

CDC published ACCLPP's *Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women*. The document is dedicated to the memories of Dr. Michael Shannon and Dr. Kathryn Mahaffey who were former ACCLPP members. Drs. Shannon and Mahaffey devoted their entire careers to reducing lead and other environmental health risks to children. The dedication recognizes the tireless efforts and contributions of Drs. Shannon and Mahaffey and acknowledges that CDC continues to deeply miss its two dear colleagues and friends.

Dr. Brown presented a series of slides illustrating camps for displaced persons in Kosovo that were located near mine tailings and caused exposure to lead dust. Persons have been displaced in Kosovo since 2000, but October 10, 2010 was the last day of residence in Cesmin Lug camp. Dr. Brown presented another slide illustrating the new community of apartments and townhomes in Kosovo where displaced persons were relocated. Frequent testing of soil at the new site has confirmed that soil lead levels are <400 ppm.

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Dr. Brown will return to Kosovo in December 2010 to ensure that children relocated from the camps receive lead testing, chelation protocols are available if needed, and local clinicians are aware of the signs of a lead-poisoned child. CDC expects to receive a request from the Kosovo government to review BLLs of the entire community due to the continued presence of waste materials from a large smelter that ceased operations in 2005. CDC will assist Kosovo in designing and conducting a population-based survey if invited.

A U.S. group representing CDC, other federal agencies and ACCLPP traveled to China to promote lead poisoning prevention. The U.S. group found that the two major barriers to implementation and enforcement of lead poisoning prevention regulations in China were poor coordination of existing resources and lack of political will and support in this area.

A global partnership with CDC, the U.S. Environmental Protection Agency (EPA), World Health Organization (WHO), and United Nations Environment Programme has been initiated to promote the phase-out of the manufacture, sale and use of lead in paints internationally.

HHLPPB is currently participating in a population-based study in Puerto Rico to determine the prevalence of BLLs among children <6 yeas of age and also to identify potential sources of lead exposure among these children. Puerto Rico exceeds the EPA limits of the Lead and Copper Rule in water. The study includes the collection of water and dust samples and an assessment of residential paint conditions.

HHLPPB is collaborating with the Puerto Rico Department of Health and the University of Puerto Rico School of Public Health to use the study results to develop a waiver for BLL testing of Medicaid children if warranted. As an additional component of the population-based study, 200 samples will be collected from homes in Puerto Rico, including publicly subsidized properties, to determine residential use of legal and illegal pesticides.

HHLPPB is continuing its efforts to deploy the Healthy Homes/Lead Poisoning Prevention Surveillance System. At this time, seven programs are preparing for full implementation of the system, seven programs are planning production details with the system, and eight programs are planning procurement and migration details with the system.

The web-based system electronically collects BLL testing data, case management data of children with elevated BLLs (EBLLs), and a series of healthy homes variables. Over the next year, HHLPPB plans to use the system to replace the Systematic Tracking of Lead Levels and Remediation database that was deployed in 1991.

HHLPPB conducted several activities in support of National Lead Poisoning Prevention Week (NLPPW) on October 24-30, 2010. The NLPWW social media campaign toolkit is available on the CDC website. Twitter and Facebook were used to send lead-related messages each day of NLPPW. The campaign was featured on the CDC.gov website. The "Boo at the Zoo" event sponsored by the Smithsonian National Zoological Park was particularly targeted to the NLPPW theme of "Lead-Free Kids for a Healthy Future."

The NLPPW graphics and products included a widget with tips to prevent lead poisoning, the campaign logo and a prevention button. NLPPW activities represented collaborative efforts among CDC, EPA, the U.S. Department of Housing and Urban Development (HUD) and other agencies. The "Health e-Card" is another healthy housing campaign that is available on the CDC website. The electronic greeting cards provide helpful information on lead poisoning and safe/healthy homes and can be sent to family members, friends or coworkers who are moving.

The Healthy Homes/Lead Poisoning Prevention Training Center and Network is funded by HUD, sponsored by CDC and implemented by NCHH. In 2010, 2,517 persons received training over the course of 93 sessions. The titles of three new training courses offered in 2010 were "Childhood Lead Poisoning Prevention Program Transitions;" "Green and Healthy Management Strategies in Multi-Family Housing;" and "Health Opportunities in Energy Audits and Upgrades."

A DVD with a "healthy homes checklist" is currently undergoing the CDC clearance process and is expected to be completed by the end of November 2010. HHLPPB produced the DVD in response to requests from numerous voluntary organizations (e.g., Red Cross and Meals and Wheels) that have an interest in assessing the health and safety of homes while providing other in-home services.

The 1988 Lead Contamination Control Act gave CDC authority to fund lead screening, case management, education and outreach, and surveillance. However, the Congressional language did not authorize CDC to fund healthy homes activities. CDC is using the U.S. Public Health Service Act to overcome this barrier. After financial management officials and General Counsel finalize authoritative language for CDC to fund healthy homes activities, HHLPPB plans to release a new Notice of Funds Availability (NOFA) by the end of November 2010 along with a Healthy Homes Guidance Document.

The document will provide guidance on addressing lead exposure and other housing-related issues in a more comprehensive manner and also will give advice to state, large-city, tribal and territorial Childhood LPPPs (CLPPPs) and other agencies during their transition to a Healthy Homes Program. Applicants will be required to respond to the three components of the NOFA in their proposals: a comprehensive needs assessment; a strategic plan that includes goals, measurable objectives and a timeline for addressing issues; and best practices or interventions with sufficient evidence for improving health.

Applicants that meet one of two requirements will not be required to apply for lead funding. Applicants must document a strong collaboration with another entity that conducts lead poisoning prevention activities. Applicants must submit data to demonstrate that lead is not a problem in their geographical areas.

HHLPPB has not yet determined eligibility criteria for healthy homes funding, but Dr. Brown's preference is to continue to use CDC's authority under the Lead Contamination Control Act to fund state, large-city, tribal and territorial LPPPs. Her preference is based on the fact that HHLPPB does not employ a sufficient number of project officers to oversee, manage and monitor new healthy homes programs across the country at smaller levels. However, large

grantees at state, large-city, tribal and territorial levels would be allowed to subcontract healthy homes activities to community-based organizations (CBOs), local jurisdictions and other groups.

HHLPPB is currently exploring a scoring system to evaluate and rank healthy homes applications. Applicants that demonstrate committed and active partnerships with CBOs and other groups would receive higher scores. HHLPPB has not fully defined a "committed and active partnership" at this time, but a sole letter of support will not be sufficient.

HHLPPB drafted a logic model with inputs, activities, outputs, objectives and an overarching goal for the funded entities to develop healthy housing programs. Because the proposed logic model was designed at a generic level, grantees will be required to clearly define specific terms (e.g., "identify," "improve" and "evaluate") to achieve the healthy homes outputs.

Dr. Brown reported on one of the largest and most serious lead poisoning outbreaks in modern times that occurred in Zamfara State, Nigeria in May-October 2010. The outbreak investigation was conducted in response to 200 cases of suspected lead poisoning that were reported on May 8, 2010 among children <5 years of age and resulted in hundreds of deaths beginning in February 2010. A rapid response team with representation by CDC-Atlanta, CDC-Nigeria, federal and state Ministries of Health (FMOH/SMOH), and the Nigeria Field Epidemiology Laboratory Training Program (FELTP) was deployed to provide expertise in controlling the outbreak.

Zamfara State has a population of 3.2 million persons and ranks 21st of 36 states in terms of populations. The Hausa and Fulani ethnic groups are primarily Muslim and live in pastoral communities. Zamfara State is rich in minerals and has recently seen an increase in mining activities. Lead in the environment is a result of mining operations, gasoline, paint, food can solder, batteries, soil, pottery, toys, traditional medicines and plumbing.

The timeline of the outbreak investigation is summarized as follows. On March 29, 2010, SMOH and Doctors Without Borders/Médecins Sans Frontières (MSF) were responding to a meningitis outbreak and found 39 new child graves in two villages and a large number of children <5 years of age with vomiting and convulsions. On April 2-May 8, 2010, active case finding was performed and resulted in the identification of >100 graves in six villages. FMOH was notified. Venous blood samples that were collected with the LeadCare II instrument and submitted to a laboratory in Europe showed BLLs ranging from 100-400 μ g/dL with an average BLL of 197 μ g/dL.

On May 11 and 16-19, 2010, CDC was formally notified of the lead poisoning cases, FELTP was deployed and a CDC team arrived in Zamfara State. On May 20-June 4, 2010, the rapid response team targeted its clinical, epidemiological and environmental health efforts to Dareta and Yargalma. On June 2 and 8, 2010, MSF initiated chelation and SMOH initiated remediation of the lead-contaminated soil in the two target villages. After the MSF physicians were trained in the administration of succimer, the fatality rate in field hospitals dramatically decreased from \sim 50% to <1%.

The three phases of the outbreak investigation are described as follows. Phase 1 was conducted in May-June 2010 with goals to identify children with life-threatening lead poisoning in the villages of Dareta and Yargalma; begin environmental remediation of villages where lead-poisoned children lived; and educate villagers on the hazards of the artisanal gold processing method.

The MSF Team maintained a line list and administered a cross-sectional household survey that served as a census of children <5 years of age. The survey was designed to gather information on ore processing activities, drinking water sources and livestock deaths. The Clinical and Laboratory Team supported case management activities, collected and analyzed venous blood samples with the LeadCare II portable blood lead analyzer, and submitted samples to CDC for testing. The Environmental Team performed environmental assessments by collecting and analyzing soil samples with x-ray fluorescence (XRF) spectrometers and also crafted public health messages.

The MSF case definition of a "suspected" lead poisoning case was an individual from a village with a high death rate among children in early 2010. The symptoms of a suspected case included vomiting, abdominal pain, weakness, excessive crying, headache, restlessness, numbness, decreased play, ataxia, change in skin color and loss of consciousness. A "probable" lead poisoning case was an individual who met the definition of a suspected case and had an onset of convulsions in the past six months.

Children were categorized into three groups for purposes of the household survey: BLLs \geq 65 µg/dL with symptoms, BLLs 65 µg/dL without symptoms, and all other BLLs. In Dareta, 65 of 90 available compounds (or 72%) were surveyed. Of 204 children <5 years of age, 40 (or 20%) died. In Yargalma, 100% of 54 available compounds were surveyed. Of 259 children <5 years of age, 78 (or 30%) died. The age-stratified six-month crude mortality rate of 12.19/10,000 children per day in Dareta and Yargalma was far higher than the action level of a crude mortality rate of 1/10,000 children per day in refugee camps.

Dr. Brown presented a series of slides illustrating adults and children in villages who were entering the mine, breaking, grinding and sluicing ore rock, mixing mercury by hand, and drying ground ore. She also presented slides showing the living conditions of villagers, the site that housed the MSF physicians, bricks made with highly lead-contaminated gold mining waste in Dareta, and other areas and events in Zamfara State during the outbreak response activities.

Dr. Brown is actively recruiting academic partners to address the extremely high concentrations of lead and manganese in sluicing ponds and conduct follow-up studies of lead-poisoned children in Zamfara State. The rock grinding process was found to expose pregnant women and children to enormous amounts of dust. Of 205 venous blood samples taken, 100% indicated lead poisoning (or BLLs >10 μ g/dL), 97% met the criteria for chelation therapy (or BLLs >45 μ g/dL), and 85% exceeded the capacity of the LeadCare II instrument to measure BLLs (or BLLs >65 μ g/dL). Mean BLLs were 107.5 μ g/dL in Dareta and 153.3 μ g/dL in Yargalma.

Soil sample results showed that 82% of soil and dust from surveyed villages exceeded the EPA threshold of 400 ppm with a range of 400->100,000 ppm. Yargalma had more lead-contaminated soil than Dareta. Mercury, arsenic and other heavy metals also were found in the soil samples. If ore processing produces 0.10 g of gold that is worth ~\$100, a villager typically would receive ~\$25.

The Phase 1 results of the major outbreak of acute lead poisoning related to ore processing activities in Zamfara State, Nigeria are summarized as follows. Of all children <5 years of age in the surveyed villages, 26% died in the last 12 months with 83% of these deaths occurring within the last six months. Of all children <5 years of age who were tested, 100% met CDC's definition of an EBLL and 97% were candidates for chelation therapy based on BLLs \geq 45 µg/dL. Of all villages surveyed, 70% had soil lead levels above the EPA standard for children.

Public health actions have been taken in several areas in response to the acute lead poisoning outbreak Zamfara State. For remediation, the degree and sources of lead contamination were characterized and recommendations were made for remediation. After WHO visited three additional villages, three children were admitted to field hospitals from Abare and an additional 180 children are known to need treatment. Clean-up efforts were initiated in Abare on October 12, 2010. The villages of Tunga Dail and Tunga Guru collectively reported 97 child deaths that were consistent with the MSF case definition. No evidence of lead poisoning was observed in the villages of Duza and Duhua.

For case management, >400 children have been treated for lead to date with no substantial side effects. A prioritized list was developed of children who should receive chelation therapy. In Dareta, outpatient chelation therapy is being administered to 135 children and 33 breastfeeding mothers, BLLs have decreased to ~40-80 μ g/dL, more than one course of treatment has been given to the entire cohort, and six children are currently receiving their fifth courses of treatment. In Yargalma, >280 children are receiving outpatient chelation therapy.

For communication and education, UNICEF created and disseminated public health messages, conducted health education in villages, and developed the capacity of local non-governmental organizations to address the lead poisoning problem. For training, CDC developed the capacity of partners to train laboratory staff at state, local and MSF levels.

Phase 2 was initiated in October 2010 with goals to estimate the extent of the lead poisoning outbreak with a focus on Bukkuyum and Anka local government areas and institutionalize the response by increasing reliance on the Nigerian federal government and Zamfara State government. Phase 2 is ongoing with implementation of response activities in ~50 villages to date.

The desire of Nigerian policymakers at federal and state levels for rapid resolution of the lead poisoning problem was a significant barrier to the Phase 2 response. During an interview on CNN on June 16, 2010, the Nigerian Minister of Environment stated "the situation is contained." Other challenges included the lack of dedicated funding for outbreak response activities. The response activities are logistically difficult due to the need for teams to drive six hours per day,

impassable roads during the rainy season, and difficult or slow evacuation. The teams are not allowed to remain in the villages after dark.

State and federal agencies have attempted or threatened to close the mines as a result of the response activities. Because the mines are a primary source of income, the villages most likely would resent the continued presence of the response teams. However, religious leaders of the villages have been extremely supportive of the response activities.

Phase 3 is ongoing and has an overarching goal of economic development. To improve the safety of the artisanal gold processing method at the small village level, low-cost interventions are being implemented to remove flour mills from villages that are used in ore processing and CDC recommends the provision of lockers to villagers to securely store their processed ore.

To improve the artisanal gold processing method at the large industrial level, the U.S. Embassy in Nigeria is currently developing a regulatory process for mining and smelting and calling for international attention to the lead poisoning problem. Similar to the Phase 2 response, however, no funding has been dedicated to the Phase 3 activities.

Dr. Brown concluded that after all of the data have been submitted and analyzed, CDC will make decisions on its future role in the lead poisoning outbreak response in Zamfara State. She clarified that CDC uses external resources rather than its domestic lead poisoning prevention budget to support activities in Kosovo, China, Nigeria or other international settings.

ACCLPP was impressed by the extensive amount of healthy homes/lead poisoning prevention projects and initiatives HHLPPB has conducted over the past year since the last meeting in October 2009. The ACCLPP members made a number of suggestions in two areas for HHLBBP to consider in enhancing these ongoing efforts.

To expand the healthy homes portfolio and increase the budget, ACCLPP advised HHLPPB to collaborate with its federal partners. For example, EPA's current efforts to revisit the Lead and Copper Rule should be used as an opportunity to also revisit the Safe Drinking Water Act. This approach might promote safe and healthy drinking water as an additional healthy homes activity by regulating private wells and small water authorities that currently are unregulated.

Moreover, HHS is using health reform dollars to make large investments in rural health care and home visiting programs for elders. A portion of these funds could be used to increase HHLPPB's budget for healthy homes/lead poisoning prevention activities in rural communities.

For the second area, ACCLPP commended Dr. Brown for her leadership in deploying CDC's unique expertise and leveraging outside resources to respond to the acute lead poisoning outbreak in Zamfara State, Nigeria. The ACCLPP members emphasized the need to devote time during a future meeting to explore strategies and engage CDC in an in-depth discussion on taking a formal, planned and strategic approach rather than implementing an ad hoc process to develop a global lead poisoning prevention portfolio and budget.

Several ACCLPP members were concerned that CDC has no budget to address the ongoing global lead poisoning epidemic. For example, the United States accounts for only 2% of the lead poisoning epidemic worldwide, but contributes 90% of global resources to address this problem. The ACCLPP members were aware that after Dr. Thomas Frieden assumed his position as the new Director of CDC in June 2009, he identified "extending and intensifying global health activities" as one of CDC's core priorities and established a new Center for Global Health to achieve this goal.

The ACCLPP members were interested in publicizing CDC's response to the major outbreak of acute lead poisoning related to ore processing activities in Zamfara State, Nigeria as a solid model of CDC's efforts to expand its role in global health.

Update by the Lead in Consumer Products Workgroup (CPWG)

Michael Kosnett, MD, MPH

Associate Clinical Professor, University of Colorado Health Sciences Center ACCLPP Member and CPWG Chair

Dr. Kosnett provided an update on activities CPWG has conducted since the October 2009 ACCLPP meeting. Dr. Kosnett and Mr. Perry Gottesfeld represented ACCLPP on the U.S. group that traveled to China to promote lead poisoning prevention. The U.S. group made presentations on lead poisoning problems in the United States during the Fifth International Conference on Occupational and Environmental Medicine. The U.S. group also had one-on-one conversations with policymakers in China to discuss the deleterious effects of lead in children's toys, pharmaceutical products and other items imported from China to the United States.

The domestic lead poisoning prevention community is aware that border inspections will not solve the problem of the importation of lead-contaminated products from China. Instead, the United States and China will need to engage in a collaborative effort to increase their knowledge of lessons learned and best practices in lead poisoning prevention in both countries. The U.S. group was pleased that its colleagues in China acknowledged the lead poisoning problem and welcomed a collaborative approach.

The trip to China resulted in agreement to establish multifaceted partnerships with several entities to begin conducting joint U.S.-China lead poisoning prevention activities in the future. Most notably, an International Conference on Lead Poisoning Prevention would be convened in China. Brochures and other educational materials on lead poisoning prevention that have been developed in the United States would be translated into Chinese for wide dissemination in China. Academic expertise would be shared by inviting Chinese colleagues to LPPPs and laboratories in the United States to better understand case management, blood lead testing technologies, reference materials and standardized testing.

The trip to China also led to the U.S. group forming alliances in China with several entities: Chinese Research Academy of Environmental Sciences, China CDC, Research Center for Children's Environmental Medicine, National Institute of Occupational Health and Poison Control, WHO-China, National Center for Clinical Laboratories, Capital Institute of Pediatrics, and U.S. CDC-Beijing. The U.S. group established a formal agreement with the CDC Foundation to raise funding for joint U.S.-China lead poisoning prevention efforts in the future.

In addition to initiating strong partnerships in China, CPWG also is identifying strategies for state and local LPPPs in the United States to understand and report occurrences of lead hazards in consumer products in communities. CPWG has a strong interest in developing and launching a new web portal on the CDC website. The web portal would be designed to provide clear guidance to LPPPs in the United States and agencies in other countries on entities to contact and specific public health actions to take if lead in consumer products is identified.

Thomas Gilmore, MD

Thomas Jefferson University Hospital

Dr. Gilmore presented results of a lead testing study that was conducted in a specific population. The study was designed to answer two research questions. What is the prevalence of lead in consumer products in stores in Chinatown, Philadelphia? Is there a difference between the prevalence of lead in ceramics from Chinatown and ceramics from dollar stores and larger retail chains?

For purposes of the study, both Chinatown and other areas of Philadelphia were divided into four regions. Medical students purchased five ceramic items from each store in the four Chinatown regions at a cost not to exceed \$10 per item. A smaller number of items were purchased from the non-Chinatown regions due to budget constraints.

In accordance with the product insert, pottery was washed with water, dried and tested with LeadCheck. Items with positive lead results were tested twice. The inter-reliability rate between testers was found to be 100% with a Kappa score of 1. LeadCheck is a qualitative test that turns an item either red (higher level) or pink (lower level) to denote the level of lead. However, leaching is the only process to determine the quantity of lead in an item.

The data analysis showed that the prevalence of lead in ceramics was 25.3% in the Chinatown regions and 10% in the non-Chinatown regions. However, the prevalence in the Chinatown regions increased to ~40% after the items were sanded. Of 87 items purchased from the Chinatown regions, 22 tested positive for lead. Of 49 items purchased from the non-Chinatown regions, five tested positive for lead. The Chi-square analysis showed that the difference in lead in ceramics between the Chinatown and non-Chinatown regions was statistically significant.

Vendors that sold lead-containing products were notified of the problem, but were not required to remove the items. Leachable lead testing data were not available at that time to determine whether the lead levels were illegal or allowable. When the Food and Drug Administration (FDA) previously screened for leachable levels of lead and conducted follow-up testing, the leachable level typically was found to be at the lowest level of 1 ppm.

FDA changed the levels of leachable lead to the following limits in the early 1990s: 3 ppm for flatware, 2 ppm for small Hollowware, 1 ppm for Hollowware, and 0.5 ppm for cups, mugs and pitchers. The lowered sensitivity of 0.5 ppm has resulted in the identification of more items that test positive for lead.

The next steps in the study will be to use inductively coupled plasma mass spectrometry or atomic absorption spectroscopy to perform the leaching quantification. Patients from a clinic in Chinatown will be asked to provide ceramic items for testing. Patients with lead-containing products will be screened for lead to determine a clinically-relevant correlation between their ceramics and BLLs.

Brenda Reyes, MD, MPH

Bureau Chief, Community and Children's Environmental Health Bureau City of Houston Health and Human Services ACCLPP Member

Dr. Reyes presented an overview of the investigation and proposed regulatory action plan to address lead in Mi Patria Pottery. Houston strengthened its attention on lead in pottery beginning in March 2008 after investigators tested Mi Patria Mexicanos pottery and other brands that were confiscated from local flea markets. At that time, Houston educated flea market owners and vendors on existing regulations and ordinances regarding lead in consumer products and provided training on complying with these laws. Houston also distributed information on the impact of lead on children and their families.

After the flea market initiatives, sanitarians were trained to check labels of Mi Patria Pottery during restaurant inspections. Labels confirmed that some products complied with FDA requirements for preparing, serving or storing food, but XRF testing showed the pottery contained lead. A local grocery store chain voluntarily removed Mi Patria pottery from all 29 of its Houston stores in August 2009 after a sanitarian took two pottery samples for laboratory analysis.

Houston contacted CDC, FDA, EPA and the Federal Trade Commission (FTC) to obtain expertise and guidance on appropriate public health actions Mi Patria Pottery should take to resume the sale of its products in Houston. Houston was given a number of suggestions in this regard. For example, Mi Patria Pottery was advised to change the label on its products from "lead free" to "lead safe."

FDA proposed an action plan with four components. Houston should inform Mexican authorities about Mi Patria Pottery's labeling claims. Houston should continue to test more pottery samples. If the pottery has high levels of leachable lead, Houston must inform the manufacturer that the importation of products is not permitted without a certificate of analysis from a U.S.-accredited laboratory demonstrating the pottery meets FDA requirements. Houston may give the manufacturer a deadline to correct violations and allow the manufacturer to resume importation of products after resolving the violations.

Houston received laboratory results of the products that were tested for lead in November 2009. Of 23 Mi Patria Pottery samples tested, 11 (or 47.8%) exceeded FDA's limits for lead use. Of 10 Mi Pueblo Coffee Cups tested, 100% were within the acceptable range of FDA's limits for lead use in ceramic ware. Dr. Reyes presented a series of slides illustrating these pottery samples.

Several public health actions were taken based on laboratory results of the products that were tested for lead. Batches of Mi Patria Pottery from two sources were returned to Mexico with a letter of explanation in November 2009. Houston participated in a conference call with CDC, FDA and FTC in December 2009 to further discuss the suspected causes and sources of lead in Mexican pottery that were labeled "lead free." The conference call resulted in assigning specific roles and responsibilities to each agency to advance the lead in pottery action plan.

Houston issued a press release in March 2010 warning the public not to use Mi Patria Pottery because the product contained lead. Dr. Reyes made appearances on local English and Spanish television programs to increase community awareness of the Mi Patria Pottery health alert. Houston and Mi Patria Pottery are continuing to meet to review the data analysis, discuss options to resume the sale of clay pottery on Houston, and formulate recommendations to correct violations.

Houston thoroughly reviewed recommendations that were provided on the use of lead-free glazes and prevention of cross-contamination. Regulatory officials in Mexico were given brochures and other educational materials for potters. The possibility was raised of using a third-party organization to train potters in using lead-free glazes.

In addition to the public health actions, Houston also is interested in taking more aggressive and proactive steps to address the problem of lead in pottery. A step-wise and streamlined protocol should be developed with clear guidance for agencies and organizations at state and local levels to effectively respond to communities that are exposed to lead in pottery. The protocol should identify federal agencies to contact to obtain expert advice on testing products for lead in accordance with FDA regulations or conducting an investigation of these items.

ACCLPP thanked CPWG for presenting a series of informative overviews on actions that are being taken at federal and local levels to address the complex issue of lead in consumer products. ACCLPP also thanked Dr. Michael Kashtock, a Consumer Safety Officer and Food Scientist at FDA, for joining the meeting by conference call.

Dr. Kashtock announced that FDA would publish a policy statement on Mexican pottery on November 22, 2010. He confirmed that he would provide Ms. Samantha Harrykisson, of HHLPPB, with a link to the policy statement on the FDA website for distribution to ACCLPP for review and comment.

The ACCLPP members made several suggestions for CPWG to consider in its ongoing efforts to address lead in consumer products.

- CPWG should engage U.S. Trade Representative Ron Kirk in its activities to advocate for increased tariffs or other penalties when illegal amounts of lead are identified in consumer products.
- Dr. Gilmore should consult with the Department of Environmental Medicine at the University of Pennsylvania. This institution has a grant from the National Institute of Environmental Health Sciences and is required to develop and implement a community outreach program as a condition of funding. Dr. Gilmore should collaborate with the institution to enhance its outreach in Chinatown on lead in ceramics.
- The new web portal that CPWG is proposing to design and post on the CDC website should clearly identify the roles, responsibilities and capabilities of various federal agencies in addressing and responding to lead in consumer products.
- CPWG should review and attempt to replicate the housing model. Voluntary groups have outreached to federal agencies to coordinate a federal response to housing issues and publicize these problems to improve housing. A major foundation could fund a voluntary organization or award small grants to other groups to play the same role to address lead in consumer products. The funded groups could outreach to FDA, FTC and other federal agencies with a mission to address toxic chemicals in consumer products.
- ACCLPP is chartered to provide advice and recommendations to the Director of CDC and Secretary of HHS. As a result, ACCLPP should send a letter to the HHS Secretary to formalize and strengthen interagency efforts among CDC, FDA, EPA and the U.S. Consumer Product Safety Commission (CPSC) in addressing lead in consumer products.

Dr. Brown made follow-up remarks on CPWG's update and ACCLPP's discussion. She advised Dr. Gilmore to consult with Dr. Carla Campbell at Children's Hospital of Philadelphia. Dr. Campbell would be able to facilitate communications between Dr. Gilmore and staff of the Philadelphia Childhood LPPP. To refine the Chinatown study, Dr. Gilmore should obtain blood lead testing data for Philadelphia residents by addresses and use these data to gather baseline information on residents who have self-identified as Chinese.

Dr. Brown announced that the Center for Environmental Health is a non-profit organization in California with a mission to promote the elimination or reduction of lead and other toxic chemicals in consumer products through outreach, education and legal action if necessary. Moreover, several CBOs and other organizations in California have organized a grassroots effort to support Proposition 65 that would require the state to publish a list of chemicals, including lead, known to cause cancer, birth defects or other reproductive harm.

The California Attorney General also is coordinating efforts with the Mexican government to discontinue the importation of products with illegal levels of lead into the United States. Dr. Brown confirmed that she would identify appropriate entities in California to present ACCLPP's ongoing lead in consumer products initiatives.

Update by the Laboratory Methods Workgroup (LWG)

Patrick Parsons, PhD

Chief, Laboratory of Inorganic and Nuclear Chemistry New York State Department of Health Laboratory Methods Workgroup Member

Dr. Parsons presented an update on LWG's recent activities and reviewed current federal criteria that are used to assess acceptable performance of blood lead testing in proficiency testing (PT) programs. The LWG membership includes Dr. George Rhoads as chair, who is also the Chair of ACCLPP, and representation by state health departments, academic universities and a commercial laboratory. Technical assistance by Dr. Brown and other CDC staff has been critical to LWG's progress.

ACCLPP charged LWG with completing two major tasks. LWG would address whether blood lead PT acceptability limits should be more stringent than the current Clinical Laboratory Improvement Amendments (CLIA) of 1998 regulation of $\pm 4 \ \mu g/dL$ or $\pm 10\%$ (whichever is greater) and identify new acceptability limits.

LWG would draft ACCLPP's letter to the appropriate federal agency and recommend implementation of a change in the CLIA regulations to tighten the minimum acceptable PT limits for BLLs. LWG met in person and via web conferences in February, August and November 2010 to explore strategies to fulfill its charge. LWG emphasized the need to base its guidance to ACCLPP on the most current data from PT programs.

The capability of laboratories that perform analytical methods for blood lead testing is critical to public health actions and recommendations. "Lead poisoning" was defined as 60 μ g/dL in the 1960s, but BLLs have been lowered over time to CDC's current level of concern of 10 μ g/dL. Public health actions have resulted in a dramatic decrease in the geometric mean BLL in children from 15 μ g/dL to <2 μ g/dL. The Centers for Medicare and Medicaid Services (CMS) is responsible for enforcing CLIA and established a generous standard for laboratory testing of BLLs of \pm 6 μ g/dL or \pm 15% in 1992.

At that time, PT programs emphasized the critical need to establish a more stringent limit for laboratory testing of BLLs as a result of CDC lowering the level of concern to 10 μ g/dL in 1991. PT programs were successful in persuading the federal government to decrease the blood lead PT acceptability limit to $\pm 4 \mu$ g/dL or $\pm 10\%$. PT programs collected quality assurance/quality control data to demonstrate that laboratories could achieve and maintain this standard.

New techniques have been developed over time to meet public health requirements for laboratory testing of BLLs. The colorimetric and flame atomic absorption techniques were used to measure BLLs in the 1960s, but these laboratory methods were relatively crude and required large amounts of blood.

The bench-top anodic stripping voltammetry (ASV) technique was introduced in the 1970s to better measure BLLs with capillary blood and enable mass lead screening of children. ASV is a non-automated and highly complex technique with a detection limit of ~2-3 μ g/dL and a purchase price of \$10,000-\$15,000. ASV is no longer available for purchase, but the manufacturer still supports current users. The flame atomic absorption technique was modified in the 1970s to enable microsampling and further improve laboratory performance.

Graphite furnace atomic absorption spectrometry (GFAAS) was introduced in the 1980s with capacity to test lower concentrations of lead in blood. GFAAS is an automated and highly complex technique that provided a more cost-effective approach to screening. GFAAS has a detection limit of ~1 μ g/dL and a unit can be purchased for \$30,000-\$50,000. GFAAS is the preferred technique of many laboratories.

Inductively coupled plasma mass spectrometry (ICP-MS) was introduced in the 1990s with capacity to test BLLs <1 μ g/dL. ICP-MS is an automated and very highly complex technique with a detection limit of ~0.05 μ g/dL and a purchase price of \$180,000-\$250,000. ICP-MS can be used for the purposes of lead screening, diagnosing cases and biomonitoring.

The handheld ASV LeadCare I device has a detection limit of ~2 μ g/dL and could be purchased for \$2,000-\$3,000. LeadCare I is a non-automated and moderately complex device that was designed for use in the field at the point of care. LeadCare I is no longer available for purchase, but the manufacturer still supports current users. The handheld ASV LeadCare II device has a detection limit of ~3 μ g/dL and can be purchased for \$2,000-\$3,000. Lead Care II is a non-automated and CLIA-waived device that does not require PT.

ISO Standard 13528 defines "proficiency testing" as a process to determine laboratory testing performance based on inter-laboratory comparisons. External Quality Assessment Schemes (EQASs) in Europe and Canada are the equivalent of PT programs in the United States, but these mechanisms have philosophical differences. EQASs are voluntary and used as an educational tool, while PT is mandatory. U.S. laboratories with unsuccessful PT performance face severe consequences, such as a letter to discontinue testing of patient specimens until the resolution of problems is demonstrated.

The PT model under CLIA covers the entire spectrum of clinical laboratory medicine and includes three test events per year with five challenges (*i.e.*, PT samples) per test event. Each CLIA-certified laboratory is required to participate in a PT program. To achieve "satisfactory" PT performance, laboratories must score 80% (*i.e.*, obtain correct results on four of five challenges in each blood lead test event). To achieve "cumulative" PT performance over time, laboratories must maintain a score of \geq 80% on at least two of three consecutive blood lead test events.

Several factors are used to decide an "acceptable" total error for blood lead testing, including clinical and public health needs, performance of methods, laboratory capabilities and capacity, and recommendations from other bodies. Guidance, policies and other data on acceptable errors for blood lead testing are outlined in the published literature. The 2002 Taylor, *et al.* study recommended an acceptable error rate of $\pm 3 \mu g/dL$ or $\pm 10\%$. The 2001 Clinical and

Laboratory Standards Institute Guidelines recommended an acceptable error rate of $\pm 2 \mu g/dL$ or $\pm 10\%$. The 2005 APHA policy recommended an acceptable error rate of $\pm 1 \mu g/dL$ or $\pm 10\%$.

Performance criteria for laboratory testing of BLLs worldwide range from $\pm 2 \mu g/dL$ (Italy) to $\pm 6 \mu g/dL$ (U.S. Occupational Safety and Health Administration (OSHA)). A disconnect exists between the current CLIA standard of $\pm 4 \mu g/dL$ or $\pm 10\%$ for laboratory testing of BLLs and the current public health threshold of 10 $\mu g/dL$. A lower blood lead testing performance limit of $\pm 3 \mu g/dL$ or $\pm 10\%$ or $\pm 2 \mu g/dL$ or $\pm 10\%$ would force laboratories to improve performance, precision and accuracy.

Jeffrey Jarrett, MS

Research Chemist, Division of Laboratory Science, NCEH Centers for Disease Control and Prevention

Mr. Jarrett presented results of CDC's evaluation with 2009-2010 PT program data. CLIA currently approves four PT programs for laboratory testing of BLLs in the United States: College of American Pathologists, Pennsylvania Department of Health, the NYS Department of Health Wadsworth Center, and Wisconsin State Laboratory of Hygiene. NYS and Wisconsin account for ~50% of blood lead testing laboratories in the United States.

The NYS blood lead program was established in 1973 and provides laboratory certification for New York and other states, CLIA-certified laboratories and OSHA. At this time, ~100 laboratories participate in and pay fees to fund the NYS PT program. The first 2010 testing event showed that 86% of laboratories used highly-complex CLIA methods and 14% used moderately-complex or CLIA-waived methods.

The Wisconsin PT program was established in 1988 and provides laboratory certification for Wisconsin, CLIA, the Joint Commission and other regulatory bodies. Wisconsin is primarily funded by a federal grant from the Health Resources and Services and Administration. With the exception of 10% of laboratories that choose to pay for regulatory testing, Wisconsin provides PT at no charge. The first 2010 testing event showed that of ~850 enrolled laboratories with a subset of ~750 participating laboratories, 47% used CLIA-waived methods, 33% used moderately-complex CLIA methods, and 20% used highly-complex CLIA methods.

The evaluation of the NYS and Wisconsin PT programs was based on all three testing events in 2009 and the first testing event in 2010. CDC selected 20 blood samples from both the NYS and Wisconsin PT programs (or five samples from each of the four testing events). NYS's results ranged from 3-51 μ g/dL, while Wisconsin's performance ranged from 1-36 μ g/dL.

CDC used the following criteria to assess acceptable performance: $\pm 4 \ \mu g/dL$ or $\pm 10\%$, $\pm 3 \ \mu g/dL$ or $\pm 10\%$, $\pm 2 \ \mu g/dL$ or $\pm 10\%$, and $\pm 1 \ \mu g/dL$ or $\pm 10\%$. Performance on individual samples was satisfactory if reported concentrations were within acceptable ranges as defined by assessment criteria of $\pm 4 \ \mu g/dL$ or $\pm 10\%$. The PT programs passed if satisfactory performance was achieved on $\ge 80\%$ of samples (or four of five samples). Unsuccessful performance was a failure of two consecutive PT events or a failure of two of three PT events. Laboratories that did not participate in all four testing events were excluded from the evaluation.

The NYS and Wisconsin PT programs were required to interpret alphanumeric results or data with qualifiers, such as concentrations below the limit of detection or quantification and those above reportable ranges. Treatment differences were maintained within the respective data sets of the two PT programs that were evaluated. Mr. Jarrett highlighted key findings of the PT program evaluation.

The percentage of the 61 NYS participating laboratories with unsuccessful performance was 2% at $\pm 4 \mu g/dL$ or $\pm 10\%$; 5% at $\pm 3 \mu g/dL$ or $\pm 10\%$; 10% at $\pm 2 \mu g/dL$ or $\pm 10\%$; and 16% at $\pm 1 \mu g/dL$ or $\pm 10\%$. The percentage of the 357 Wisconsin participating laboratories with unsuccessful performance was 5% at $\pm 4 \mu g/dL$ or $\pm 10\%$; 7% at $\pm 3 \mu g/dL$ or $\pm 10\%$; 13% at $\pm 2 \mu g/dL$ or $\pm 10\%$; and 31% at $\pm 1 \mu g/dL$ or $\pm 10\%$. Unsuccessful performance between the two PT programs in the four criteria was more similar when an analysis was conducted of 61 NYS participating laboratories and 90 Wisconsin participating laboratories that used the highly-complex ICP-MS, GFAAS and bench-top ASV methods.

With the exception of one Wisconsin participating laboratory with unsuccessful performance at $\pm 1 \mu g/dL$ or $\pm 10\%$ using ICP-MS, the 10 NYS participating laboratories and the remaining 10 Wisconsin participating laboratories had successful performance in all four criteria using ICP-MS. The percentage of laboratories with unsuccessful performance in the four criteria using GFAAS ranged from 3%-9% among 35 NYS participating laboratories and from 0%-18% among 63 Wisconsin participating laboratories.

The percentage of laboratories with unsuccessful performance in the four criteria using benchtop ASV ranged from 0%-44% among 16 NYS participating laboratories and from 6%-63% among 16 Wisconsin participating laboratories. The percentage of laboratories with unsuccessful performance in the four criteria ranged from 5%-23% among 133 Wisconsin participating laboratories using the LeadCare I device and from 6%-43% among 134 Wisconsin participating laboratories using the LeadCare II device. The number of NYS participating laboratories that use the LeadCare I or LeadCare II device was insufficient for adequate data analysis.

In terms of performance within individual PT events, acceptable laboratory performance varied due to different concentrations of blood lead samples that were included in each of the four testing event. Within each individual event, differences in performance were minimal in the NYS and Wisconsin participating laboratories when criteria were tightened from $\pm 4 \ \mu g/dL$ or $\pm 10\%$ to $\pm 3 \ \mu g/dL$ or $\pm 10\%$.

From the first to last testing events, downward trends were observed in the performance of all Wisconsin participating laboratories and those that used the LeadCare II device. From the first to last testing events, the number of all Wisconsin participating laboratories increased from 557 to 657 and the number of LeadCare II laboratories increased from 203 to 207. The performance of Wisconsin participating laboratories that used the LeadCare I device was relatively consistent across all four testing events.

For "consensus," current CLIA regulations require 80% of laboratory results that are used to establish a target concentration to be within the acceptable range of $\pm 4 \,\mu$ g/dL or $\pm 10\%$ of the target. Agreement of <80% on the target concentration is used to define "non-consensus." Because non-consensus invalidates formal scoring of a test sample, all participating laboratories would be graded with a satisfactory score for the test sample.

Target values are assigned using one of two approaches. Refereed groups include a mean of ~10 top-performing laboratories, a cross-section of group methods and removal of outliers if necessary. Non-consensus is unusual with this approach due to careful selection of refereed groups.

Peer groups include a mean of all laboratories within the peer group and removal of outliers if necessary. Non-consensus is more likely with this approach because samples are not from a select number of top-performing laboratories. The NYS PT program uses one "all-methods" refereed group to assign target values. The Wisconsin PT program uses a refereed group for ICP-MS, GFAAS and ASV and peer groups for the LeadCare I and LeadCare II devices.

The 100-105 NYS participating laboratories maintained ~ \geq 80% acceptable performance as a function of blood lead concentration at \pm 2 µg/dL or \pm 10%. The 557-657 Wisconsin participating laboratories had a general decline in performance as blood lead concentrations increased. The refereed group only had one instance of non-consensus at \pm 1 µg/dL or \pm 10%.

The number of instances of non-consensus with the Wisconsin participating LeadCare I laboratories were two at $\pm 4 \mu g/dL$ or $\pm 10\%$, three at $\pm 3 \mu g/dL$ or $\pm 10\%$, six at $\pm 2 \mu g/dL$ or $\pm 10\%$, and 50% at $\pm 1 \mu g/dL$ or $\pm 10\%$. The instances of non-consensus with the LeadCare II laboratories were 35% at $\pm 2 \mu g/dL$ or $\pm 10\%$ and 13 of 20 samples at $\pm 1 \mu g/dL$ or $\pm 10\%$. These data show that tighter criteria would result in a larger number of ungradable PT samples with the peer group approach.

In terms of methods performance, most methods used by the NYS participating laboratories for one sample in the second testing event were in the $\pm 2 \mu g/dL$ range with an observed blood lead target of 5 $\mu g/dL$. Bench-top ASV methods resulted in underreporting by ~60% of laboratories. Most methods used by the refereed group of Wisconsin participating laboratories for one sample in the second testing event were in the $\pm 2 \mu g/dL$ range with an observed blood lead target of 2 $\mu g/dL$.

The performance of the LeadCare I peer group of Wisconsin participating laboratories for the same sample in the second testing event was in the $\pm 2 \mu g/dL$ range with an observed blood lead target of 3 $\mu g/dL$. The performance of the LeadCare II peer group of Wisconsin participating laboratories for the same sample in the second testing event was in the $\pm 3 \mu g/dL$ range with an observed blood lead target of 4 $\mu g/dL$.

LWG has fulfilled the first part of its charge as follows. LWG recommends more stringent CLIA criteria for assessing acceptable performance for blood lead testing. The PT performance data showed that at $\pm 2 \mu g/dL$ or $\pm 10\%$, >90% of laboratories had reasonably satisfactory performance with highly-complex methods and 87%-90% of laboratories maintained successful

performance. Laboratory performance would significantly decrease with criteria of $\pm 1 \mu g/dL$ or $\pm 10\%$.

ICP-MS and GFAAS are the newest of the highly-complex technologies and demonstrated the best performance. Most laboratories with unsuccessful performance used the ASV electrochemical technique. However, a tighter PT acceptability limit from $\pm 4 \mu g/dL$ or $\pm 10\%$ to $\pm 2 \mu g/dL$ or $\pm 10\%$ would have an unintended consequence of being unable to grade 30%-35% of PT samples in accordance with current CLIA criteria. This outcome indicates the need for an alternative model to assess point-of-care performance in the future.

LWG's second recommendation is to ask blood lead PT programs to immediately begin providing laboratory performance grades based on performance criteria of $\pm 2 \mu g/dL$ or $\pm 10\%$ in addition to the existing CLIA criteria of $\pm 4 \mu g/dL$ or $\pm 10\%$. The more stringent PT acceptability limit most likely would lead to several changes:

- Significant improvement in the quality of data produced by laboratories (e.g., less misclassifications of patients and fewer false-positive or false-negative results).
- Improvements in monitoring and surveillance data and better inter-laboratory agreement.
- Retirement of older blood lead testing techniques.
- Withdrawal of less competent laboratories from the market.
- A modest increase in the cost of blood lead testing due to the need to purchase new technologies and train laboratory staff.
- An increase in quality control of blood lead testing at low concentrations for the purpose of biomonitoring.
- An increase in repeat testing prior to reporting results to meet quality control standards.

Marissa Scalia Sucosky, MPH

Epidemiologist, Healthy Homes/Lead Poisoning Prevention Branch Centers for Disease Control and Prevention

Ms. Sucosky described LWG's activities to fulfill the second part of its charge. LWG recognized the need to first identify the appropriate federal agency that should receive ACCLPP's letter regarding more stringent blood lead PT acceptability limits. Most notably, the CDC Clinical Laboratory Improvement Advisory Committee (CLIAC) recommends PT limits, but CMS has regulatory oversight for implementation.

Based on guidance from CDC, LWG proposes to send the ACCLPP letter to HHS Secretary Kathleen Sebelius with copies to the following persons: the CLIAC Chair and Designated Federal Official; Dr. Donald Berwick, Administrator of CMS; and the CMS liaison who serves on CLIAC. Based on ACCLPP's formal adoption of LWG's recommendations and its comments on the draft letter, Dr. Rhoads would immediately send the letter.

Before ACCLPP's discussion on the update, Dr. Parsons added that LWG was given another charge to address in the future. LWG will develop a process to characterize LeadCare as a "screening method" and refereed techniques as a "diagnostic technology" and separate the two

categories of technology. LWG will extract language from package inserts of the LeadCare devices and collect additional data from the manufacturer to formulate recommendations and provide education to end-users on using LeadCare data for screening purposes only.

ACCLPP thanked LWG for presenting a series of comprehensive overviews on its most recent activities to improve the current federal criteria to assess acceptable performance of blood lead testing in PT programs (e.g., data collection efforts and evaluation of the NYS and Wisconsin PT programs). To support its formal vote on LWG's recommendations, ACCLPP used the discussion period to ask questions and obtain additional information from Dr. Parsons and Mr. Jarrett on the PT program evaluation.

Dr. Rhoads entertained a motion to send the ACCLPP letter to the proposed recipients with the proposed content:

"ACCLPP recommends that CLIAC advise CMS to tighten the criteria for assessing acceptable performance for blood lead testing in PT programs from the current CLIA regulatory standard of $\pm 4 \mu g/dL$ or $\pm 10\%$ to $\pm 2 \mu g/dL$ or $\pm 10\%$. ACCLPP further recommends that CLIAC advise blood lead PT programs to immediately begin providing laboratory performance grades based on performance criteria of $\pm 2 \mu g/dL$ or $\pm 10\%$ in addition to the existing CLIA criteria of $\pm 4 \mu g/dL$ or $\pm 10\%$. This approach should be used for laboratories to submit performance results to PT programs in preparation of changing the CLIA regulatory standard to $\pm 2 \mu g/dL$ or $\pm 10\%$."

A motion was properly placed on the floor and seconded by Dr. Megan Sandel and Mr. Dana Williams, respectively, for Dr. Rhoads to send the ACCLPP letter with the proposed content to the HHS Secretary with copies to the four persons proposed by LWG. **ACCLPP unanimously approved the motion.**

Public Comment Session

Ronnie Levin

Private Citizen

Ms. Levin made the following comments for the record. ACCLPP's update and discussion on lead in consumer products primarily focused on the definition of "lead free" based on ancillary testing and laboratory analysis as well as "fraud" based on dishonest product labeling. A centralized body should be formed to both establish and enforce standards.

ACCLPP's update on blood lead testing in PT programs emphasized that the current performance of laboratories is at the CLIA standard of $\pm 4 \ \mu g/dL$ or $\pm 10\%$. Although the current BLL of concern is $\geq 10 \ \mu g/dL$, BLLs $\geq 5 \ \mu g/dL$ also have enormous clinical significance. Laboratories should notified at this time that after the CLIA regulatory standard is changed to $\pm 2 \ \mu g/dL$ or $\pm 10\%$, the criteria will be further tightened to $\pm 1 \ \mu g/dL$ or $\pm 10\%$ within the next five or seven years. More stringent criteria will capture a larger percentage of the mean population.

Craig Boreiko

Environment and Health Manager International Lead Zinc Research Organization

Mr. Boreiko made the following comments for the record. Dr. Brown should be thanked for publicly recognizing the Blacksmith Institute for its instrumental role in the early and continued response to the remediation of lead in Zamfara State, Nigeria. The Blacksmith Institute website at <u>www.blacksmithinstitute.org</u> will feature its annual report in the near future with a detailed description of the current status of lead remediation efforts in Zamfara State.

In terms of lead in consumer products, Mr. Boreiko advised Dr. Gilmore to contact Richard Lehman, a Professor of Materials Science and Engineering at Rutgers University, to obtain expertise on ceramics technologies in general and the leaching quantification component of the Chinatown study in particular. Professor Lehman oversees the ISO Secretariat for lechate standards for ceramics. As an additional resource, Dr. Gilmore should visit the <u>iomc.org</u> website to review numerous issues of interest (e.g., the safe production of ceramics and the influence of various glaze compositions) that are outlined in a 200-page technical guide.

Thomas Carroll

Housing Hygiene Section Chief New York State Department of Health

Mr. Carroll made the following comments for the record. NYS frequently receives requests to address lead in various consumer products (e.g., lunchboxes, ceramics, cosmetics and herbal remedies). Similar to other state and local health departments, NYS also is challenged by addressing these problems without clear, concise and simple guidelines on specific federal agencies with authority of consumer products.

Health departments would greatly benefit from guidelines and standards on appropriately responding to reports of lead in consumer products at state and local levels. For example, NYS is aware of numerous products that have reappeared on the market and poisoned children after being recalled or included on import alert lists for illegal levels of lead.

Ruth Ann Norton

Executive Director, National Coalition to End Childhood Lead Poisoning ACCLPP Liaison

Ms. Norton made the following comments for the record. The National Academy of Public Administration is sponsoring the National Green and Healthy Homes Dialogue to compile best practices, barriers and recommendations on implementing housing interventions that efficiently integrate lead hazard control, energy efficiency, weatherization and healthy homes concepts. Guidance from this activity will be shared with the federal interagency Healthy Homes Workgroup, national organizations and other stakeholders of the National Dialogue.

Members of the public can visit <u>www.greenandhealthyhomesdialogue.org</u> to post ideas and make recommendations, but the public comment period for the National Dialogue will close on November 21, 2010. The National Dialogue would greatly benefit from expert opinions by the ACCLPP members on enhancing lead poisoning prevention efforts in the United States.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 4:56 p.m. on November 16, 2010.

Opening Session: November 17, 2010

Dr. Brown reconvened the meeting at 9:00 a.m. on November 17, 2010. She opened the floor for introductions and confirmed that the ACCLPP voting members and non-voting *ex-officio* members in attendance constituted a quorum.

Dr. Rhoads noted that he neglected to formally introduce the four new ACCLPP members and liaisons during the opening session on the previous day. He welcomed these persons to the meeting:

- Perry Gottesfeld, MPH, Executive Director, Occupational Knowledge International
- David McCormick, Director, Indiana Childhood Lead Poisoning Prevention Program, Indiana State Department of Health
- Ruth Ann Norton, Executive Director, National Coalition to End Childhood Lead Poisoning
- Donald Simmons, PhD, Association of Public Health Laboratories

Dr. Rhoads reminded the ACCLPP voting members of their responsibility to recognize potential conflicts of interest and recuse themselves from participating in discussions or voting on issues for which they have a real or perceived conflict of interest.

Overview of National Performance Measures of Blood Lead in Children

Will Wheeler, MPH

Epidemiologist, Healthy Homes/Lead Poisoning Prevention Branch Centers for Disease Control and Prevention

Mr. Wheeler presented an overview of national performance measures of blood lead in U.S. children 1-5 years of age. Data from the National Health and Nutrition Examination Survey (NHANES) showed a dramatic reduction in the prevalence of EBLLs in 1976-2008. The national estimate of the prevalence of EBLLs decreased by 91% in 1976-2008 and declined an additional 50% in 1988-1991. The national prevalence of EBLLs is estimated to be 0.9% based on the last NHANES cycle in 2005-2008. A sharp and steady decline in EBLLs has been

observed in this population over the past 30 years, but estimates have become less robust as the prevalence declined.

NHANES is a national representative survey designed to determine the health and nutrition status of non-institutionalized civilian adults and children in the United States. NHANES was launched as a periodic survey in the 1960s and was redesigned as a continuous survey in 1999. The new NHANES design provided data on the health status of the U.S. population on a more frequent basis, informed sound public health policy, and assisted in the development of health programs and services.

NHANES includes home-based interviews; the collection of demographic, socioeconomic and dietary information; and examinations with medical, dental and physiological measurements and laboratory tests. NHANES data are used to assess a number of conditions, including cardiovascular disease, environmental exposures, obesity, respiratory diseases and sexually transmitted diseases.

The NHANES methods include a complex multi-stage survey design and a probability sampling frame. The first sampling stage is all U.S. counties or a cluster of counties with small populations. The second sampling stage is clusters of households in each selected county. The third sampling stage is the selection of \geq 1 persons in the household after all household members have been selected. NHANES was designed to quantify sampling errors associated with the sampling design to characterize the precision of estimates.

Of all household members interviewed and screened, ~80% are selected for participation in NHANES. From 15 counties (or 20-30 per cycle) selected each year, ~5,000 persons (or 10,000 per cycle) are selected for NHANES participation. Estimates of a two-year NHANES cycle typically are based on 24-26 counties. In the 2007-2008 cycle, Hispanics and non-Hispanic blacks and persons >60 years of age were over-sampled due to the importance of and interest in the health characteristics of these populations.

A complex sample survey design makes analysis more complicated than for a simple random sample. Weights for a simple random sample are the inverse of the probability of selection. For NHANES, information on the sample design must be explicitly used when producing statistical estimates. Stratification, clustering and over-sampling must be incorporated into the analysis to obtain accurate estimates and standard errors. Specialized statistical software is used to analyze NHANES data. The study design must be accounted for in the analysis.

As the prevalence of EBLLs continues to decrease in the population, fewer children with EBLLs are selected for NHANES participation. The number of sampled children with EBLLs has remained fairly consistent over the past five NHANES cycles, but fewer children with EBLLs were included in the 2005-2006 and 2007-2008 cycles. This downward trend has affected the estimate in several areas, such as reduced stability and decreased precision of estimates, increased influence of clustering, and more difficulty in measuring significant changes. The lack of statistical precision has decreased the meaningfulness of estimates.

NHANES can no longer provide statistically stable estimates of the prevalence of EBLLs in children 1-5 years of age. CDC has identified potential solutions to address this problem, but recognizes that barriers are associated with these options. Multiple NHANES cycles could be combined to increase stability of estimates, but capacity would be limited in immediately determining changes in policy and practice. NHANES could be funded with additional dollars to increase the number of sampled children, but medical examinations are already expensive and young children 1-5 years of age frequently resist participation as a result of blood draws.

Surveillance data could be used to estimate national prevalence, but these data are incomplete and depend on screening patterns. Moreover, some states do not report data to CDC's surveillance systems. The geometric mean, 95th percentile and disparities could be reported, but these data are less "user-friendly" than prevalence estimates and would be more difficult for non-experts to understand and apply to children with EBLLs. Advanced statistical techniques could be used with the entire distribution of BLLs to estimate prevalence or demonstrate improvements in each NHANES cycle, but this approach would be difficult to explain to lay audiences and might only reduce instability of estimates.

CDC collected data to explore the feasibility of using the geometric mean and 95th percentile of BLLs for the entire population of children 1-5 years of age to track overall estimates and disparities in BLLs among race/ethnicity and poverty groups. The geometric mean would provide a much more stable measurement of progress, but still could be used to report prevalence for historical records.

To calculate the geometric mean, BLLs of all sampled children would be used. A new performance goal would be established to lower the overall geometric mean, decrease the 95th percentile, and reduce disparities in BLLs across race/ethnicity, poverty status and other demographic categories. The new EPA regulation would provide a target level for this performance goal.

The geometric mean of BLLs among children 1-5 years of age decreased from ~2.4 in the 1999-2000 NHANES cycle to 1.5 in the 2007-2008 cycle. The 95th percentile of BLLs among children 1-5 years of age decreased from ~6.9 in the 1999-2000 NHANES cycle to 4.1 in the 2007-2008 cycle. In terms of disparities by race, the geometric mean of BLLs in the 2007-2008 NHANES cycle was 1.94 among non-Hispanic blacks and 1.42 among non-Hispanic whites, Mexican American and other racial groups. Although racial disparities in BLLs have decreased over time, the gap in the geometric mean continues to be significant.

In terms of disparities by poverty-to-income ratio (PIR), the geometric mean of BLLs in the 2007-2008 NHANES cycle was 1.74 among children in households with the lowest PIR (or <1.3) and 1.20 among children in households with the highest PIR (or >3.5). Disparities in the 95th percentile of BLLs between non-Hispanic blacks and other racial/ethnic groups were not found to be significant. Disparities in the 95th percentile of BLLs between the lowest and highest categories remain significant.

Overall, CDC is currently exploring more statistically stable methods to estimate the number of children 1-5 years of age with EBLLs and quantify changes in BLLs. These potential methods

include estimating prevalence based on the entire distribution of BLLs among all children 1-5 years of age surveyed in NHANES and calculating area differences over time by comparing differences in distribution curves across NHANES cycles.

ACCLPP extensively discussed the advantages and disadvantages of CDC's proposal to change the national performance measures of BLLs in children. The ACCLPP members made several suggestions for CDC to consider over the course of its decision-making process.

- CDC should compile data from states and large cities (e.g., California and New York City) that administer state-level Health and Nutrition Examination Surveys or maintain biomonitoring surveillance programs. The NCEH Division of Laboratory Sciences has provided technical assistance to states to foster the development of state-level medical surveillance programs. Scientific samples from state-level surveillance systems could yield information that would be helpful to NHANES in determining trends in BLLs.
- CDC should give careful consideration to the challenges in making comparisons between state-level and NHANES data if a decision is made to use geometric means rather than prevalence to estimate EBLLs in children. Laboratory data typically do not measure BLLs <3 µg/dL and are not sufficient to provide a geometric mean.
- CDC should explore the possibility of increasing the NHANES sample to include children 1-10 years of age. Several longitudinal studies that have demonstrated an association between EBLLs and IQ deficits were conducted with older children in grade school. These studies showed that EBLLs in older children were an equal or stronger predictor of IQ deficits versus EBLLs in children two years of age.
- CDC should include more environmental samples in NHANES to compliment biological samples to increase understanding of the most prominent sources of lead to children in the environment. Most notably, lead in consumer products and environmental sources are substantially contributing to EBLLs in children.
- CDC should explore a process to assist state and local LPPPs in promoting lead screening in healthcare settings. Most notably, clinicians will be increasingly reluctant to perform lead screening because the 2007-2008 NHANES cycle was based on only nine children with EBLLs.

Dr. Brown made several comments in response to ACCLPP's comments and questions. Health and housing surveys that are administered in the United States need to be closely linked. As an initial step in achieving this goal, HUD agreed to pilot five new health-related questions in the American Housing Survey that were proposed by CDC. Based on results of the pilot, HUD will permanently include the new questions when the survey is redesigned in 2012.

CDC, EPA and HUD all use the percent of children with BLLs $\geq 10 \ \mu g/dL$ as a performance goal. The federal agencies will be challenged in explaining to elected officials the rationale for shifting to more sophisticated metrics of lowering the overall geometric mean, decreasing the 95th percentile, and reducing disparities in BLLs. However, the new measures will require agencies to more thoughtfully consider the overall evaluation of their performance.

In terms of comparing state and NHANES data, CDC is on record with its opposition to this practice. Because states target lead screening to high-risk populations and do not administer population-based surveys, state data are not comparable to NHANES data. In terms of increasing the NHANES sample size to children 1-10 years of age, the numerators and denominators may not significantly change because BLLs in school-age children are lower than those among children 1-5 years of age. However, Dr. Brown was open to further discussion with ACCLPP to explore this approach in more detail.

Proposal for a New ACCLPP Workgroup

Perry Gottesfeld, MPH

Executive Director, Occupational Knowledge International ACCLPP Member

Deborah Cory-Slechta, PhD

Professor, Department of Environmental Medicine University of Rochester School of Medicine ACCLPP Member

Mr. Gottesfeld and Dr. Cory-Slechta presented a proposal for ACCLPP to establish a new workgroup that would be charged with recommending a new approach, terminology and strategy for EBLLs among children. Along with Mr. Gottesfeld and Dr. Cory-Slechta, the other members of the ad hoc group that developed the proposal include Dr. Michael Kosnett, Ms. Linda Kite and Dr. Walter Rogan.

ACCLPP previously explored the possibility of revising the CDC guidelines on EBLLs in children in 2004 and reached agreement at that time to maintain the BLL of concern at 10 μ g/dL. ACCLPP also agreed to update guidance documents to health departments and physicians on EBLLs in children. The ad hoc group revisited ACCLPP's previous discussion of the CDC guidelines on EBLLs in children in light of more recent policy and scientific developments.

CDC has lowered the BLL of concern over time from 40 μ g/dL in 1970 to 10 μ g/dL in 1991. The percent of U.S. children with BLLs >10 μ g/dL decreased from 88.2 μ g/dL in 1976-1980 to 0.9 μ g/dL in 2007-2008. The ad hoc group is interested in performing a more in-depth examination of BLLs <10 μ g/dL at this time due to several factors. Subsequent to ACCLPP's last review of this issue in 2004, 27 articles have been published on neurodevelopmental and neurobehavioral effects from children's exposure to low levels of lead.

Recent studies have included more subjects with BLLs <10 μ g/dL. The scientific community has reached consensus that no safe BLL threshold has been identified for children. This research has influenced policy in the United States and other countries. For example, WHO, Canada and other countries are currently in the process of updating or revising their BLL guidelines. Germany issued new BLL guidelines in 2009 based on results of a literature review and findings that were published by the German Human Biomonitoring Commission (HBC).

HBC determined that identifying thresholds for lead and defining a "tolerable intake dose" would be impossible. HBC analyzed background levels of lead in subpopulations and proposed the following BLL action levels: $3.5 \mu g/dL$ for children 3-14 years of age, $7 \mu g/dL$ for adult women, and $9 \mu g/dL$ for adult men. HBC assumed that BLLs greater than reference values would come from a specific source and would be undesirable. HBC called for verification testing and repeat testing after three months for persons with BLLs above the action levels.

The United States established a national goal in 1990 to lower BLLs to <10 μ g/dL by 2010, but HHS recently extended the deadline to 2020. The ad hoc group supports ACCLPP taking a formal position at this time of either declaring success with the current prevalence of EBLLs in children 1-5 years of 0.9 or articulating a new national goal for the next 20 years.

Because CDC's BLL of concern of 10 μ g/dL has not changed since 1991, federal and state agencies have taken steps to establish "trigger points" at BLLs <10 μ g/dL. Minnesota recently administered an informal survey and determined that several local health departments also have implemented programs to address BLLs 5-9 μ g/dL. EPA is using the association between BLLs and IQ deficits to trigger the Clean Air Act and the proposed Lead Dust Standard in housing at BLLs <10 μ g/dL. California is using the association between an incremental BLL of <1 μ g/dL and a one-point IQ deficit in the population to trigger environmental programs.

Alameda County, California distributes educational materials to parents that recommend retesting of children for lead every six months. Long Beach, California distributes lead screening educational materials and performs home visits with dust wipe sampling in households with children <3 years of age. Minnesota enacted a new law that requires the state health department to issue guidelines for children with BLLs $\geq 5 \,\mu g/dL$.

Minneapolis performs home visits. Cincinnati performs home visits with full environmental evaluations. Washington, DC performs home visits upon request with dust wipe sampling. Grand Rapids, Michigan awarded an outside contractor to provide lead screening education to parents. Vermont is using $\geq 5 \ \mu g/dL$ as a trigger level.

Despite the growing body of scientific evidence, opposition against lowering the BLL of concern must be considered. A proven intervention has not been developed to date to lower BLLs <10 μ g/dL. No threshold exists for BLLs either below or above 10 μ g/dL. Epidemiologic studies have identified a possible bias or confounding factors with BLLs <10 μ g/dL. The potential for misclassification of "EBLLs" at BLLs <10 μ g/dL might increase as a result of laboratory errors. Stigma potentially could increase as a result of characterizing children with BLLs <10 μ g/dL as "lead poisoned."

Although these concerns are valid, the position of the ad hoc group is that new guidelines can be developed to account for these issues. A change in the CDC policy would have implications for state and local health officials and physicians, but new directions must be explored at this time to achieve the ultimate goal of prevention. Moreover, problems with the current "BLL of concern of 10 μ g/dL" terminology are beginning to affect CDC's credibility.

Physicians routinely interpret BLLs <10 μ g/dL as "no problem." Public health professionals and physicians are increasingly challenged by the tension between the perceived lack of concern among programs regarding health effects at BLLs <10 μ g/dL versus the acknowledgement that no threshold exists for lead. A discrepancy exists between CDC's BLL of concern and approaches taken by EPA, local health officials, and other agencies and countries to communicate risk. A National Lead Poisoning Prevention Strategy cannot be developed without reaching consensus on a prevention threshold for BLLs.

In developing the proposal, the ad hoc group identified several reasons to make a clear distinction between medical recommendations at the individual treatment level and public health goals at the population level. Medical recommendations on re-screening and chelation should be separate decisions. Decisions on lead abatement versus interim control measures are currently linked to BLLs \geq 10 µg/dL. Local and state housing codes use BLLs \geq 10 µg/dL to trigger enforcement.

A standard EPA risk assessment is based on target organ endpoints, an exposure assessment, dose-response and uncertainty factors. EPA risk assessments define no observed adverse effect levels, lowest observed adverse effect levels, minimal risk levels, or no significant risk levels. EPA's standard risk assessment is based on an observed threshold and would not be suitable options for assessing BLLs.

The ad hoc group explored two major options to revise the BLL of concern. The existing risk assessment could be used as recommended in the 2010 Wilhelm, *et al.* study. An entirely new methodology could be developed based on results of three activities. A risk assessment could be performed on human studies of cognition or other target organ endpoints. A risk assessment could be performed on human studies of IQ deficits. A reference range or level could be established based on background lead levels in the populations. Levels above the background level that would be greater than the reference range could be assumed to come from a specific source.

The ad hoc group discussed new language to revise the "BLL" terminology, such as "action level," "reference value or reference range," or "risk level." Reference values are statistically derived values that indicate the upper margin of background exposure to a given pollutant in a given population at a given time. Reference values can be used to classify individuals or population groups as "elevated" or "not elevated."

The ad hoc group discussed other important considerations and the required scope to revise the BLL of concern, including the laboratory level of quantifying BLLs with proposed variability of $\pm 2 \mu g/dL$; new terminology to replace "level of concern" and remove its association with "lead poisoned;" and units other than $\mu g/dL$ to denote BLLs (e.g., $\mu g/l$).

If ACCLPP formally approves the establishment of the new workgroup, its charge and scope would be defined as follows. A decision would be made on the new BLL and terminology. Recommendations would be made on increases in BLLs over time, intervals for re-screening, notification procedures and other interventions (e.g. chelation). Recommendations would be made on appropriate materials to disseminate to healthcare providers. Recommendations

would be made to CDC on the development and delivery of education messages to address lead as a public health hazard. A list of best practices would be compiled and needed research would be proposed.

Because the ad hoc group has proposed an extremely broad scope and charge for the new workgroup, activities would be conducted in two phases. In phase 1, the workgroup would limit its focus to new BLL terminology, a new "BLL of concern" and laboratory measures. Outcomes, results and key discussion points from the phase 1 activities would not be shared outside of the workgroup members.

In phase 2, the workgroup would compile its findings from phase 1, address issues for the field and draft recommendations to ACCLPP. The workgroup would then solicit ACCLPP's formal approval to adopt the recommendations for submission to CDC. The ad hoc group proposed a work plan for the workgroup that was distributed to ACCLPP for review and comment. The ad hoc group estimated that ~6 months would be required for the workgroup to complete the first two tasks in the proposed work plan (e.g., formulating guidance to replace "BLL of concern" and determining the lowest practical level of laboratory quantification for lead in blood).

Overall, the ad hoc group supports the development of a strategy to deliver interventions to children with BLLs $\geq 9 \ \mu g/dL$ to reduce BLLs in this range and ensure that BLLs do not increase. The ad hoc group is now soliciting ACCLPP's formal endorsement to establish a new workgroup that would focus on setting a goal for a National Lead Poisoning Prevention Strategy over the next 10-20 years.

Before Dr. Rhoads opened the floor for ACCLPP's discussion, Dr. Brown made several remarks in response to the proposal. CDC has never advised EPA to use 10 μ g/dL as a cutoff to trigger cleanup of Superfund sites. CDC fully supports the activities of Massachusetts and other states to separate lead-safe housing interventions from a qualifying BLL. CDC continues to strongly encourage all of its funded LPPPs to take a similar approach.

Dr. Brown also informed ACCLPP of issues that CDC must consider if formal recommendations are made in the future for a new approach, terminology and strategy for EBLLs in children. In terms of the feasibility of the proposal, CDC must seriously consider the role of science in driving populations to a specific value through education, regulatory policy or other strategies. CDC made strong efforts in 2005 to separate issues related to BLLs by clearly distinguishing between "public health" goals and "diagnostic medical treatment."

CDC has attempted to broadly communicate and educate the public on its use of BLLs other than 10 μ g/dL to take action (e.g., 25 μ g/dL for legal inspection and lead abatement of homes in some states and localities without the owner's approval or consent, 45 μ g/dL for chelation, and 70 μ g/dL for an emergency).

For children who already have BLLs <10 µg/dL, CDC has been disappointed with efficacy data gathered to date on individual interventions that have been piloted to further lower their BLLs. However, solid data have been collected to demonstrate that BLLs have decreased in U.S.

children on a population level each time sources of lead in the environment were controlled or eliminated.

ACCLPP supported the proposal to establish a new workgroup that would be charged with recommending a new approach, terminology and strategy for EBLLs in children. The members listed several reasons to justify ACCLPP's formal approval of the new workgroup.

- Results from commercial laboratories routinely cite CDC's BLL of concern of 10 μg/dL. Despite wide dissemination of rigorous scientific evidence in the literature that has demonstrated adverse health effects to children at BLLs <10 μg/dL, pediatricians and primary care physicians typically will take no further action if laboratory results confirm a BLL <10 μg/dL.
- Some state and local agencies have taken progressive actions to lower the BLL of concern to <10 μg/dL, but this trend is not the norm for the vast majority of the country. Most state and local agencies will take no action at BLLs <10 μg/dL without a change in CDC policy.
- The existing terminology interferes with care. For example, a clinician most likely would take no action if a child's BLL was 6 μg/dL because the "level of concern" begins at 10 μg/dL. However, the same clinician most likely would take action on the "geometric mean" of BLLs in children of 0.9 if a child's BLL was 6 μg/dL.
- 4. Even if activities by the new workgroup does not result in any changes, the existing BLL of concern warrants review at this time because CDC established the policy nearly 20 years ago in 1991.

ACCLPP discussed several issues that should be considered if a formal resolution was passed to establish the new workgroup.

- CDC should eliminate its national BLL of concern and allow states to establish their respective BLLs of concern based on the needs of their populations. Other ACCLPP members strongly opposed this suggestion because clinicians in states with a low prevalence of BLLs most likely would never screen their patients for lead.
- If ACCLPP formally adopts the proposal, the new workgroup also should be charged with gathering data to make evidence-based recommendations on interventions that can be offered at BLLs <10 µg/dL. For example, a lower BLL of concern would have serious implications on triggering EPA clearance levels and delivering interventions in industrial hygiene and occupational settings.
- The proposal to recommend a new approach, terminology and strategy for EBLLs in children is an excellent concept in theory, but clinicians are overlooked in this strategy. The current or a new BLL of concern in the United States cannot be implemented without clear instructions to clinicians on appropriate interventions to deliver at a specific value. To address this issue, the workgroup should not conduct its activities in a twophase process. While guidance is being developed on BLL terminology, a new BLL of

concern and laboratory measures, for example, a subgroup could formulate clinical care guidance at the same time on appropriate interventions for clinicians to deliver to children with BLLs <10 μ g/dL, such as an assessment of iron status.

- The workgroup should include study designs other than observational studies, (e.g., prevention trials, social epidemiology data or separate analyses of pica) in its literature review. Observational studies historically have been based on tooth lead or blood lead and did not account for other contributing sources.
- The workgroup's guidance document should provide a strong rationale for targeting public health resources to BLLs <10 µg/dL in light of competing priorities that have a greater impact on children's health.

The following motion was properly placed on the floor and seconded by Dr. Megan Sandel and Mr. Dana Williams, respectively. ACCLPP recommends the establishment of a new "Blood Lead Level Workgroup" with two focal areas: (1) a review of the evidence in establishing a different BLL threshold and (2) a review of the evidence of interventions if a new BLL threshold is recommended. **ACCLPP unanimously approved the motion.**

Dr. Brown described the next steps for the new workgroup. ACCLPP should submit written comments on the proposed work plan to Mr. Gottesfeld and Dr. Cory-Slechta via e-mail to ensure that the workgroup's charge is clearly articulated. Mr. Dana Williams expressed his interest in serving on the new workgroup; Drs. Brown and Rhoads would solicit additional volunteers to serve on the workgroup via e-mail.

Dr. Brown informed ACCLPP of Federal Advisory Committee Act rules that must be followed. A workgroup must have representation by three voting members of the parent committee. Discussions among workgroup members do not constitute formal recommendations of an advisory committee, are not subject to Freedom of Information Act requests, and are not required to be released in the public domain. Dr. Brown emphasized that because HHS is currently reviewing the composition and use of workgroups, these rules might change in the future.

Update by the Educational Intervention Workgroup (EIWG)

Sher Lynn Gardner, MD

Assistant Professor of Pediatrics, Department of Pediatrics, Emory University ACCLPP Member and EIWG Chair

Dr. Gardner presented an update on activities EIWG has conducted since the October 2009 ACCLPP meeting. The EIWG members represent ACCLPP, CDC, academic institutions, CDC-funded CLPPPs, professional associations, parents of lead-poisoned children and CBOs. EIWG's charge covers three major areas:

- 1. Gather available data to support evidence-based recommendations on the association between neurobehavioral and neurodevelopmental deficits and EBLLs in children.
- 2. Compile existing laws and regulations that cover educational assessments and interventions for children with EBLLs.
- 3. Develop an action plan for educators, clinicians, public health professionals, advocates and other stakeholders to use a common data set in documenting EBLLs as children progress through school.

During its last meeting in July 2010, EIWG created a working outline to guide the development of the four components of the educational intervention paper: clinical, educational, legal and advocacy aspects. Dr. Gardner's review of EIWG's working outline is summarized as follows. Section 1 is the "Introduction." This section will provide background information on EIWG's charge and direction and cite studies to articulate the rationale of the paper.

Section 2 is "Neurodevelopmental Consequences of Lead Exposure." This section will describe only those outcomes that are supported by evidence: BLLs and IQ, other neurodevelopmental deficits associated with BLLs, speech and language, attention, other behavioral outcomes, and fine motor skills deficits. Based on ACCLPP's previous suggestion, EIWG will develop and include a chart in this section to illustrate developmental, neurodevelopmental and behavioral effects by age (e.g., 0-1 year or 1-2 years).

Section 3 is "Vulnerable Populations" (*i.e.*, children at most risk). This section will describe factors that affect children's risks for neurologic sequelae, inter-child variability, the importance of age, and the time lag in associations between effects and EBLLs. Section 4 is "Outcomes of Medical Interventions to Reduce Lead and Improve Outcomes." This section will describe the persistence of neurodevelopmental effects and the effectiveness of reducing BLLs. Section 5 is "Effects of Lead on Learning and Educational Achievement." This section will cite various cross-sectional studies and describe reading readiness.

Section 6 is "Rationale for the Impact of Interventions on Children with Lead Exposures." This section will clarify that no studies have been conducted to date demonstrating the efficacy of various interventions (e.g., education, parenting training, behavior training, or attention deficit hyperactivity disorder medications) on children with EBLLs. This section will support the rationale by describing other studies, such as programs for children 0-3 years of age, programs for preschoolers and school-age children, and data on the benefits of addressing behavior concerns.

Section 7 is "Assessing Children for Educational Needs." This section will describe surveillance and screening as recommended by American Academy of Pediatrics (AAP) guidelines. EIWG plans to move this section to the beginning of the paper.

Section 8 is "Educational Resources." This section will describe actions parents can take in home and early intervention services (e.g., programs for children 0-3 years of age, child development and parenting programs for children <3 years of age, and preschool programs). For each of these services, the section will provide information on the types, functions and

funding sources of available programs, children who are eligible for the programs, and access to the programs.

Section 9 is "Regulations Governing Access to Resources for Children with Problems." This section will provide a comprehensive overview of existing federal and state regulations.

Section 10 is "Individual Regulations." This section will provide detailed information on each regulation referenced in Section 9: Child Find, Individual with Disabilities Education Act Parts B and C, Section 504 (*i.e.*, education of children with disabilities), regulations for children who do not receive special education, American with Disabilities Act, and the Early Periodic Screening, Diagnosis and Treatment Program. For each of these regulations, this section will describe the history and meaning of the law, covered services, including children with EBLLs, responsible or mandated agencies, access to services, and funding applications submitted by states.

Section 11 is "Telling the Story." This section will feature call-out boxes of personal experiences and anecdotal information on the use of services and programs by various states to serve children. Section 12 is "Advocacy." This section will clearly define the role of advocacy based on various perspectives, provide guidance on using laws to obtain services for children, and describe specific information that schools need to provide services.

Section 13 is "Recommendation for Change of Policy." This section will target guidance to several groups: parents, schools, non-governmental organizations and clinicians; federal, state and local policymakers; public health agencies; and educators, including early childhood educators. EIWG is aware that this section repeats the content of other sections and might be deleted from the final version of the paper.

Section 14 is "Research Needs." This section will describe research that is needed related to the effects of interventions on cognitive and behavioral attainment in children with past lead exposures. Section 15 is "Linkages to Other Aspects of Lead Prevention Efforts." This section will provide information on home services, emphasize the need to ensure that BLLs have decreased, and describe strategies to place children in safe environments. Section 16 is "Resources." This section will provide links to success stories and online resources, such as parenting skills to promote development.

A new "Principles of Screening and Evaluations" section will be placed at the beginning of the paper. This section will provide guidance in four major areas: surveillance, screening and monitoring, evaluation, school referrals and entry, and interventions. The guidance in this section will be targeted to specific subgroups of children based on their ages and BLLs. EIWG is requesting ACCLPP's feedback at this time to draft this section. EIWG hopes to complete the first draft of the paper by the spring of 2011.

ACCLPP and CDC made several suggestions in response to Dr. Gardner's request for feedback on EIWG's working outline of the draft educational intervention paper.

- New language should be added to the "Principles of Screening and Evaluations" section under the "surveillance, screening and monitoring" subsection: "Developmental screening should be performed any time a parent or guardian suspects his/her child has been exposed to lead."
- Guidance targeted to "pediatricians" should be expanded to "pediatric healthcare providers" to engage a wider group of providers who also treat children (e.g., family practice physicians, nurse practitioners and physician assistants).
- A new section should be added to the paper to clearly describe the role of CDC-funded CLPPPs. CDC has proposed a standard case management model in which CLPPPs would continuously perform surveillance of children who previously had EBLLs. The surveillance would be designed to ensure that a child's BLL does not increase at another point in the future and maintain a record until the child reaches school age. CDC hopes to include the surveillance language in the next program announcement for CLPPPs.
- The outline should be reviewed and edited to clarify that the paper is intended for all preschool children 0-4 years of age who are eligible for educational assessments and interventions prior to school entry. For example, references to "0-3 programs" exclude preschool children 4 years of age.
- EIWG should provide the new BLL Workgroup with the "Principles of Screening and Evaluations" section after this portion of the paper has been completed because the guidance is targeted to children with BLLs >5 μg/dL.
- EIWG should focus on developing an implementation plan to release and publish the paper in peer-reviewed journals during its ongoing efforts to develop the draft paper. For example, the paper will serve as an important resource to clinicians in appropriately delivering educational interventions to children with EBLLs.
- EIWG should continuously distribute interim drafts of the paper directly to the AAP Early Development Group to obtain endorsement at the outset and ensure full implementation of the recommendations among physicians.
- The paper should advise developmental pediatricians to inquire about BLLs of their patients during the medical history intake. This approach could help to distinguish the actual capacity and benefits of remedial programs in addressing developmental problems between children with and without EBLLs.
- EIWG should explore the possibility of recommending developmental surveillance with a validated instrument to ensure that pediatricians are more vigilant with children with EBLLs during screening.
- The paper should include a strong statement to clarify that only a subpopulation rather than all children whose IQs are affected by EBLLs would reach the established "threshold" or "deficit" to be eligible for early educational assessments or interventions.
- EIWG should revise the "Research Needs" section to emphasize the need for validated behavioral and intellectual assessments for special populations.

Dr. Brown explained that if EIWG meets its deadline to complete the first draft of the paper in the spring of 2011, multiple versions could be distributed to ACCLPP for review and comment before the next meeting. The final draft then could be presented to ACCLPP during the November 2011 meeting for a formal vote.

Overview of the Center for Evaluation of Risks to Human Reproduction (CERHR)

Walter Rogan, MD

Medical Epidemiologist, National Institute for Environmental Health Sciences National Institutes of Health ACCLPP *Ex-Officio* Member

Dr. Rogan provided an overview of CERHR. The National Toxicology Program (NTP) is a federal interagency program that is housed in the National Institute for Environmental Health Sciences with a mission to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology.

CERHR is a component of NTP that was established in 1998 to serve as an environmental health resource to regulatory and health agencies and the public. NTP-CERHR publishes monographs that assess evidence on adverse effects to reproduction and development caused by environmental chemicals, physical substances or mixtures. NTP-CERHR also provides opinions on whether these substances are hazardous to humans.

The next NTP-CERHR monograph will evaluate health effects of lead at lower levels of exposure. Dr. Elizabeth Whelan, of the National Institute for Occupational Safety and Health (NIOSH), nominated this topic for the next monograph based on the following factors. The occupational exposure limit allows a BLL 40 μ g/dL, but health effects are well established at BLLs \geq 10 μ g/dL. Epidemiological evidence has demonstrated health effects <10 μ g/dL. Worker populations include women of childbearing age.

The NTP Board of Scientific Counselors (BSC) expressed unanimous support of a monograph on low-lead exposure. After NTP received public comments on the proposed monograph, the BSC accepted the nomination during its December 2007 meeting and outlined the scope and approach of the evaluation during its May 2010 meeting.

NTP-CERHR is using epidemiological health effects data on BLLs <10 μ g/dL in the evaluation to support the development of the monograph. These data show that health effects at higher BLLs are well established in the literature. CDC's definition of EBLLs is \geq 10 μ g/dL for all age groups. A focus on health effects <10 μ g/dL would provide a weight-of-evidence evaluation in areas with more uncertainty. An expanded scope of the monograph beyond effects on reproduction and development would include cardiovascular, renal and immune endpoints as well as effects of exposure prenatally, during childhood, adolescence or as adults.

The evaluation is designed to address the following questions. What is the weight of evidence for adverse health effects associated with BLLs <10 μ g/dL? What health effects are associated with BLLs <10 μ g/dL? At which life stages (e.g., prenatal, childhood, adolescence or adulthood) are effects identified? Do other biomarkers of exposure exist that are associated with effects (e.g., bone lead)? How do these biomarkers relate to BLLs?

After NTP-CERHR, technical advisors and other experts conduct an internal review of the draft monograph, the document will be released for external public comment. A technical advisory meeting will be convened for NTP-CERHR to present the revised document and responses to external comments. NTP-CERHR will draft recommendations and articulate its level of concern on whether health effects from low-level lead exposures would occur. The final version of the monograph will be released as NTP policy.

Outcomes of the NTP-CERHR monograph on low-level lead exposures are expected to address four significant areas. An evaluation will be provided on epidemiological data on health effects associated with BLLs <10 μ g/dL. Health effects of lead at lower exposure levels will be clarified. Data gaps will be identified for evaluating health effects associated with BLLs <10 μ g/dL. Research recommendations will be developed based on the data gaps.

Previous NTP-CERHR monographs have been influential in the reproduction and development community. NTP-CERHR welcomes input and expertise from ACCLPP during the evaluation of low-level lead exposures. As a result, ACCLPP should designate a member to represent its interests during NTP-CERHR's deliberations on developing the low-level lead monograph.

Dr. Brown confirmed that she and Dr. Rhoads would poll the members via e-mail to identify a volunteer to represent ACCLPP during NTP-CERHR's deliberations on the low-level lead monograph.

Dr. Walter Alacorn is the ACCLPP *ex-officio* member for NIOSH. He suggested that in addition to participating in NTP-CERHR's deliberations on the low-level lead monograph, ACCLPP also should outreach to OSHA. OSHA recently announced that lead is not included in its regulatory agenda at this time and no plans have been proposed to change its lead standard in the foreseeable future. However, ACCLPP should utilize OSHA's existing process to submit comments and data that support the need to revise and update occupational regulations for lead exposure.

Panel Presentation: Update on Housing Codes

Jane Malone

Policy Director, National Center for Healthy Housing ACCLPP Liaison

Ms. Malone presented an update on housing codes. Housing codes provide a minimum standard of care for rental properties and all other types of housing and cover basic structural safety issues. The common gaps in healthy housing codes include relative inattention to moisture and mold, unsafe response to infestation, no focus on lead-safe practices to remediate deteriorated paint, infrequent citing of ventilation safety issues, and unacceptability of technology and testing. Enforceability and enforcement are key factors in the success of housing codes.

The first known housing code was established in 1760 BC. Since that time, housing codes have been developed and implemented at federal, state and local levels in the United States. In 1850 and 1867, Massachusetts and New York City created housing codes for sanitation, windows, roofs and water closets. In 1901, 1941 and 1955, New York City, Baltimore and the Building Officials Code Administrators (BOCA) passed the Tenement House Act, the Baltimore Hygiene of Housing Ordinance, and the first uniform housing code. In 1938, 1952 and 1985, APHA and CDC issued basic housing principles, a model ordinance and minimum housing standards.

"Model codes" are consensus-based standards developed by government agencies. State and local jurisdictions have authority to develop their own codes, but the adoption of model codes has several advantages. Experts gather policy research and conduct screening to develop model codes. In most cases, model codes are equally protective as, but are not stricter than individual local and state policies. Model codes are palatable to elected officials.

The International Code Council (ICC) was formed in 1995 as a result of a merger among BOCA, the Southern Building Council and other groups. The ICC membership of code officials develops, publishes and updates model codes. The National Fire Protection Association (NFPA) coordinates with the American Society of Heating, Refrigerating and Air Conditioning Engineers to develop consensus-based model codes. NFPA uses its own construction and safety code (*i.e.*, NFPA 5000) rather than ICC model codes.

Model housing codes are grouped into three categories. Building construction codes affect building or substantial remodeling of properties. The major model codes in this category are the International Building Code, International Residential Code, International Existing Building Code, and NFPA 5000 and other fire and safety codes. Systems codes affect plumbing, electrical and other housing systems. Property maintenance codes (e.g., housing or sanitary codes) govern the condition of housing, allow rental occupancy and define habitability. The major model codes in this category are the International Property Maintenance Code (IPMC) and the BOCA Uniform Housing Code.

Emphasis should be placed on ICC's IPMC due to several factors. Construction codes do not address conditions after occupancy. Deteriorated paint causes lead hazards, but peeling paint is considered to be "cosmetic" or a "non-priority" issue. However, the EPA Renovation, Repair and Painting (RRP) Rule will make significant changes in this area in the future by addressing the prevention of both lead and non-lead housing hazards. On an annual basis in the United States, EPA estimates that the RRP Rule will affect ~8 million painting and remodeling renovations and will have implications for ~950,000 renovation companies, supervisors and workers.

IPMC addresses key housing-based allergens, such as pests, mold and moisture. However, a mainstream policy is needed for the entire housing stock to focus on primary prevention and fulfill public health goals at both population and patient levels. To date, eight states and 1,000 localities have adopted IPMC.

Efforts have been made recently to improve IPMC in a number of areas: clarification of the role of tenants regarding pests, outside placement of vent dryers, lead-safe work practices (LSWP)

in paint repair, installation of carbon monoxide alarms, cleanable floors, and health and safety standards. During a final action hearing in October 2010, however, decisions by the IPMC Committee on LSWP and carbon monoxide alarms were reversed.

Several activities will be conducted nationwide prior to the next ICC hearing in 2013 to amend IPMC. Healthy homes code officials and advocates will reach consensus and obtain political support for new model codes, such as the development of a workable radon-resistant approach for new construction. Public health agencies, CBOs and advocates will support the enactment and enforcement of policies to address local priorities.

Local code agency staff will be encouraged to collaborate with colleagues in advocating for protective policies at county, state, ICC and NFPA levels. Federal agencies and the National Safe and Healthy Housing Coalition (NSHHC) will regularly communicate with state-level code officials and other groups, provide education to ICC staff and related bodies, and strengthen national and international model codes. The mission of NSHHC is to implement the most promising and realistic recommendations for a National Healthy Housing Action Plan. NSHHC's 90 members represent local and national organizations.

Ms. Malone highlighted several issues that would be important for ACCLPP to consider in its ongoing discussions of issues related to housing codes. Systematic code enforcement (SCE) involves periodic inspections of units beyond the response to complaints by tenants, case managers or public health officials. Public health officials typically inspect the entire housing stock every 3-5 years regardless of whether a complaint has been made.

The SCE process is objective and fair, provides advance notice to property owners of an upcoming inspection, specifies a deadline for property owners to correct problems, and ensures accountability in units that have low turnover of tenants. Fees per unit, fines or a combination of both mechanisms provide revenue for the SCE process. To date, Greensboro, the District of Columbia, and eight local jurisdictions in California, including Los Angeles, have implemented the SCE process.

State and local code agencies can take several actions to play a major role in the enforcement and reinforcement of the RRP Rule. Code agencies that expect compliance with local laws, ordinances or codes could apply these authorities to enforce the RRP Rule. Code agencies could place RRP literature on permit desks or in other prominent locations. Code agencies could require renovators of pre-1978 housing to submit a copy of their renovation certification or their EPA or state certification number along with the building permit application.

During inspections of renovations to pre-1978 properties, code agencies could check for common problems (e.g., no containment, use of power tools without a high efficiency particulate accumulator (HEPA) attachment, use of open flame burning or a heat gun >1,100°F, improper disposal of construction trash, or retention of visible dust or debris at a worksite). Code agencies could make random site visits to identify non-permitted RRP activities in the field (e.g., revonation activity at private properties, work activity at construction sites, large amounts of building materials in Dumpsters, or continuous sounds of power tools and scraping).

Code agencies could require certified firms to submit checklists after permitted renovations are completed, encourage training providers and LPPPs to broadly distribute "renovation tips", and publicize mandated renovation activities at the local level. Code agencies could encourage other local agencies to maintain ongoing communications about renovation activities. Code agencies could perform inspections and take photographs to observe the setup, cleanup and all other aspects of renovation activities.

Many opportunities are available to make an impact on housing codes, including the upcoming ICC hearing in 2013 to change the IPMC as well as enforcement and reinforcement of the RRP Rule. Moreover, HUD is exploring the possibility of adopting the United Kingdom Housing Health and Safety Rating System, advancing integrated pest management efforts, implementing green initiatives in subsidized housing, and updating property standards. NSHHC has formed a Standards Workgroup to identify model codes that ICC and other bodies should consider on a systematic basis.

Doug Farquhar, JD

Program Director for Environmental Health National Conference of State Legislatures

Mr. Farquhar presented an overview of an ongoing healthy housing code project. NCHH and the National Conference of State Legislatures (NCSL) are jointly conducting the project to identify aspects of building codes that address health. The project focuses on landlord-tenant laws (e.g., the Uniform Residential Landlord Tenant Act and the Property Maintenance Code), but will be expanded in the future to include more healthy housing code issues in other areas. Local building departments enforce building codes for insurance companies and state agencies, but the codes are designed to protect buildings rather than individuals.

At the state level, North Dakota is the only state without regulatory language on landlord-tenant duties, 12 states have developed health or housing codes, two states have adopted IPMC, six states require legislative action to revise their codes, five states amend their codes via regulation, and California may use either legislative action or regulation to revise codes.

Minnesota passed a law to ensure compliance with its state building code. Municipalities must verify lead certification qualifications of the licensee when issuing permits to residential building contractors who submit applications to perform renovations on pre-1978 housing. At the local level, many jurisdictions will not release building permits without RRP certification.

Beth McKee-Huger

Executive Director, Greensboro Housing Coalition

Ms. McKee-Huger described a local model that is being implemented to strengthen housing codes in Greensboro, North Carolina. The Greensboro Housing Coalition (GHC) is a community-based non-profit organization that advocates for safe and affordable housing. Because GHC has no legal authority or funding to enforce housing codes, advocacy is the most important factor in these efforts. GHC utilizes the Rental Unit Certificate of Occupancy (RUCO)

that requires all rental units in the Greensboro city limits to be inspected and certified to meet IPMC standards prior to rental.

RUCO is valid throughout the life of a property unless the certificate is revoked for violations that have not been corrected within 45 days of a repair order. Local data collected from a random sample show that 2% of certified units are re-inspected each year. Substandard housing cases have declined by 77% in the seven years since the Greensboro City Council passed the RUCO ordinance. Moreover, RUCO enforcement has been instrumental in dramatically decreasing the number of housing complaints and substandard units in Greensboro from the time periods of 2003-2004 to 2009-2010. Landlords were given a five-year period from January 2004-January 2009 to certify their properties.

RUCO does not specifically address RRP requirements, but several aspects of the ordinance focus on lead safety to promote healthy homes. Most notably, deteriorating paint is a code violation. Plumbing and leaking roofs are code violations due to their contributions to paint deterioration. RRP methods are encouraged to promote healthy housing maintenance and reduce or eliminate factors that contribute to lead hazards (e.g., moisture, mold, mildew or pest infestation).

Prior to Greensboro's enforcement of RUCO, property inspections were reactive rather than proactive, complaints were limited to deplorable housing conditions, and the enforcement process was lengthy and ineffective. Inspections of residential properties were conducted only when owners or residents issued complaints; signed and submitted petitions typically as a result of exterior problems; inspectors identified a probable cause typically as a result of exterior problems; or local government officials from fire, police, health or tax departments issued complaints.

Greensboro issued only two types of penalties for code violations prior to its enforcement of RUCO. The "repair or close" order targeted condemned vacant properties that needed repeated monitoring. The "repair or demolish" order targeted properties that virtually had been abandoned over many years. However, this order was complicated by legal and practical problems in demolishing properties due to the potential to correct violations. Greensboro achieved a compliance rate of only ~10% to the two types of repair orders.

To address these problems, Greensboro designed RUCO to increase compliance with housing codes. RUCO is a proactive inspection that acknowledges emerging problems and promotes preventive maintenance. The requirement of RUCO for rental properties provides a positive incentive for maintenance. The revocation of RUCO rather than demolition is a proportionate penalty to non-compliance. Orders by inspectors typically achieve prompt adherence to the 45-day deadline to correct violations. Most property owners comply with RUCO prior to an inspection.

The timeline of developing, enacting and modifying RUCO in Greensboro is summarized as follows. In 2002, the Greensboro City Council asked code enforcement agencies to identify solutions in response to GHC's presentation on substandard housing. In 2003, city inspection staff proposed RUCO and the City Council unanimously approved advocacy efforts by GHC and

the Greensboro Neighborhood Congress to support the ordinance. In 2004, RUCO inspections were initiated and a requirement was added for tenants to give permission for inspections in writing.

In 2007, the City Council amended RUCO to allow sampling of multi-family properties with >50 units. In 2008, the Apartment of Association of North Carolina introduced state legislation to prohibit RUCO inspections, but the proposal was defeated. In 2009, the City Council eliminated the five-year re-inspection requirement and added a new requirement of 2% annual sampling. In 2010, property owners organized an effort to eliminate the requirement of RUCO certification, but this proposal was defeated.

Greensboro has been collecting anecdotal information from landlords since RUCO inspections were enacted in 2004. For properties in generally good condition, landlords typically address any maintenance issues before the inspector arrives to prevent delayed maintenance. However, some of these landlords believe "they are not the problem" and have complained about devoting their time to accompanying inspectors to each unit.

For properties with a long history of code violations, landlords have emphasized that significant investments would be needed to remediate properties to meet minimum standards. Some landlords welcome the opportunity to contribute to mainstream inspection efforts as opposed to being identified as "part of the problem." Most notably, the landlord of the largest number of substandard units in Greensboro that caused serious lead poisoning to a child is now an enthusiastic supporter of RUCO.

Ms. Jacqueline Mosby is the ACCLPP *ex-officio* member for EPA. She noted that the RRP Rule was frequently mentioned during the panel presentation on housing codes. Before Dr. Rhoads opened the floor for ACCLPP's discussion, she provided an update on the RRP Rule. Since EPA finalized the RRP Rule in April 2008, 412 training providers have received RRP accreditation and 516,000 persons have received LSWP training in 23,000 courses.

ACCLPP thanked the panel of speakers for presenting overviews of successes, challenges and future directions in housing codes that contribute to childhood lead poisoning prevention at federal, state and local levels. The members made suggestions in two key areas on ACCLPP's potential role in advancing these efforts.

ACCLPP should explore strategies to play a role in enhancing enforcement of the RRP Rule, encouraging a larger number of building inspectors to comply with RRP requirements, and increasing public awareness of the RRP Rule. For example, ACCLPP members could inform their state and local constituents to report EBLLs in children that were caused by RRP violations in large multi-family properties. The ACCLPP members could then compile this feedback and advise CDC and EPA to publicize contractors of large properties with RRP violations on their websites.

ACCLPP should send a letter to the HHS Secretary that expresses two key points. First, ACCLPP fully supports using the RRP Rule as a mechanism to widely publicize ongoing healthy homes/lead poisoning prevention efforts. Second, ACCLPP endorses using the RRP Rule to

deliver messages to the public regarding housing-based lead hazards to children when renovation contractors do not follow RRP requirements.

Public Comment Session

Michael Schock, MS, BS

Chemist, Drinking Water Research Division U.S. Environmental Protection Agency

Mr. Schock made the following comments for the record. Because plumbing inspections of residential properties typically are limited to leaks and cross-connections, plumbers need to be educated on the health impacts of plumbing codes. Most notably, exterior lead pipes left in the ground and interior lead reservoirs in galvanized pipes left in the home are preventable sources of lead exposure.

Because these lead sources have not been adequately addressed to date, drinking water regulators continue to be challenged by enforcing corrosion control of central water treatments to protect against lead exposure. ACCLPP should discuss sources of lead in residential drinking water at a future meeting as an initial step in promoting healthy homes interventions in this area.

Craig Boreiko

Environment and Health Manager International Lead Zinc Research Organization

Mr. Boreiko made the following comments for the record. During the CERHR overview, Dr. Rogan stated that the occupational exposure limit allows a BLL of 40 μ g/dL. However, the OSHA value for occupational exposure to lead is actually a BLL of 50 μ g/dL. A BLL of 40 μ g/dL is a voluntary industry standard.

The ACCLPP ad hoc group is to be commended for reviewing data from other countries to consider a new "BLL of concern" in the United States. The literature review by the new ACCLPP BLL Workgroup should include a review of a recently published paper by Dr. David Bellinger on the state of the epidemiology of environmental neurotoxicants.

The paper notes flaws in the current state of the science in this area due to the lack of consensus on study designs and study analyses. The paper emphasizes the critical need to build consensus on standards to design studies and analyze data on the affects of environmental neurotoxicants. The workgroup will be extremely challenged in attempting to identify a new BLL of concern that will be scientifically defensible with consensus.

David Jacobs, PhD, CIH Research Director National Center for Healthy Housing

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Dr. Jacobs made the following comments for the record. During the previous discussion on national performance measures of blood lead in U.S. children, Dr. Brown emphasized the need to link housing and health surveys that are administered in the United States. Dr. Brown is to be applauded for her successful efforts in collaborating with HUD to pilot five new health-related questions in the American Housing Survey (AHS).

Data that will be collected from the five pilot questions will be extremely powerful for the field. For example, EPA has greatly benefited from a recently published dust lead study with NHANES data to inform its regulatory decision-making on revising the current dust lead standards. CDC should explore the possibility of incorporating environmental or biometric sampling into AHS. AHS is administered to ~50,000 housing units every two years and is a much larger sample than NHANES.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 4:48 p.m. on November 17, 2010.

Opening Session: November 18, 2010

Dr. Brown reconvened the meeting at 9:00 a.m. on November 18, 2010. She opened the floor for introductions and confirmed that the ACCLPP voting members and non-voting *ex-officio* members in attendance constituted a quorum.

Dr. Brown reminded the ACCLPP voting members of their responsibility to recognize potential conflicts of interest and recuse themselves from participating in discussions or voting on issues for which they have a real or perceived conflict of interest.

Panel Presentation: Federal Healthy Housing/Lead Poisoning Prevention Activities

Christopher Portier, PhD

Director, National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry Centers for Disease Control and Prevention

Dr. Portier provided an overview of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) environmental public health (EPH) portfolio. The mission of NCEH/ATSDR is to serve the public through responsive public health actions to promote healthy and safe environments and prevent harmful exposures. The vision of NCEH/ATSDR is "safer, healthier people in a safer healthier environment." After assuming his position as the new Director of NCEH/ATSDR in August 2010, Dr. Portier established an additional broader vision for NCEH/ATSDR of "building a sustainable healthy nation through comprehensive environmental public health."

The U.S. Blood Lead Surveillance Report showed a dramatic decrease in confirmed EBLLs in children from 1997-2007 and represents one of the most significant achievements in EPH. CDC's leadership and ACCLPP's expertise have been instrumental in demonstrating the critical role of public health in preventing disease and illness by reducing lead exposures to U.S. children. The NCEH Asthma Program has not been as successful as the Lead Program. The number and rate of hospital discharges for asthma cases have not dramatically changed from 1980-2004 despite improvements in air quality in numerous communities throughout the United States.

Maslow's Hierarchy of Human Needs is an appropriate model to analyze the complex nature of and association between the environment and human health needs. The first level represents basic needs that humans need to survive: air, food, water and shelter. The first level is interconnected with the remaining three levels of the model: safety and security, community factors and personal factors. Studies have shown that all four levels impact public health.

The environment (e.g., air, water and soil quality, weather and ecosystems) has a direct effect on human health (e.g., physiological, security, personal and endogenous factors). Because environmental exposure to lead impacts human health, Dr. Portier has established a goal for NCEH to conduct more comprehensive evaluations that extend beyond lead in particular communities and homes.

The 2006 Gohlke and Portier study showed that the environment affects various human systems, including molecular, intercellular, respiratory, reproductive development, nervous, and gastrointestinal systems. The impact of the environmental on human systems leads to diseases and changes in human health. All aspects of the environment play a role in overall human health, such as the solar system, ecosystem, land, water, climate, air and social factors (e.g., the built environment, economics, family and the government).

Dr. Portier was pleased that NCEH/ATSDR has strong capacity and expertise to achieve the additional vision of building a sustainable healthy nation through comprehensive EPH. The Human Clinical Laboratory conducts human clinical studies and analyzes tissue samples to better understand and measure exposures and their effects. NCEH/ATSDR's other initiatives that are targeted to human systems include epidemiology groups, the Asthma Program, NCEH laboratories, multiple disease registries, toxicological profiles to guide Superfund site cleanup, and training and outreach.

NCEH/ATSDR's initiatives that are targeted to the relationship between the environment and human systems include HHLPPB, the Climate Change Program, health consultations and assessments, built environment activities, and the Environmental Health Services and Tracking, Vessel Sanitation, Air Pollution, and Chemical Weapons Elimination Programs.

Dr. Portier thanked the ACCLPP members for continuing to contribute their valuable time and expertise to assist CDC in improving its EPH portfolio to further enhance public heath in the United States. He urged ACCLPP to expand its focus beyond lead to include healthy homes. Aspects of the NCEH Lead Program can result in improved evaluation and better understanding

of the overall health of children in their homes. He then encouraged ACCLPP to broaden its healthy homes focus to analyze the impact of an entire community on a particular home.

Maria Doa, PhD

Director, National Program Chemical Division Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency

Dr. Doa presented an overview of recent developments in the EPA Lead Paint Program. At the international level, EPA, CDC and other federal partners are collaborating with WHO and the United Nations Environment Programme to promote the phase-out of the manufacture, sale and use of lead in paints in South Asia, Africa and China.

At the domestic level, EPA is currently conducting several regulatory and non-regulatory activities to further reduce lead poisoning in the United States. EPA issued the final RRP Rule in April 2008 to address lead-based paint hazards created by RRP activities that disturb lead-based paint in "target housing" and "child-occupied facilities." The RRP Rule requires renovators to take action in three major areas to minimize exposure to residents during and after renovations.

Renovations in target housing and child-occupied facilities that will be performed for compensation must be completed by certified firms. Renovators and other trained workers must be trained in LSWP by an EPA-accredited training provider. Renovators must use LSWP and follow three simple procedures: contain the work area, minimize dust and thoroughly clean the area. EPA may authorize states, territories and tribes to administer and enforce their own RRP programs.

Of 412 training providers EPA has accredited as of November 4, 2010, 242 are accredited to provide training in multiple states. Training providers have conducted >23,714 courses. EPA estimates that 516,000 persons have been trained to use LSWP under RRP. At this time, nine states are authorized to implement RRP programs: Iowa, Kansas, Massachusetts, Missouri, North Carolina, Oregon, Rhode Island, Utah and Wisconsin.

EPA included an opt-out provision in the final RRP Rule on July 6, 2010 that allows owneroccupants of target housing to "opt-out" of the rule if no children <6 years or age or pregnant women live in the property and no children <6 years of age are regularly present at the property. EPA issued a proposal on April 22, 2008 requiring renovation firms to conduct dust wipe testing after multiple renovations and provide testing results to owners and occupants of the building. For some renovations, the proposal also would require dust lead levels after the renovation to be below regulatory hazard standards. EPA closed the public comment period on the proposal on August 6, 2010 and expects to take final action on the proposal by July 2011.

EPA issued an Advance Notice of Proposed Rulemaking in April 2010 announcing its intent to apply LSWP to renovations of both interiors and exteriors of public and commercial buildings. The notice also announced EPA's investigation of lead-based paint hazards that may be created by renovations on the interiors of these buildings. EPA accepted public comments on

the notice through July 6, 2010 and is currently developing a proposed rule on exteriors of public and commercial buildings. EPA intends to issue the proposal in December 2011.

EPA issued a final rule on its residential lead dust hazard standard in August 2009, but a petition was submitted in August 2009 to review this standard. EPA consulted with its Science Advisory Board (SAB) in July 2010 to obtain independent expertise and will convene a follow-up meeting with SAB in December 2010 for further review. EPA is scheduled to release the Notice of Proposed Rulemaking on the lead dust hazard standard in January 2012. EPA consulted with SAB in July 2010 on its dust hazard standard for public and commercial buildings and will convene a follow-up meeting with SAB in December of SAB in December for further review. EPA may initiate rulemaking depending on the outcomes of SAB's deliberations.

EPA, HUD, the Ad Council and National Coalition to End Childhood Lead Poisoning (NCECLP) are jointly sponsoring the Lead Poisoning Prevention Campaign. CDC has provided extensive technical assistance and expertise to support this effort. The campaign targets lead poisoning prevention messages to consumers, particularly parents and caregivers of children <6 years of age. The objective of the campaign is to distribute information to the target audience on protecting their families from lead-based paint hazards. To ensure broad access to the information, the multimedia campaign includes print and web-based materials, television and radio public service announcements (PSAs), a website at <u>www.leadfreekids.org</u>, and a toll-free hotline.

On April 20, 2010, PSAs were distributed to >33,000 media outlets nationwide. Television and radio PSAs were customized for 35 state and local organizations in 72 designated market areas. Preliminary data from monitoring reports indicate that the messages reached >56.5 million persons in the two weeks following the launch of the campaign. The Ad Council secured nearly \$6.5 million in donated media support in the second quarter of 2010. The lead poisoning PSA is broadcast in both English and Spanish. Media stations were reminded in September-October 2010 to again incorporate the lead poisoning prevention PSAs into their broadcasts in recognition of National Lead Poisoning Prevention Week on October 24-30, 2010.

EPA launched the Lead RRP Outreach Campaign with national radio PSAs and print and webbased materials in English and Spanish to increase awareness of the rule among renovation contractors and also to empower consumers to demand LSWP during renovations of their properties. EPA collaborated with its state partners to engage permitting organizations and unions as a secondary target audience.

The key features of the campaign include the "Renovate Right" flier that was updated to be consistent with the most recent regulations. The "Consumer Sell Sheet" flier was given to contractors to provide to their clients. The "Contractor Sell Sheet" flier informed contractors of the advantages of receiving lead-safe renovation training and obtaining certification for their firms. PSA trade advertisements, postcards, web banners and buck slips were used to educate contractors about the RRP Rule.

Full-page advertisements targeted to consumers were published in several national magazines. A tri-fold pamphlet was specifically designed for property managers, hospitals and schools.

EPA's analysis of the RRP Outreach Campaign showed that to date, major newspapers have accounted for 53 million impressions, 13 million impressions have occurred among consumers, the e-mail mass mailing has surpassed the government average, and >250,000 persons have visited the <u>www.epa.gov/getleadsafe</u> web page.

Jon Gant, JD

Executive Director, Office of Healthy Homes and Lead Hazard Control U.S. Department of Housing and Urban Development

Mr. Gant presented an overview of HUD's ongoing activities and future directions for healthy homes/lead hazard control. HUD is currently redesigning its strategic plan with new goals and objectives. One of HUD's five strategic goals is to utilize housing as a platform to improve health. Most notably, zip codes are a strong predictor of a child's health status over time. A reduction in the severity and prevalence of asthma is a significant goal for HUD. As a result, HUD intends to propose an Advanced Notice of Rulemaking in the near future to make assisted public housing smoke free.

HUD data show that ~33% of residents in public housing are smokers and spend 10%-15% of their average annual incomes of <\$20,000 on cigarettes. Smoking in public housing is much higher than the national average and regularly exposes 40% of U.S. children in these settings to secondhand smoke. HUD is currently collaborating with public housing authorities in several jurisdictions to develop an implementation plan to make public housing smoke free, but support and assistance will be needed at other levels to successfully enforce a smoking ban.

At the federal level, CDC, EPA and other agencies would need to collaborate with HUD in developing a cost-benefit analysis to make a strong and evidence-based case for banning smoking in public housing. At the grassroots level, CBOs, advocates and groups of residents would need to demand that Public Housing Resident Councils appeal to HUD to ban smoking in their buildings.

The reduction of health hazards in homes continues to be one of HUD's most significant national priorities. As an initial step in achieving this goal, HUD agreed to pilot five new health-related questions in the American Housing Survey that were proposed by CDC.

HUD's current healthy homes/lead hazard control budget is ~\$140 million (or \$100 million for lead grants and \$40 million for healthy homes grants) and is expected to remain stable in the near future. HUD's 271 healthy homes/lead hazard control grants total ~\$600 million at this time. Due to strong competition, grantees must demonstrate tremendous success in order to continue to receive funding. Of 120 applications HUD received for lead hazard control and lead demonstration projects for the most recent funding cycle, grants will be awarded to only ~33 applicants.

HUD formed the Healthy Homes Workgroup with CDC, EPA and other federal partners to propose strategies and identify barriers to improving healthy homes/lead hazard control activities in the United States. The federal partners emphasized the need to leverage funding from the large \$5 billion weatherization budget that was established with American Recovery

and Reinvestment Act dollars. Because homes with health-related issues typically are not candidates for weatherization, the federal partners have expressed their strong support of using a portion of these resources to allow HUD to fully address and correct healthy homes aspects prior to weatherization.

The Healthy Homes Workgroup is attempting to harmonize various measures that federal agencies use to address health-related issues in housing. To overcome this barrier, the workgroup developed and submitted a legislative proposal that would allow for standardization across agencies. The proposal calls for grantees of weatherization, healthy homes or other types of programs to be able to use a certain dollar amount or percentage of their federal grants in the field, regardless of the funding agency, to correct health-related problems in housing. The Office of Management and Budget (OMB) was receptive to the legislative proposal.

The Healthy Homes Workgroup developed a strategic plan for all agencies that currently is undergoing the OMB clearance process. The workgroup also is addressing comments submitted by the Department of Defense and the Department of Veterans Affairs. HUD is a member of the Presidential Task Force on Environmental Health Risks to Children and cochairs two of the three priority areas: asthma and healthy homes.

HUD and NCECLP are jointly piloting the National Green and Healthy Homes Dialogue in 15 cities and tribes to compile best practices, barriers and recommendations on implementing housing interventions that efficiently integrate lead hazard control, energy efficiency, weatherization and healthy homes concepts. Outcomes from the pilot will be used to scale-up the project at the national level and leverage funding from philanthropic organizations. HUD will convene its national conference in June 2011 and expects participation by ~3,500 persons. HUD will use the conference as an opportunity to describe the current status and future directions of healthy homes/lead hazard control.

ACCLPP thanked the panel of federal leaders for presenting ongoing activities and strategic directions of their agencies in healthy homes/lead poisoning prevention. ACCLPP commended Dr. Portier on developing a new and innovative vision for CDC to focus on hazards in the environment as a whole. ACCLPP also was pleased that the federal interagency Healthy Homes Workgroup is attempting to use a portion of weatherization dollars to address health-related issues in housing.

ACCLPP and CDC expressed strong support of HUD's efforts to ban smoking in public housing. Most notably, Mr. Dana Williams, Sr. is an ACCLPP member and a single parent of a leadpoisoned child. He pointed out that children with asthma who live in public housing miss a large number of school days because their conditions are exacerbated by secondhand smoke. Mr. Williams informed HUD that public housing residents across the country would welcome the opportunity to launch a grassroots effort to advocate for HUD's proposed smoking ban in public housing.

Panel Presentation: State of the Science of Lead in Water

Marc Edwards, PhD

Charles Lunsford Professor of Civil Engineering Virginia Tech

Dr. Edwards presented data to demonstrate the public health concern of elevated lead levels in water. EPA enacted the Lead and Copper Rule (LCR) in 1991 to protect consumers from exposure to elevated lead and copper levels at the tap. At that time, EPA estimated water accounted for 5%->50% of children's total lead exposure and >85% of blood lead in infants who depended on reconstituted formula.

LCR requires water facilities to treat drinking water to minimize its ability to corrode lead pipes and also to monitor drinking water in residential homes by capturing worst-case lead levels at the tap under normal water use conditions. LCR requires 90% of tested homes in a city to have lead in water <15 ppb, but up to 10% of tested homes are allowed to have taps that dispense any amount of lead. If >10% of sampled homes test above the action level of 15 ppb, water utilities are required to take additional measures that may include performing source water treatment, optimizing corrosion control, educating the public, and replacing the lead service line.

LCR has been extremely effective as a low-cost community-based intervention to reduce exposure to lead in water. However, modifications are needed because LCR is not effective in preventing individual exposures to high levels of lead in water. Available data, current knowledge and existing data gaps on lead in water were compiled in a paper that was distributed to ACCLPP for review.

If lead dust standards were modeled after the current LCR standard, landlords would be given responsibility for collecting and submitting dust samples for analysis. Instructions could be added to federal sampling protocols at will, including wet mopping surfaces to be tested for five minutes the evening before samples were collected.

A U.S. city with the most cases of lead-poisoned children used the following sampling procedure in 2005 to test lead and copper in water. The screen aerator and any other faucet attachments were removed. The index finger was used to probe the mouth of the faucet to reveal and remove any lead particulate matter. The cold water faucet was flushed for 5-6 minutes. The aerator was left off until the sample was collected six hours later.

Cold water was sampled based on the first draw from the faucet. Valves were slowly opened to a low or medium flow during sampling. Fast, rushing water was not used for sampling. Each of these instructions could be added to the federal protocol for sampling water and would overlook the presence of lead hazards.

In terms of sampling if lead dust standards were modeled after the current LCR standard, landlords would be allowed to discard collected samples for any reason at will prior to analysis without disclosure. In terms of compliance if lead dust hazard standards were modeled after the

current LCR standard, federal regulations would require sampling of only 100 high-risk homes built before 1950 even in New York and other major cities. If \leq 10% of these homes exceeded the standard by any amount, the entire city would be informed that lead dust was not a problem.

In terms of public health interventions if lead dust standards were modeled after the current LCR standard, landlords would be required to partially replace lead paint in 7% of homes in the city annually when >10% of sampled homes exceeded the federal lead dust standard. A procedure that is known to sometimes increase consumer lead exposure for an undetermined duration could be used at a cost of thousands of dollars with no evidence the intervention would ever reduce consumer exposure to lead. In environmental assessments of lead-poisoned children, CDC would recommend sampling of lead dust in the child's home only if >10% of homes in the city exceeded the federal dust lead dust standard.

The Safe Drinking Water Act banned 100% pure lead pipes and pipes with 50% lead solder by weight. However, if lead paint standards were modeled after the current LCR standard, unenforceable "voluntary standards" for manufacturing lead paint would allow paint with effectively 18% of lead by weight to be used in new buildings. Congress would define paint with up to 8% lead content to be "lead free."

The University of North Carolina-Chapel Hill recently published a study in response to an investigation of lead contamination in new buildings in Chapel Hill, North Carolina that were linked to brass ball valves. The investigation was initiated because sampling determined that the water supply in new buildings contained 300 ppb of lead, but the problem could not be remediated. Ball valves that were legally installed in plumbing systems of the new buildings were found to contain as much as 18% of lead by weight on inner surfaces in contact with drinking water. The ball valves were extracted from the plumbing systems at a cost of \$30,000.

If lead dust standards were modeled after the current LCR standard, a maximum allowable lead dust level could not be enforced in any jurisdiction in the United States. Even in cities that meet LCR requirements, lead from different taps widely varies and allows a significant proportion of the population to be exposed to higher levels of lead in water. Data were gathered from thousands of samples collected from a large city over many years to demonstrate the percent distribution of lead in water samples. Lead in water in the city was 10 ppb at the 90th percentile, 70 ppb at the 99th percentile, and 1,717 ppb at the 99.9th percentile. Recent data from this city showed a 30% increase in the incidence of lead in water >15 ppb.

If lead dust standards were modeled after the current LCR standard, public education initiatives would deliver messages for reducing exposure to consumers living in cities in which 14% of sampled homes exceeded lead dust standards. Consumers also would be informed that results do not pose a health threat because elevations observed in the city's recent tests were too small to pose clear health threats. The New York City Department of Health and Hygiene published this message in *The New York Times* when the city exceeded the EPA action level for lead in water in November 2010. Despite exceeding the lead action level, the Commissioner of the New York State Department of Environmental Protection stated that the city's water was "safe and healthy to drink."

The level of lead in water that would pose a health concern is uncertain. The 2009 Edwards, *et al.* study showed that with continuous exposure to lead in water at a level of 15 ppb, the predicted geometric mean BLL would be 5.4 μ g/dL for an infant using formula at 1 year of age and 5% of infants would have BLLs >10 μ g/dL. In terms of acute heath effects, the 2004 International Commission on Radiological Protection model showed that a child 4 years of age with one-time exposure to one eight-ounce cup of drinking water would have a BLL >15 μ g/dL at 5,000 ppb and a BLL >50 μ g/dL at 20,000 ppb. The level of lead in an eight-ounce cup of drinking water at 20,000 ppb is equivalent to 14 penny-sized paint chips with 1% lead content.

The EPA website previously informed the public that lead at concentrations \geq 40 ppb would pose imminent and substantial endangerment to the health of children and pregnant women, but this guidance was removed in 2004.

At the federal level, CDC assumes EPA is addressing lead in water and EPA assumes CDC would notify the agency if lead in water posed a public health concern. At the local level, water utilities and consultants generally disavowed any connection between LCR and public health during EPA's LCR stakeholder meeting in November 2010. Assumptions by the federal agencies and the flexibility given to water utilities in collecting samples and decoupling samples from actual human exposure are extremely problematic in protecting the health of children.

Of all cities in the United States, Chicago has the highest number of lead-poisoned children and the highest incidence (*i.e.*, 98%) of 100% pure lead service lines. A 1993 *Consumer Reports* article reported that >17% of first-draw samples from homes in Chicago had lead in flushed water >15 ppb, but testing by the Chicago Department of Water showed only 3% of first-draw samples had lead levels >15 ppb. EPA never fulfilled its commitment that was made in 1993 to conduct a special investigation of the lead in water problem in Chicago.

The University of North Carolina-Asheville performed consumer sampling through 2008 and found continued problems with lead levels in water in Chicago. Virginia Tech was awarded research dollars to perform free lead-in-water sampling in the homes of lead-poisoned children in Chicago, but the Chicago CLPPP has been uncooperative in providing assistance to collect samples.

Efforts are underway to better understand reasons for the high incidence of lead poisoning in Chicago and other cities. To calculate a national lead poisoning index relative to at-risk housing, CDC data were gathered on the number of children with confirmed EBLLs in cities and states in 2005 (the numerator) and the number of pre-1950 housing units in cities and states per thousand (the denominator).

Based on this calculation, the U.S. average of EBLL rates would have been 2.1 in 2005 with median lead service line use of 0%. The EBLL rate in Chicago would have been 11 in 2005 (or 529% higher than the U.S. average) with lead service line use of 98%. Chicago still had the highest EBLL rate when the calculation was performed with pre-1950 housing and children in poverty. The calculation also demonstrated an association between high lead service line use and high EBLL rates in other cities.

Overall, LCR has been a solid and low-cost approach to reducing exposure of the overall population to lead in water, but this intervention is not designed to eliminate individual cases of water lead poisoning. A proposal was submitted to CDC with strategies to modify LCR to address key concerns. The scientific community would greatly appreciate ACCLPP's formal recommendation to CDC to publicize a clear message that lead in water can be a significant public health concern. ACCLPP should further advise CDC to identify a level of lead in water (e.g., 15, 40 or 100 ppb) at which unambiguous public health warnings would be issued with no caveats that unfiltered tap water would be unsafe to drink.

Michael Schock, MS, BS

Chemist, Treatment Technology Evaluation Branch Water Supply and Water Resources Division U.S. Environmental Protection Agency

Mr. Schock presented data to demonstrate the public health impact of lead corrosion in water systems. Lead corrosion occurs in lead 2 and lead 4 ion states. The majority of the historical lead corrosion literature focuses on the lead 2 state. Lead can be released in either particulate or soluble forms, but non-control of the lead 4 state would result in endemic high lead exposure from soluble lead.

Foreign deposits that are often on lead pipe surfaces can impede the effectiveness of treatment, but several cities (e.g., the District of Columbia and Oakwood and Cincinnati, Ohio) have installed pipes in their water systems to achieve stable and low levels of lead. Lead occurs in different parts of plumbing systems and is not uniformly distributed.

The Lead Contamination Control Act banned the use of pipes with 50% lead solder, but brass devices that contain variable amounts of lead are still permitted. At this time, 75%-80% of water utilities form lead 2 carbonates and hydroxycarbonates. Lead 2 orthophosphates with low solubility are the basis for the preponderance of lead corrosion control, while hydroxycholorides and hydroxysulfates have high solubility and increase the difficulty in controlling lead release. Lower carbonate levels account for lower solubility.

Phosphate treatment has been effective in the United Kingdom and in water utilities in the United States. Phosphate solids are far less soluble than lead 2 carbonate solids at lower pH ranges. Phosphate solids are less likely to form at higher pH ranges and become more soluble. Depending on the carbonate concentration, the minimum point of solubility for phosphates ranges from pH 7.2-7.8. Many water systems have pH ranges >9.5, but solid research has not been conducted in this area to date.

The ability of phosphates to prevent lead corrosion depends on carbonate and phosphate dosages. The effectiveness of phosphate concentrations to substantially improve lead releases changes depending on the amount of carbonate. For example, low carbonate concentrations in water of 1-2 ppm would yield a minimal return on the investment in phosphate treatment. Standing water in pipes causes an increase in lead concentrations, but this condition is reversible.

Lead solder corrosion is a complex function that is caused by factors other than lead solubility, including galvanic corrosion of copper joints. Leaded brass corrosion varies with water chemistry and time. Dissolved lead accounts for the minimum level of contamination in water. The removal of all lead pipes in the homes of consumers does not fully eliminate lead exposure caused by erratic particulate releases that remain in the plumbing system. The adjustment of pH and carbonates is the most successful treatment strategy central water utilities can use to reduce water lead levels.

Pipe sampling under LCR covers the first liter of lead service lines and provides an aggregated gross average of accumulated lead sources. Because diagnostic encroachment control sampling of the first liter of lead service lines does not always detect all sources of lead, sequential sampling should be performed in terms of distance to identify lead sources.

CDC, its partners and grantees should consider taking the following actions to better address lead corrosion in water systems. More studies should be conducted to assess the association between lead exposure patterns of children and plumbing systems in single and multi-family dwellings. The relative merits of different sampling programs should be characterized to identify sources and risks and determine programs that are most protective of public health.

Collaborative efforts should be established with EPA and the plumbing industry to conduct research on potential long-term health impacts of metal lechates from newly-emerging materials that will replace brass devices. Reference materials should be created and training should be offered to researchers and public health practitioners in the field to strengthen capacity in sampling lead in drinking water and assessing threats from lead in water.

Unambiguous and clear documentation should be produced to promote a strong rationale in the public health community to address adverse health effects from lead in drinking water. Health expertise from CDC-funded LPPPs should be leveraged to implement scientifically-based voluntary and involuntary standards for devices and materials used for the storage and conveyance of drinking water. Existing best practices for the reduction and eventual elimination of lead contamination should be scaled at the national level in Healthy Homes and Lead-Free Environment Programs, including the adoption and integration of national model plumbing codes.

CDC also should consider conducting the following activities to improve LCR. A narrative and documentation should be developed outlining state-of the art technology that can be used for EPA to increase current health protection levels and create a health-based drinking water standard. Expertise should be leveraged from other programs to investigate strategies to achieve a practical national approach to remove remnant lead pipes regardless of ownership.

Technical assistance should be provided to EPA to develop the most effective risk communication materials and appropriate monitoring requirements for consumers who are exposed to voluntary lead service line replacement. Risk communication and public education materials also should be designed to inform consumers of the importance of investing in lead service line replacement to reduce lead risks from plumbing systems.

Technical expertise should be provided to EPA to pursue innovative regulations and control strategies focusing on new designs of plumbing products with less lead content and new approaches to remove existing lead pipes (e.g., mandatory disclosure of lead pipes in real estate transactions). Active and ongoing participation in materials standards development workgroups (e.g., NSF International) should be maintained to provide expertise on improving existing standards and developing better standards in the future.

Collaborative efforts should be established with EPA researchers to broaden the existing audience of CDC's lead in drinking water research portfolio to have a greater impact. Water utility managers, water treatment regulators and other decision-makers typically do not read journals that publish CDC's studies on lead in drinking water.

David Jacobs, PhD, CIH

Chair, DC Lead and Healthy Homes Advisory Committee Research Director National Center for Healthy Housing

Dr. Jacobs presented a different perspective on examining the role of lead in water on lead poisoning prevention. Lead is characterized as a public health success story, but lead actually is a "pyrrhic victory" due to tremendous challenges that need to be addressed. Of the 20 leading risk factors that contribute to the global distribution of the burden of disease, WHO ranked lead as 16th in disability life-years in 2002. However, this ranking was based on blood pressure and mild retardation only and most likely underestimated the burden.

The 1992 Smith and Flegal study analyzed natural background BLLs. The mean national BLL in children decreased from <3 μ g/dL in 1994 to <2 μ g/dL in 2002. However, the mean national BLL is still 100 times higher than the background BLL of 0.016 μ g/dL. Large sources of lead exposure still remain and have not been addressed to date.

Recent developments in lead poisoning prevention in the District of Columbia include enforcement of a new primary prevention lead law that mandates dust lead testing before children can occupy homes. The District of Columbia also developed and distributed its Lead and Healthy Homes Strategic Plan; convenes quarterly meetings with all DC agencies that have responsibility for enforcing the lead law; and holds monthly advisory committee meetings in response to a strong request by CDC.

The District Department of the Environment regularly meets with water advocates. Moreover, the District of Columbia has greatly improved its data to provide a more accurate picture of the total number of children <6 years of age who receive blood lead testing in each ward and the total number of children tested with BLLs \geq 10 µg/dL.

Research has been funded over time to ensure that lead in water is not ignored or minimized (e.g., pooled research on dust analysis, the lead in dust study, studies on lead sources and HUD guidelines). However, clarity is needed on EPA's authority in addressing lead in water. HUD funded a study on environmental lead exposure in Rochester, New York in the early

1990s. Water lead was statistically significant and was responsible for a substantial percentage of BLLs in children 6-24 months of age.

A second HUD-funded study on environmental lead exposure showed that both dust lead and water lead levels were important variables in contributing to children's BLLs. A third HUD-funded study on environmental lead exposure pooled and analyzed 12 epidemiologic studies to determine the contribution of lead-contaminated house dust and residential soil to children's BLLs. Water lead was not found to be a significant contributor to children's BLLs in the pooled analysis, but this outcome most likely was due to different methodologies used to measure lead in water across the various studies.

The HUD guidelines on evaluating lead control of lead-based paint hazards in housing were developed in the mid-1990s, but the document continues to play an important role in providing advice on properly conducting a lead inspection, risk assessment or abatement as well as implementing interim controls. HUD and CDC co-authored Chapter 16 of the guidelines, "investigation of children with EBLLs." If a child's home is identified as a probable source of lead exposure, the chapter recommends taking first-drawn and flushed water samples from the tap most commonly used for drinking water, infant formula or food preparation.

The 2006 Brown and Jacobs study analyzed sources of blood lead in children other than soil (e.g., air, housing and water) and emphasized the following: "The lack of a safe threshold reinforces the realization that to prevent adverse health effects caused by lead exposure, we must exercise the wisdom to recognize and address the many sources of lead in children's environments. The reality is too complicated and the cost of failure is too devastating to reduce this to a one-source solution." APHA passed a policy in November 2007 calling for a global ban on all non-essential uses of lead in consumer products.

A number of actions should be taken to advance remediation techniques to better address lead in water. Existing water lead sampling protocols should be standardized to produce reliable data on compliance across all jurisdictions. Water lead levels rather than BLLs should be used to determine the presence of a water lead problem. BLLs integrate all sources of exposure. Moreover, other media-specific programs (e.g., air and housing) quantify exposures to take targeted and specific action.

EPA- and CDC-funded local water and lead programs should communicate to determine the best education messages to deliver to residents in the jurisdiction. EPA- and CDC-funded water and lead programs should avoid duplicating water sampling. Legal authority should be clarified to end partial pipe replacements. For source control, lead service line replacements should be integrated with other infrastructure improvements with a national goal of eliminating all lead water pipes.

For management control, a determination should be made on whether water chemistry changes to reduce other contaminants are likely to increase lead levels before chemistry and treatment changes are implemented. Drinking water in daycare centers and other facilities for young children should be monitored and controlled. Plumbing components should contain the lowest possible levels of lead and one federal agency should have monitoring and enforcement authority.

Monitoring and enforcement of the lead in drinking water standard should be strengthened. The allowable lead content in drinking water should be reduced with a target BLL of 1 μ g/dL. EPA should replicate its existing models of updating the National Ambient Air Quality Standards for lead and the residential dust lead standard to update LCR. Potential buyers or renters of housing with lead service lines or other lead plumbing should receive disclosure about these systems before becoming financially obligated to the property.

ACCLPP thanked the panel of speakers for presenting recent data on the state of the science of lead in water. ACCLPP also applauded CDC on its proactive efforts to develop and deliver public health messaging to end partial lead pipe replacements.

ACCLPP devoted the vast majority of the discussion to a question and answer session for the panel of speakers to clarify and provide more details on their proposed recommendations. Based on suggestions by the members, Dr. Rhoads summarized four key focus areas that ACCLPP should address in 2011 to advance the ongoing lead in water efforts.

- 1. ACCLPP should explore strategies with CDC to monitor and harmonize protocols to test water lead levels in communities (*i.e.*, homes with lead service lines versus those without). Existing testing protocols to determine water lead levels are inconsistent and difficult to implement. The standardized testing protocols should be used to integrate other infrastructure improvements to eliminate all lead water pipes at the national level.
- 2. ACCLPP should assist CDC in developing a research agenda on appropriate actions to take at the local level when elevated lead levels are detected in water.
- 3. ACCLPP should provide CDC with advice and guidance on developing and distributing public health messaging on lead in water to both consumers and public health officials. For example, public health messaging on water lead and lead paint hazards could be integrated, repackaged and re-branded to promote a broader healthy homes vision. Public health messages targeted to consumers should include general information on lead in water and more specific information on the best water filters to use, appropriate use of filters, and the safety and content of purchased bottled water.
- 4. ACCLPP should maintain extensive involvement in ongoing efforts to modify LCR.

Dr. Brown made several remarks in response to two of ACCLPP's focus areas to address lead in water. For focus area 3 (public health messaging), bottled water is categorized as a "food" and is regulated by FDA. Because the FDA lead limit for bottled water is 5 ppb, elevated lead levels are extremely rare. Due to FDA's strict regulatory control of bottled water, Dr. Brown's position was that a focus on lead in this product would not be a productive use of ACCLPP's time and effort. However, she welcomed ACCLPP's advice and guidance on helping CDC to craft public health messaging on bottled water in other areas, such as fluoridation and the limited capacity of low-income families to purchase bottled water due to competing needs. For focus area 4 (modification of LCR), Dr. Brown confirmed that CDC would distribute the *Federal Register* notice to ACCLPP when EPA opened the public comment period for revisions to the existing rule. However, she clarified that ACCLPP members must submit feedback on LCR based on their individual roles as experts in lead poisoning prevention to ensure their comments are not misinterpreted as formal ACCLPP or CDC recommendations. Dr. Brown also confirmed that she would consult with the EPA Office of Ground Water and Drinking Water to identify additional contact points and explore other opportunities for ACCLPP to remain involved in the ongoing efforts to revise LCR.

Public Comment Session

Dr. Rhoads opened the floor for public comment; none of the participants responded.

Closing Session

ACCLPP thanked CDC and all of the invited guest speakers for presenting extremely informative overviews over the course of the meeting. With no further discussion or business brought before ACCLPP, Dr. Rhoads adjourned the meeting at 12:00 p.m. on November 18, 2010.

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

George G. Rhoads, M.D., M.P.H. Chair, Advisory Committee on Childhood Lead Poisoning Prevention

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