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 14-16, 2011
Atlanta, Georgia

Record of the Proceedings

TABLE OF CONTENTS

ATTACHMENT 1

List of Participants

(*Note:* The Chair and Designated Federal Official opened the floor for introductions on November 14, 15 and 16, 2011 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. Kim Dietrich
Dr. Sher Lynn Gardner
Mr. Perry Gottesfeld
Dr. Kimberly Hansen
Dr. Michael Kosnett
Mr. David McCormick
Ms. Elizabeth McKee-Huger
Dr. Patrick Parsons
Dr. Brenda Reyes
Dr. Megan Sandel
Mr. Dana Williams, Sr.

***Ex-Officio* Members**
Dr. Walter Alarcon (National Institute for Occupational Safety and Health)
Dr. Warren Friedman (U.S. Department of Housing and Urban Development)
Dr. Kristina Hatlelid (U.S. Consumer Product Safety Commission)
Ms. Lori Michaelson (U.S. Department of State)
Ms. Jacqueline Mosby (U.S. Environmental Protection Agency)
Dr. Walter Rogan (National Institute of Environmental Health Sciences)
Ms. Cynthia Ruff (Centers for Medicare and Medicaid Services

Liaison Members
Dr. Carla Campbell (American Academy of Pediatrics)
Mr. Steve Hays (American Industrial Hygiene Association)
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)

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

CDC Representatives
Dr. Thomas Sinks
NCEH/ATSDR Deputy Director
Dr. Sharunda Buchanan, EEHS Director
Behrooz Behbod
Sandy Bonzo
Barry Brooks
Bernadette Burden
Jay Dempsey
Tim Dignam
Kayim Harris
Robin Ikeda
Jeffrey Jarrett
Robert Jones
Claudine Johnson
Sarah Merkle
Edward Murray
Paris Ponder
Rose Glass Pue
Marissa Sucosky
Denise Tevis
Connie Thomas
Tiffany Turner
Will Wheeler
Joyce Witt

Guest Presenters and Members of the Public
Craig Boreiko (International Lead Zinc Research Organization)

Timmerly Bullman (Environmental Planning Specialists, Inc.)
Forrest Daly (Georgia Childhood Lead Poisoning Prevention Program, Georgia Lead Hazard Control Program)
Cynthia Driscoll (Jones Day)
Joel de Jesus (Magellan Biosciences)
Richard Gragg (Florida A&M University School of the Environment) [via teleconference]
Carolyn Grossman (Magellan Biosciences)
Christopher Saranko (Environmental Planning Specialists, Inc.)
Michael Shaw (National Coalition to End Childhood Lead Poisoning)
Gwen Smith (Georgia Department of Public Health)
Robert Vanderslice (Rhode Island Department of Health)

ATTACHMENT 2

Glossary of Acronyms

AAP	American Academy of Pediatrics
ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
ADHD	Attention Deficit Hyperactivity Disorder
APHA	American Public Health Association
APHL	Association of Public Health Laboratories
ASV	Anodic Stripping Voltammetry
BLL	Blood Lead Level
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CLIA	Clinical Laboratory Improvement Amendments
CLPPP	Childhood Lead Poisoning Prevention Program
CMS	Centers for Medicare and Medicaid Services
CoC	Certificate of Conformance
CPSC	U.S. Consumer Product Safety Commission
CPWG	Lead in Consumer Products Workgroup
DOS	Department of State
EBLLs	Elevated Blood Lead Levels
ED	Department of Education
EEHS	Division of Emergency and Environmental Health Sciences
EIS	Early Intervention Services
EIWG	Educational Intervention Workgroup
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FEP	Free Erythrocyte Porphyrin
GFAAS	Graphite Furnace Atomic Absorption Spectrometry
GHHI	Green and Healthy Housing Initiative
HHLPPB	Healthy Homes/Lead Poisoning Prevention Branch
HHLPSS	Healthy Homes Lead Poisoning Surveillance System
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
HUD	U.S. Department of Housing and Urban Development
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IDEA	Individual with Disabilities Education Act
IV	Intravenous
LAMP	Lead and Multi-element Proficiency
LBP	Lead-Based Paint
LOC	Level of Concern
LOD	Level of Detection
LOQ	Level of Quantitation
LPP	Lead Poisoning Prevention
LSLs	Lead Service Lines
LWG	Laboratory Methods Workgroup
MDI	Mental Development Index

MMWR	*Morbidity and Mortality Weekly Report*
MSF	Doctors Without Borders/Médecins Sans Frontières
NAEP	National Assessment of Educational Progress
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
NECAP	New England Common Assessment Program
NHANES	National Health and Nutritional Examination Survey
NIEHS	National Institute of Environmental Health Sciences
NTP	National Toxicology Program
OSHA	U.S. Occupational Safety and Health Administration
PEHSU	Pediatric Environmental Health Specialty Unit
POC	Point of Care
PRDOH	Puerto Rico Department of Health
PT	Proficiency Testing
QA/QC	Quality Assurance/Quality Control
RCT	Randomized Controlled Trial
RRP	Renovation, Repair and Painting
RRT	Rapid Response Team
RSD	Relative Standard Deviation
SD	Standard Deviation
SES	Socioeconomic Status
STELLAR	Systematic Tracking of Lead Levels and Remediation
USDA	U.S. Department of Agriculture
WHO	World Health Organization
WIC	Women, Infants and Children
XRF	X-Ray Fluorescence

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ADVISORY COMMITTEE ON
CHILDHOOD LEAD POISONING PREVENTION
November 14-15, 2011
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 14-16, 2011 at the Westin Atlanta Perimeter North Hotel in Atlanta, Georgia.

Opening Session: November 14, 2011

Mary Jean Brown, ScD, RN
Chief, Healthy Homes/Lead Poisoning Prevention Branch, NCEH, EEHS
Centers for Disease Control and Prevention
ACCLPP Designated Federal Official

Dr. Brown opened the floor for introductions to determine the ACCLPP voting members, *ex-officio* members and liaison representatives who were in attendance. She confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for ACCLPP to conduct its business on November 14, 2011. She called the proceedings to order at 8:48 a.m. and welcomed the participants to the meeting.

Dr. Brown announced that the ACCLPP voting members are responsible for recognizing and publicly disclosing their individual conflicts of interest identified by the CDC Committee Management Office and recusing themselves from participating in or voting on these matters. The list of participants is appended to the ACCLPP minutes as Attachment 1.

Sharunda Buchanan, PhD, MS
Director, Division of Emergency and Environmental Health Services
Centers for Disease Control and Prevention

Dr. Buchanan joined Dr. Brown in welcoming the participants to the meeting. She thanked the ACCLPP members for their continued commitment and support to help CDC in strengthening its environmental health portfolio, particularly in the context of lead poisoning prevention and healthy homes efforts. ACCLPP's expertise has been invaluable to CDC in reviewing the science of lead, its health effects, policy implications and other nuances. ACCLPP's expanded focus on healthy homes issues over the past few years also has been extremely important to CDC.

Dr. Buchanan acknowledged ACCLPP's significant contributions to CDC over time (e.g., an exhaustive review of the blood lead level (BLL) of concern and numerous publications to advance the field). In addition to its past accomplishments, ACCLPP is continuing to make landmark decisions on policy issues that will be captured in the lead poisoning prevention historical record and tremendously impact the nation as a whole. Most notably, ACCLPP established workgroups to specifically address lead in consumer products, laboratory methods, educational interventions, and the BLL of concern.

Dr. Buchanan emphasized that CDC is extremely grateful to the time and effort ACCLPP devotes to emerging and priority issues outside of meetings. However, she candidly admitted that upcoming cuts in CDC's budget will be unprecedented. As a result, the extent to which CDC will be able to continue supporting ACCLPP's workgroups and other activities outside of meetings is questionable.

Despite these dire projections, Dr. Buchanan confirmed that CDC would make every effort to retain the process of obtaining ACCLPP's important expertise and valuable contributions. She emphasized that CDC leadership at the highest level is aware of the critical need to continue ACCLPP's activities in lead poisoning prevention and healthy homes issues.

In addition to the ACCLPP members, Dr. Buchanan also thanked Dr. Brown for leading her staff in conducting critical activities in the field with state and local grantees, investigating domestic and international outbreaks, and strengthening relationships with key partners. The participants joined Dr. Buchanan in applauding ACCLPP, Dr. Brown and CDC staff for their outstanding efforts.

Dr. Buchanan concluded her opening remarks by particularly recognizing the longstanding tenures of several ACCLPP members: Dr. Warren Friedman (*ex-officio*, U.S. Department of Housing and Urban Development (HUD)); Mr. Steve Hays (liaison, American Industrial Hygiene Association); Ms. Jacqueline Mosby (*ex-officio*, U.S. Environmental Protection Agency (EPA)); and Dr. Walter Rogan (*ex-officio*, National Institute of Environmental Health Sciences (NIEHS)). Dr. Rogan has served in this capacity since the inception of ACCLPP.

Dr. Carla Campbell was a former ACCLPP member and the former ACCLPP Chair. She was welcomed back to ACCLPP in her new role as the liaison for the American Academy of Pediatrics (AAP).

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
ACCLPP Designated Federal Official

Dr. Brown covered the following areas in her Branch Chief's report to ACCLPP. In 2011, CDC published a number of articles in peer-reviewed journals related to lead poisoning and healthy homes issues. These papers covered the following topics:

- residential light and risk for depression and falls [this publication was based on results from the World Health Organization (WHO) Large Analysis and Review of European Housing and Health Status study in 8 European cities];
- lead poisoning among Burmese refugee children in Indiana in 2009;
- a quantitative measurement of airborne cockroach allergens in indoor air of New York City apartments;
- neighborhood differences in exposure and sensitization to cockroach, mice, dust mite, cat and dog allergens in New York City;
- an association between building level characteristics and indoor allergens in households; and
- potential strategies to eliminate built environment disparities for disadvantaged and vulnerable communities.

CDC's publication on the association among children's BLLs, lead service lines (LSLs) and water disinfection in Washington, DC from 1998 to 2006 received a high level of public attention. The key finding of the study was the use of partial lead pipe replacement and its impact on the risk for elevated BLLs (EBLLs) (e.g., BLLs 5-9 µg/dL or BLLs $\geq$10 µg/dL). These data were produced after chloramine became a disinfectant and were "buffered" with orthophosphate.

Lead levels within the water for DC as a whole were at historic low levels by 2006. However, partial replacement of LSLs continued until a determination could be made on whether DC was in compliance with EPA's water safety rules. The current requirement is that water authorities out of compliance with EPA's water regulations must replace LSLs. The water authority is only responsible for paying for the replacement to the water meter. Property owners are responsible for the cost of replacing LSLs from the meter to the home. Due to this cost, many DC property owners declined to pay for their portion of replacing LSLs.

CDC's study focused on the risk for EBLLs in homes with partial replacement of LSLs versus homes without an LSL or homes in which the existing LSL was not replaced. The study showed that homes without an LSL were much less likely to be associated with EBLLs. Compared to homes with an existing LSL that was not replaced, partial replacement did not generate any benefits.

An EPA Advisory Committee criticized CDC's study due to several limitations: (1) an extremely small number of homes in the cohort; (2) the absence of rigorous data from a randomized controlled trial (RCT); (3) an inability to definitively determine the time between LSL replacement and blood lead testing of children; and (4) a study design that was not population-based and relied on blood lead testing data of children who were tested.

In response to criticism 3, CDC analyzed the time between the replacement of LSLs and blood lead testing of children for over a year. CDC found no relationship between the time of blood lead testing and LSL replacement in the risk for EBLLs. Based on these findings, CDC believes its study is sufficient to publicly state that partial replacement of LSLs will not improve the risk for EBLLs. As a result, CDC did not recommend partial replacement of LSLs to EPA, but CDC will continue to collaborate with EPA to address any outstanding issues.

An EPA committee currently is reviewing the Clean Water Act and the 15 ppb standard in the context of testing. CDC informally and formally provided input to EPA and will publish a *Morbidity Mortality and Weekly Report* (*MMWR*) article on this issue. CDC is aware that a policy decision needs to be made on whether each LSL across the country needs to be replaced.

CDC published other studies in the *MMWR* in 2011 examining (1) inadequate and unhealthy housing in 2007 and 2009 and (2) lead poisoning of a child associated with the use of a Cambodian amulet in New York City in 2009. CDC published a glossary of keywords related to lead poisoning (e.g., "blood lead level," "deteriorated," "compliance" and "risk assessment"). The glossary explains these terms in a very simple and concrete manner. The publication was a recipient of the 2011 Clear Mark Award for Health Communication.

CDC analyzed the health impacts of manufactured housing. Data showed that in 2002, ~17,200 structure fires in manufactured housing occurred in the United States and caused 210 deaths and $134 million in direct property damage. Confined spaces, lower ventilation levels and air exchange rates make indoor air quality a concern in manufactured structures compared to site-built structures. Broken windows, rats/mice and moisture damage are particularly problematic in manufactured structures.

Based on these data, CDC was aware of the importance of informing the public about safety and health issues in manufactured housing. The *CDC/HUD Safety and Health in Manufactured Structures* document was published in March 2011 and is available on the CDC.gov website. CDC and HUD broadly solicited input from experts in the field to develop the document. The document serves as a helpful resource to persons who live in or may purchase manufactured structures, manufacturers and large purchasers (e.g., the Federal Emergency Management Agency).

CDC published educational materials in honor of Adoption Month in November. For the International Adoption and Lead Poisoning Prevention Health Campaign, CDC developed an eCard, bookmark, parent flier, web buttons, fact sheet for healthcare providers, a blurb for a parent listserve and a conference poster. CDC posted these materials on its website and also shared the resources with AAP and international adoption agencies. The purpose of the educational materials was to raise awareness of the need for internationally adopted children to be tested for lead.

CDC developed the *Healthy Homes Manual: Smoke-Free Policies in Multiunit Housing*. The manual has been well received in communities and describes benefits to property owners in implementing smoke-free policies (e.g., elimination of the need to replace carpet and repaint units due to smoke damage and reduced chance of fires). CDC is evaluating the impact of the manual in Los Angeles in the context of a reduction in asthma or other improved health effects in children who reside in multi-unit housing.

CDC will use the evaluation results to conduct an in-depth epidemiologic study. Qualitative research also will be conducted to determine barriers to adopting the manual among property managers and compile success stories. A website is regularly updated on the list of publicly-owned housing facilities that are adopting smoke-free policies. CDC developed the Healthy Homes Checklist in the format of a 100-minute DVD. The DVD is targeted to voluntary organizations (e.g., the Red Cross, Meals on Wheels and other groups that serve elderly persons).

In June 2012, CDC will replace its Systematic Tracking of Lead Levels and Remediation (STELLAR) database with the Healthy Homes Lead Poisoning Surveillance System (HHLPSS). HHLPSS will allow for case initiation and will maintain more information on healthy homes issues and environmental hazards related to lead. Internal and external users will be able to use HHLPSS to collect information on moisture, mold, pests, fire alarms and other safety devices. HHLPSS has been fully implemented in the District of Columbia and is being beta tested in 17 states. Based on its budget, CDC will provide technical assistance to grantees on HHLPSS, but will be unable to purchase hardware.

Healthy People 2020 is a national health agenda that envisions a society in which all persons live long and healthy lives. This agenda includes many objectives that are related to healthy homes. CDC's Healthy Homes Program addresses goal 2 of Healthy People 2020: achieve health equity and eliminate health disparities. CDC's Healthy Homes Program also addresses 8 proposed Healthy People environmental health objectives:

- reduce the proportion of occupied housing units that have moderate or severe physical problems;
- reduce BLLs in children;
- reduce indoor allergen levels;
- increase the proportion of persons living in homes at risk that have an operating radon mitigation system;

- increase the number of new homes constructed with radon-reducing features, especially in potentially high-radon areas;
- increase the proportion of persons living in pre-1978 housing that has been tested for the presence of lead-based paint hazards;
- decrease the number of U.S. homes that have lead-based paint or related hazards; and
- increase the number of territories, tribes, states, including the District of Columbia, that monitor diseases or conditions that can be caused by exposure to environment hazards.

In September 2011, CDC announced its healthy homes grantees in 34 states and the District of Columbia. Due to budget constraints, CDC was no longer able to fund grantees in large cities (e.g., Chicago, Detroit, New York City, Los Angeles County and Philadelphia). The primary goal for states in the current grant cycle is to begin a strategic planning process to adopt a healthy homes agenda with diverse partners and expertise. Funding to continue these grants at the current level may not be available in the future. CDC is providing extensive technical assistance to the grantees to achieve this goal.

The President's budget recommends an integration of healthy homes and asthma into one line item. The combined line item, healthy homes and community environments, would be funded at $32.6 million. The combined funding would represent a budget cut of 50%. The asthma line item currently is funded at ~$32 million and the lead poisoning prevention line item currently is funded at ~$30 million. The proposed Senate mark includes an asthma line item of $27.4 million and no healthy homes line item.

The Senate bill proposes that the Health Resources and Services Administration (HRSA) Maternal and Child Health Bureau incorporate childhood lead poisoning into its Home Visiting Program using healthcare reform dollars. The proposed Senate mark is problematic in some areas. HRSA funds Title V Early Childhood Visiting Programs in states, but CDC conducts many more activities than home visits (e.g., a quality assurance/quality control (QA/QC) function in its laboratory, policy initiatives through ACCLPP and primary prevention activities). The draft House budget does not include line items for either asthma or healthy homes.

If the Senate and House budgets are approved and lead poisoning prevention (LPP) funding is moved to HRSA, Dr. Brown is considering the possibility of maintaining important components that would benefit the entire country without the need for extensive staff support. These core components include laboratory services, ACCLPP, the surveillance system and outbreak response capacity.

CDC's laboratory services include the Lead and Multi-element Proficiency (LAMP) program. This voluntary laboratory standardization program focuses on whole-blood multi-analyte quality assurance. At this time, >100 laboratories, including 30 international laboratories, participate in LAMP. Other key functions of CDC's laboratory include blood lead testing when outbreaks occur in the field and the National Health and Nutrition Evaluation Survey (NHANES).

Dr. Brown announced that CDC and HRSA had an informal discussion about continued support for LPP activities if these funds are transferred to HRSA. CDC will continue to pursue potential

strategies to better integrate LPP activities into HRSA. Without a budget or Congressional mandate, however, HRSA will not take over CDC's leadership role in LPP.

ACCLPP expressed grave concerns about the Congressional proposals to transfer LPP funds to HRSA and/or severely cut CDC's LPP budget by 50%. The members made several comments and proposed a number of suggestions to maintain LPP funds at CDC.

- ACCLPP's liaisons should engage their respective organizations to broadly publicize and educate Congressional staffers on the urgent need to reverse the proposed budget cuts to the CDC LPP Program. The liaisons described their ongoing efforts in this regard.
  - The National Center for Healthy Housing (NCHH) has been educating the leadership of key Congressional committees on the importance of CDC's LPP Program and harm that would occur at national and state levels if the program is eliminated, transferred to HRSA or integrated. NCHH and its partners are encouraging persons to individually contact their Senators and Congressional representatives to mobilize a national outcry. Education is imperative because some public health officials and members of Congress believe that lead poisoning has been eliminated and is no longer a public health problem in the United States. Ms. Jane Malone, the liaison to NCHH, distributed copies of the *Guide to Advocacy*. This tool contains talking points, a model press release and other resources to assist persons in advocacy efforts. The NCHH website also has advocacy materials and provides instructions for grassroots organizations, parents of lead-poisoned children and communities to create personalized policy letters for their Congressional representatives.
  - The AAP Executive Committee of the Council on Environmental Health recently discussed the proposed budget cuts to CDC's LPP Program and informed the AAP Committee on Federal Government Affairs of this issue. This committee is actively advocating to preserve LPP functions in CDC. Dr. Campbell asked ACCLPP to propose ideas on additional actions AAP could take in this regard.
  - Dr. Donald Simmons, the liaison to the Association of Public Health Laboratories (APHL), will convey the urgency of maintaining CDC's LPP Program to all state laboratory directors.
  - The American Public Health Association (APHA) Committee on Environmental Health recently issued a strong statement expressing its concerns with the proposed budget cuts to CDC's LPP Program. APHA leadership also sent a letter to leadership of Congressional appropriations committees objecting to the "attack" on CDC's entire environmental health portfolio housed in NCEH, including the LPP Program. Public Health Associations at the state level have been publicly discussing and taking action on this issue as well.
  - The National Coalition to End Childhood Lead Poisoning (NCECLP) and its partners are currently advocating to maintain or potentially restore additional funding to HHLPPB. Efforts also are underway to ensure that defined and prescriptive language is included in the budget of HRSA's Early Childhood Visiting Programs. Moreover, NCECLP is focusing on a long-term goal of changing health care and health insurance structures with public and private investments.

- ACCLPP should reissue its previous statement to the HHS Secretary to reinforce its strong concerns and opposition to the proposed budget cuts for CDC's LPP Program. The HHS Secretary particularly should be informed that state and local health departments heavily rely CDC's LPP grants for public health and laboratory purposes. CDC's proposed budget cuts would be devastating to these agencies. Most notably, state and local programs will be able to only conduct basic services for mandatory code enforcement if the CDC grants are eliminated.
- Efforts should be made to identify a strong LPP advocate in HRSA if the proposed Senate and House budgets are approved to transfer CDC's LPP responsibilities to HRSA.
- The proposed transfer of LPP responsibilities from CDC to HRSA is not encouraging. Most notably, HRSA recently terminated support for Wisconsin's well-established and solid Proficiency Testing Program. As a result, CDC's laboratory services for lead must be maintained.
- The possibility of CDC establishing interagency agreements with EPA and HUD should be explored. Because EPA and HUD benefit from CDC's strong LPP infrastructure, these agencies might be willing to provide funds to maintain LPP activities at CDC.

In response to ACCLPP's final suggestion, Dr. Brown clarified that CDC already has strong interagency agreements with and receives funding and other support from EPA, HUD, U.S. Department of Agriculture (USDA) and other federal partners for LPP activities. The White House has publicly acknowledged these collaborations as a model of a strong interagency partnership. Dr. Brown's position was that CDC does not expect to receive additional funds from its federal partners because budgets are being severely cut across the federal government.

Overview of the Rhode Island Healthy Housing Program

Robert Vanderslice, PhD
Team Lead, Healthy Homes and Environment Team
Rhode Island Department of Health

Dr. Vanderslice presented an overview of Rhode Island's efforts to shift from a categorical Childhood Lead Poisoning Prevention Program (CLPPP) to a more comprehensive Healthy Homes Program. Rhode Island developed a strategic plan in 2007 to guide these efforts. To clearly define the problem, Rhode Island created a healthy housing indicator and checklist. Potential solutions to this problem include targeting resources, creating data-driven policies and integration of services.

In using age of housing as an indicator, data showed that no other state houses more of its low-income children in pre-1980 housing than Rhode Island. The proportion of low-income children who live in older housing is 86% in Rhode Island and 62% nationally. The proportion of all

children who live in older housing is 73% in Rhode Island and 54% nationally. Across the state, 25% of housing is pre-1980, while >90% of housing is pre-1980 in inner cities.

In using BLLs as an indicator, data showed that BLLs 6-10 µg/dL in Rhode Island children are associated with poor housing. A combined indicator of age of housing, lead poisoning screening rates, and children living in poverty showed that BLLs were worst in core cities and parts of other urban areas. Rhode Island defines "core cities" as those in which >15% of children live in poverty. However, other more affluent areas in the state (e.g., Burrillvile, Westerly and East Greenwich) also showed a high risk for significant lead exposures to children with the combined indicator.

Rhode Island plans to use the combined indicator and other data sources (e.g., address-specific asthma data from health plans, emergency room discharge data and hospital admission data) to demonstrate housing problems in specific locations of municipalities and offer solutions to these problems.

Rhode Island mandated universal screening to make the shift from a CLPPP to a Healthy Homes Program. State data showed consistent screening rates over time. Among children born from 2000 to 2007, 70%-75% received one screen by 36 months and 39%-42% received two screens by 36 months. The highest screening rates were in areas of the state with highest risk (e.g., those with large Women, Infants and Children (WIC) and Head Start populations).

Rhode Island's policy to inspect significant lead poisoning is to give 2 tests 90 days apart for BLLs >15 µg/dL and one venous test for BLLs >20 µg/dL. The homes of these children also undergo a comprehensive environmental lead inspection to test paint, dust soil and water. Significant lead poisoning rates have declined in Rhode Island.

The following groups receive a healthy housing inspection in addition to a comprehensive environmental lead inspection: children with significant EBLLs, day care facilities, refugees, and tenants who submit a complaint about exposure to lead hazards. Lead Centers serve as case management groups and were given funding by the paint industry following a lawsuit. Lead Centers routinely inspect homes of children with BLLs 6-9 µg/dL. Healthy housing inspections also are conducted by partners of the Rhode Island Asthma Program (e.g., the BreatheEasy and Home Asthma Response Programs) and multiple partners in both public and private sectors.

Rhode Island developed a new healthy homes checklist that can be administered by several groups (e.g., housing inspectors, the weatherization program, Head Start, lead case manager, lead inspector, Rhode Island Housing or visiting nurse). These groups used the checklist to inspect 3,300 homes over a 3-year period. The least common problems recorded on the checklist were electrical hazards, locks on entry doors, existing handrails with >3 steps, and the security of handrails.

Problems commonly recorded on the checklist were inoperable smoke detectors, refrigerators <41 degrees, non-accessible exits, no screens on all windows and pests. The most common

problems recorded on the checklist were inoperable carbon monoxide detectors, absence of fire extinguishers and annual servicing of furnaces.

Rhode Island developed and recently began implementing a new healthy homes checklist based on the CDC model. The new checklist covers 40 questions in 10 sections: lead/radon, ceilings/floors/walls, bathrooms, water/heat/indoor air, smoking/carbon monoxide, electrical issues, stairs, windows, injuries and pests. Rhode Island has only received 100 entries on the new checklist to date primarily from lead inspectors and visiting nurses. Rhode Island currently is designing a data system module to accept healthy homes inspection results and link information to the lead poisoning, asbestos and radon databases. The new checklist is similar to, but is not the same as the HUD form.

Rhode Island is aware of both the limitations and benefits of the checklist data. In terms of data quality, hazards identified reflect the background of the inspector. In terms of data utility, tenants and inspectors are reluctant to refer the data for enforcement for fear of eviction. In terms of surveillance, the checklist data are statewide, address-specific and provide opportunities for primary prevention.

Certificates of occupancy are a key healthy homes solution, but Rhode Island does not require this type of inspection. However, Rhode Island requires a Housing Quality Standard inspection in Section 8 housing and matches these addresses to its lead poisoning database to ensure lead problems in these properties are remediated. Rhode Island also requires a Housing Resources Commission Certificate of Conformance (CoC) in which landlords must attend a 3-hour training class and hire a private inspector to make a visual inspection and conduct a dust wipe test. Other healthy housing solutions in Rhode Island include the Green and Healthy Housing Initiative (GHHI) and Rhode Island Housing.

The CoC policy for primary prevention allows for an exemption for owner-occupied properties. Non-exempt properties include single family rentals, 2- to 5-family rentals, apartment buildings with $\geq$6 units, condominium rentals and mixed-used rentals. In 682 non-exempt properties, 882 children with BLLs $\geq$10 µg/dL were identified (or 7%).

GHHI is a national program that combines multiple funding streams to provide weatherization and healthy housing assistance. GHHI weatherized ~125 units. The Rhode Island Department of Health chairs the GHHI Data and Evaluation Subcommittee and plans to publish how the data were used to target GHHI neighborhoods. The GHHI evaluation will cover factors in 5 categories: green and healthy, family stabilization, workforce, environment and government innovation.

Rhode Island designed its data hub to link individual child-level data from numerous state sources and community organizations. Key features of the integrated data system include automated administrative data transfer and individual-level linkage across datasets using deterministic and probabilistic linkage techniques; aggregation to appropriate levels to protect privacy; and highly-interactive, open-source WEAVE visualization software. Features of the web portal include reports; data stories to answer policy questions and demonstrate the use of

the WEAVE visualization software; and a full suite of tools for advanced users (e.g., maps, bar charts, scatterplots, line charts, histograms and data tables).

Rhode Island currently is utilizing its data hub to answer the question of whether poor housing makes children sick and affects school performance. Rhode Island is using its healthy housing indicator versus absenteeism data as well as blood lead data versus New England Common Assessment Program (NECAP) scores to answer the question. The preliminary analysis showed that children with the lowest BLLs were the least chronically absent (e.g., absent at least 10% of the school year) and children with the highest BLLs had the lowest NECAP scores.

Overall, Rhode Island has defined healthy housing with a healthy homes indicator that shows the magnitude of problems statewide and in each community. The indicator has the ability to demonstrate to municipalities the role of lead poisoning on higher educational costs. Rhode Island developed a healthy homes checklist that serves as a useful tool to raise awareness and target individual addresses for intervention. Address-specific data are powerful due to the ability to target resources, drive policy, and demonstrate health impacts of environmental conditions.

In response to ACCLPP's question, Dr. Vanderslice's position was that lowering the blood lead reference level from 10 µg/dL to 4 or 5 µg/dL would be essential. Most notably, parents are becoming more educated on the health effects of lead and are demanding action if their children have BLLs <10 µg/dL.

From a state health department perspective, Dr. Vanderslice saw no reason not to lower the blood lead action level. However, the ability to evaluate the success of lead programs at lower action levels has still not been determined. For example, more solid data in the future might show that a critical intervention with an associated cost had no medical benefit on an individual child at the lower action level.

Dr. Vanderslice did not believe that housing interventions would dramatically change BLLs, but most likely would positively impact asthma, injury and other healthy homes issues. Overall, data on the lower action level most likely would demonstrate improvements in multiple areas and justify this decision.

ACCLPP commended Rhode Island on its high screening rate of 70%-75%. The members made comments and suggestions in two areas for Rhode Island to consider in further enhancing its impressive Healthy Homes Program.

- A holistic approach should be taken to increase primary prevention in owner-occupied housing, including at point-of-sale and point-of-rental. This strategy should include education, resources, compelling data, incentives and enforcement. A potential model is the Philadelphia Lead Court that was established in 2002 for tenant- or owner-occupied properties. The Lead Court targets properties with lead-poisoned children and no remediation of lead hazards. The percentage of homes that achieved compliance within one year of a failed inspection dramatically increased from ~7% in 1997 to 77% in 2007.

HUD Lead Hazard Control Grants, particularly for low-income persons, played a significant role in strengthening compliance in owner-occupied housing.

- Rhode Island should explore the possibility of replicating two models in Boston. Boston will implement a new Annual Rental Inspection requirement at the end of November that will be led by the Inspection Division rather than the public health department. Boston is leveraging electronic health record data from several sources to collect granular surveillance data at the individual health level to better understand and track health outcomes over time.

Overview of Child Blood Lead Studies in Puerto Rico

Mary Jean Brown, ScD, RN
Chief, Healthy Homes/Lead Poisoning Prevention Branch, NCEH, EEHS
Centers for Disease Control and Prevention
ACCLPP Designated Federal Official

Dr. Brown described the rationale for conducting child blood lead studies in Puerto Rico. In terms of the prevalence study, no data were previously collected to demonstrate the lead poisoning problem in Puerto Rico. Most notably, Puerto Rico does not have a CLPPP. Limited resources primarily have been used to briefly follow-up children who were identified and lead poisoned in other places in the United States and then lived in Puerto Rico.

EPA Region II allocated funds to test the extent to which lead poisoning was a problem in Puerto Rico. CDC led its partners in conducting a population-based prevalence study of BLLs and environmental lead levels in Puerto Rico. The study identified three Head Start children and two children in the general population with EBLLs. All three of the Head Start children had a parent or another family member who was employed at a local battery recycling plant. Due to the low prevalence of EBLLs in Puerto Rico, another study was conducted solely focusing on children with family members who were employed at the plant.

Timothy Dignam, MPH
Epidemiologist, NCEH/EEHS, HHLPPB
Centers for Disease Control and Prevention

Mr. Dignam reported that data from the 2010 U.S. Census and the 2008 American Community Survey were used to characterize the geography and demographics of Puerto Rico. Puerto Rico is a U.S. territory in the Caribbean island that is located east of the Dominican Republic. The size of Puerto Rico is 100 by 35 square miles (or slightly less than 3 times the size of Rhode Island).

The total population is 3.7 million persons, including 289,313 children <6 years of age. The average household size is 3.2 persons. The median family income is $20,795 and 56% of families live below the Federal Poverty Level. Only 6% of the housing stock is pre-1950 and

24% of the housing stock is pre-1978. The majority of the population (or 98%) lives in urban areas. The four most populated municipalities are San Juan, Bayamon, Carolina and Ponce. The battery recycling plant is located in Arecibo.

CDC and the Puerto Rico Department of Health (PRDOH) conducted an EPA-funded prevalence study. Blood lead testing data from the Head Start program were reviewed as part of the study. Of three children identified with BLLs ≥10 µg/dL, the common link was parents employed at a local battery recycling plant. PRDOH does not have a formal CLPPP.

At the end of the prevalence study, CDC and PRDOH offered the first of four voluntary blood lead screening clinics for employees' children of all ages in November 2010. Of 14 children ≤7 years of age, 5 (or 36%) had BLLs ≥10 µg/dL. CDC recommended individual interventions to reduce BLLs in these children. PRDOH and CDC notified EPA of potential take-home lead exposures from plant workers.

In December 2010, EPA used its authority under the Resource Conversation and Recovery Act and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) to launch an investigation into the recycling, transportation, treatment, storage and disposal of lead. The large plant is 16 acres in size and recycles all car batteries in Puerto Rico and a small proportion of car batteries from the U.S. Virgin Island. The plant has been conducting secondary lead smelting and/or reclamation operation activities since 2004.

The plant breaks and sorts lead-acid batteries and refines the lead to be resold as lead blocks to battery manufacturers. The plant receives ~600 tons per month of spent batteries and produces ~500 tons per month of lead product. The plant is owned and operated by a Puerto Rican family and all 150 employees are Puerto Rican. The plant provided CDC and PRDOH with a roster of current and former employees and their family members.

CDC reviewed its 1997 study, the 1977 Baker study, and the 1978 Dolcourt study that reported EBLLs among children were caused by lead dust from employees of battery recycling or battery storage companies due to take-home lead exposures. The 2011 Henn study used data from the National Institute for Occupational Safety and Health to show that among 1,743 battery workers, 325 (or 18.6%) had BLLs ≥25 µg/dL.

The current occupational standards do not sufficiently protect workers and need to be strengthened. The Association of Occupational and Environmental Clinics produced a report on the Medical Management Guidelines for lead-exposed adults. The report concluded that the Occupational Safety and Health Administration's (OSHA) lead standards have not been substantially changed since the late 1970s and primarily are based on health effects studies over 30 years old.

In April-May 2011, CDC and PRDOH conducted three additional blood lead screening clinics with the LeadCare II instrument. The CDC laboratory performed confirmatory testing of venous blood samples. Blood lead tests were administered to 227 persons from 78 families. Of 66 children <6 years of age, 25 (or 37%) had venous-confirmed BLLs ≥10 µg/dL. Of 56 children 6-

17 years of age, 4 (or 7%) had venous-confirmed BLLs ≥10 µg/dL. Of 105 adult workers and non-workers 18-68 years of age, 44 (or 42%) had venous-confirmed BLLs ≥10 µg/dL.

Of the 105 adults tested, 48 were plant workers. Of the plant workers, 98% were males and 40% were smelter workers. The average age of the plant workers was 30 years with a range of 21-40 years of age. The average length of employment was 28 months with a range of 1-96 months. The mean BLL was 30.7 µg/dL with a range of 3.2-72 µg/dL. Of the 48 workers tested, 33 (or 69%) had a BLL ≥25 µg/dL on their initial test. Job descriptions with the highest mean BLLs were drivers, ingot makers and shredders.

Of 139 employee homes EPA has inspected to date, 43 have been decontaminated and 56 have been cleared. Of 524 household samples that have been analyzed, 50% were greater than the lead level standard of ≥40 µg/ft^2. Of 200 employee vehicles EPA has inspected to date, 137 have been decontaminated and 94 have been cleared. Of 159 samples from employee vehicles, 85.5% were greater than the lead level standard of ≥40 µg/ft^2. EPA also has collected 149 soil samples from the plant's property and partnered with agencies in Puerto Rico to collect blood and milk samples from dairy cows proximate to the plant. Of 15 home tap water samples collected, all were less than the EPA action level of concern of 15 ppb.

In terms of environmental sampling at the plant, EPA collected numerous dust wipe, sludge and air samples. The majority of samples had concentrations greater than the standard and confirmed the high level of contamination at the plant. The plant instituted temporary measures through an EPA Administrative Order (e.g., shower facilities, shoe cleaning areas, a lead-free area to change clothes and a car wash). CDC provided educational materials on prevention and health effects to employees and their families.

PRDOH used funds from CDC and EPA to hire a pediatrician/case manager in October 2011 to provide environmental follow-up and case management of children with EBLLs. PRDOH and CDC plan to send a letter to pediatric providers to encourage testing of children and pregnant or lactating women who live in communities proximate to the plant or those who live with current or former employees. PRDOH and CDC will provide educational outreach to pediatric providers during meetings of local medical societies in Puerto Rico.

Overall, the take-home link was established as the cause of EBLLs in children in Puerto Rico. The investigation found that 33 (or 69%) of workers had BLLs ≥25 µg/dL and all workers involved in battery reclamation activities had BLLs ≥10 µg/dL. Ongoing case management is necessary. EPA's involvement is extensive in the context of its ongoing remediation and legal activities. Various partner agencies convene weekly teleconferences to discuss the status of the investigation in Puerto Rico. CDC will publish the prevalence study in the *MMWR*.

Mr. Dignam provided additional details on the study in response to ACCLPP's questions. The discussion topics included:

- blood testing of female caregivers living in the home (e.g., mothers/grandmothers of children and wives/partners of workers);

- median BLLs of children who were tested;
- the absence of OSHA in occupational lead exposures at the worksite;
- take-home lead exposures from battery recycling workers to children in other geographic locations both domestic and internationally;
- soil lead testing results;
- the type of dust wipe samples (e.g., actual wipe samples or vacuum samples);
- the lack of blood lead monitoring data at the plant prior to the investigation; and
- disposal of the battery casings;

ACCLPP advised CDC to expand its outreach efforts to pediatric providers to include OB/GYN providers. OB/GYNs will be integral in encouraging blood lead testing in pregnant or lactating women who live in communities proximate to the plant or those who live with current or former employees.

Mr. Gottesfeld announced that Excide Technologies operates battery recycling plants in the United States and offered communities of Frisco, Texas and another site free blood lead testing to children of plant workers who presented to a specific pediatrician. In response to Mr. Gottesfeld's request, Dr. Brown confirmed that CDC would follow-up with its Texas program to determine data in its state surveillance system. She would report her findings on this effort to Mr. Gottesfeld.

Dr. Brown emphasized that CDC's next steps are to be placed on the World Bank agenda to make a strong case for the need to give funding and attention to take-home lead exposures. The World Bank has an obligation to link its development loans to countries to environmental contamination.

Update by the Laboratory Methods Workgroup (LWG)

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

Dr. Parsons covered the following topics in his update to ACCLPP on LWG's activities. The LWG members represent ACCLPP, CDC, APHL, the California CLPPP, and the Wisconsin State Laboratory of Hygiene. Mr. Jeffrey Jarrett is a Research Chemist in the Division of Laboratory Science at CDC and has provided LWG with invaluable support and technical expertise.

LWG was charged with addressing the need for recommended standards of practice for users of point-of-care (POC) blood lead testing devices. To fulfill its charge, LWG convened 6 web conferences from February-October 2011. During the final 2 conferences, LWG finalized its

questions for Magellan Biosciences and obtained input from Magellan Biosciences to clarify outstanding issues on the draft recommendations.

"Lead poisoning" was defined as 60 µg/dL in 1965, but BLLs have been lowered over time to CDC's current level of concern of 10 µg/dL. Techniques that were available to measure lead in blood were rather crude compared to current standards. New techniques were introduced in the 1970s to measure lead in capillary blood samples. The need for 7 mL of venous blood was eliminated and mass screening was able to be conducted with capillary fingersticks.

Additional advancements in laboratory performance and techniques used to measure blood lead have been made since that time. The handheld anodic stripping voltammetry (ASV) LeadCare I device has a detection limit of ~2 µg/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 at a clinical laboratory. 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 µg/dL and can be purchased for $2,000-$3,000. LeadCare II is a non-automated device that is waived by the Clinical Laboratory Improvement Amendments (CLIA). The device can be used at POC and does not require proficiency testing (PT). LeadCare II is associated with screening children at the point of contact and plays an important role in public health programs in terms of testing children who might otherwise be lost. Dr. Parsons presented a series of slides to illustrate the ease of using LeadCare II.

LWG's initial step in drafting its recommendations was to review blood lead practice standards for screening tests only issued by the New York State Department of Health's Clinical Laboratory Evaluation Program. LWG divided its findings into statements of recommendations and guidance in interpretations. Dr. Parsons summarized LWG's draft recommendations.

Recommendations 1a, 1b, 2 and 3 focus on "contamination control." Guidance is provided on contamination control in three areas: the work environment, materials for specimen collection (e.g., preparation of the skin collection site prior to capillary skin puncture), and sample processing. This set of recommendations will help laboratories to implement procedures to eliminate bench contamination errors.

Recommendation 4 focuses on the "use of capillary blood from a fingerstick" to ensure that no air gaps are present in the capillary. The guidance clarifies that fingerstick blood is appropriate for screening purposes only and typically is used with a POC device. Users of a POC device are advised to consult the manufacturer's directions.

Recommendation 5 focuses on the "use of venous blood" to ensure the quality of the blood specimen. The guidance clarifies that venous blood is preferred for blood lead testing purposes. Only venous blood that has been preserved with ethylene diamine tetraacetic acid or heparin should be used as anticoagulants. Other issues covered in this guidance include the appropriate fill volume, the need for mixing prior to aliquoting, and the need to monitor for blood clots.

Recommendations 6-10 focus on a "reemphasis of the manufacturer's directions." The guidance clarifies the fine print in the product insert and outlines these important practice standards in a format that is easier to understand and read. The manufacturer's directives cover storage requirements, operating requirements, power source considerations, the use of test kit components, and instrument calibration.

The manufacturer's directions are important because POC devices are not intended for the collection and testing of blood in remote locations, storage of blood for a long period of time, or refrigerated or frozen blood. The guidance on power source considerations is based on use of POC analyzers in CDC field studies.

Recommendation 11 focuses on an "analysis of QC materials." LWG's "ideal" recommendation is for 2 clinically significant levels to be run each time the analysis is run. LWG's "minimum" recommendation is for 2 clinically significant levels to be run with each new test kit lot, with each new shipment, with each new operator (e.g., every 2 weeks), or when problems are suspected or identified. The guidance clarifies that the frequency of QC should reflect the volume of testing.

Recommendation 12 focuses on "repeat testing of the original specimen." The recommendation states that if the initial result is $\geq$8 µg/dL, the original specimen should be reanalyzed if volume permits. The goal of the recommendation is for laboratories to rule out bench contamination errors and resolve discrepancies. The guidance clarifies that if the volume is insufficient (e.g., a capillary specimen), the initial result should be reported and the patient should be referred for confirmatory testing at a reference laboratory.

Large discrepancies should be resolved if possible with either additional analyses or reporting of test results as inconclusive with the following comments: "The specimen was insufficient to repeat the analysis. The patient was referred for confirmatory testing." The guidance clarifies "acceptable" differences in repeat testing for users of the LeadCare device: a discrepancy of >3 µg/dL for the concentration range of 8-20 µg/dL; a discrepancy of >4 µg/dL for the concentration range of 21-40 µg/dL; and a discrepancy in 10% of samples for the concentration range of >40 µg/dL. Further investigation would be warranted for discrepancies outside of these acceptable differences.

If discrepancies are identified, obvious outliers should be discarded and the average of the 2 remaining values should be reported. The patient should be referred for confirmatory testing for any result exceeding 8 µg/dL or if the validity of the test is uncertain.

Recommendation 13 focuses on "confirmatory testing." The recommendation states that if the BLL is $\geq$8 µg/dL, the laboratory must refer either the patient or the venous blood sample for confirmatory testing. The guidance clarifies that the BLL of 8 µg/dL was selected to maximize identification of children with lead poisoning and ensure consistency with the manufacturer's instructions for use of the LeadCare II device.

If the patient is referred, preliminary results may be released with the following comments: "The initial test result is for screening purposes only. Confirmatory testing results are pending." If the venous blood sample is referred, a CLIA-certified laboratory should perform confirmatory testing with a method that is categorized by CLIA as "high complexity." Reference laboratories ideally should be accurate within ±2 µg/dL at low BLLs, but CLIA allows accuracy at ±4 µg/dL at this time. Preliminary results may be released with the following comment: "Results of confirmatory testing are pending."

LWG was divided on issuing guidance that states an unopened venous specimen is preferable, but the following compromise was reached. When an unopened specimen is not possible or feasible and is confirmed to be elevated, the confirming laboratory should note this issue with the following comment: "The test specimen may have been compromised during previous testing. Results should be confirmed with another venous blood specimen."

Recommendation 14 is "reporting requirements" to ensure all blood lead results are reported to the proper state or federal agency. The guidance clarifies that reporting is essential for proper follow-up and public health surveillance. However, reporting requirements may vary by state due to different data, time frames or mechanisms.

Recommendation 15 is "reporting potential contamination" to indicate potential false-positive results when the specimen is received in a container not known to be lead-free. The guidance clarifies that a footnote in the report is not needed for containers cleared through in-house lot-testing.

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

Recommendation 16 is "reporting 5-10 µg/dL on patient reports." Reference ranges must indicate that BLLs 5-9 µg/dL have been associated with adverse health effects in children ≤6 years of age. The guidance attempts to resolve an ongoing conflict and clarifies that reports should not indicate BLLs <10 µg/dL are "normal." On the one hand, pediatricians are concerned that laboratories continue to report BLLs 8-9 µg/dL as "normal." On the other hand, laboratories believe that reporting all BLLs <10 µg/dL as "normal" is supported by the scientific literature and CDC's national policy.

Recommendation 17 is "method comparison" to ensure that POC BLLs are periodically compared with confirmatory testing. The guidance clarifies "acceptable" differences between the screening and confirmatory results: a discrepancy of >3 µg/dL for the concentration range of 8-20 µg/dL; a discrepancy of >4 µg/dL for the concentration range of 21-40 µg/dL; and a discrepancy in 10% of samples for the concentration range of >40 µg/dL. Personnel competency and the performance of QC and PT should be periodically reviewed to determine the root cause of discrepancies.

Recommendation 18 is "external QA" to emphasize that PT participation provides a valuable assessment of analytical performance. The guidance clarifies that no federal requirement exists for PT of CLIA-waived devices, but PT is highly recommended. Some states (e.g., California and Wisconsin) require regular participation in PT to receive reimbursement for test costs.

Dr. Parsons concluded his update by emphasizing the need for ACCLPP to defer its vote on LWG's draft recommendations until a decision is made on whether the BLL of concern will be lowered to <10 µg/dL. If ACCLPP formally adopts a lower BLL concern, this decision will impact LWG's recommendations and the guidance will need to be modified or deleted in some cases (e.g., recommendation 16).

Dr. Parsons provided additional details on standards of practice for users of POC blood lead testing devices in response to ACCLPP's questions. The discussion topics included:

- potential level of contamination of specimens received in open containers;
- the ability to use POC devices for venous blood specimens;
- the ability to confirm an elevated result from either a capillary or venous blood specimen in a complex laboratory using a reference method;
- loss of HRSA funding to the Wisconsin PT Program, including enrollment of ~300-400 laboratories;
- the cost of PT participation (e.g., $400 per year for enrollment plus an additional cost for PT testing in the laboratory); and
- the use of refrigerated blood.

ACCLPP commended LWG on drafting practical guidance to test venous specimens received in open containers. The members noted that because children 12 months of age will receive 4 injections plus a blood draw (or 5 injections plus a blood draw during influenza season), parents and pediatricians typically will refuse an additional blood draw simply because the container was open.

ACCLPP made specific comments and suggestions on two of the draft recommendations for LWG to consider in finalizing the guidance.

- Recommendation 14 should be expanded to include city/county agencies as additional recipients of blood lead results. Some local agencies have different reporting requirements than state agencies.
- Recommendation 18 regarding PT participation should be strengthened. Although the federal government does not require PT participation, LWG concluded that this technique greatly improves the quality of POC devices. However, other ACCLPP members were not in favor of stronger guidance. Mandatory PT participation would eliminate small provider practices that do not have onsite phlebotomists or laboratories. PT participation is a complex process that includes certification, travel expenses for staff training, Medicaid reimbursement issues and other requirements. Mandatory PT participation would result in the loss of a significant proportion of lead testing, particularly from small, rural and suburban provider practices.

Update by the Educational Intervention Workgroup (EIWG)

Sher Lynn Gardner, MD
Assistant Professor of Pediatrics, Department of Pediatrics, Emory University
ACCLPP Member & Educational Intervention Workgroup Chair

Dr. Gardner covered the following topics in her update to ACCLPP on EIWG's activities. EIWG was formed to draft ACCLPP's guidance to assist parents in advocating and intervening on behalf of their children with known EBLLs or deficits believed to be associated with EBLLs. The EIWG members represent ACCLPP, CDC, academic institutions, CDC-funded CLPPPs, professional associations, community-based organizations, and parents of children with EBLLs.

EIWG's formal charge is three-fold. First, existing evidence on neurodevelopmental and behavioral deficits associated with lead poisoning will be compiled, including the benefits of early intervention services (EIS) for children with a history of impairment or disability. Areas for new research will be identified. Second, Parts B and C of the Individual with Disabilities Education Act (IDEA), Section 504 and model regulations will be reviewed to provide guidance to state and local governments and ensure lead poisoning is a covered impairment. Third, specific action steps will be described for parents, clinicians and educators in an easy-to-read format that is readily accessible to these target audiences.

Dr. Gardner provided a status report on EIWG's efforts to update Chapter 5, "Developmental Assessment and Intervention," of the 2002 publication, *Managing Elevated Blood Lead Levels Among Young Children*. Drafts were completed for the Introduction (Section 1), Consequences of Lead Exposures (Section 2), and Which Children Are Most At Risk? (Section 3). These sections target providers; describe the background and rationale of the paper; emphasize the importance of prevention as the first line of defense; and provide supporting data on the behavioral and neurodevelopmental consequences of children with EBLLs who manifest deficits.

The Consequences of Lead on Learning and Educational Attainment (Section 4) are incomplete. The Rationale for Thinking That Interventions Make a Difference (Section 5) is in progress and will include supporting data. Most notably, EIS and parent/family interventions have been clearly shown to benefit children <3 years of age. However, no evidence-based studies have been conducted to demonstrate that interventions in children with delays or behavioral problems secondary to EBLLs make an impact. EIWG will highlight this issue as an area for research in the paper.

Cost (Section 6) is incomplete and will include the cost of assessments on a larger number of children due to the focus on BLLs $\leq$5 µg/dL. Issues that are cost-effective or cost-prohibitive will be considered from numerous perspectives (e.g., financial, time and resource constraints for diagnosis, treatment and special education). External input will be solicited from the Department of Education (ED) to ensure that the recommendations are feasible, realistic and practical from a cost perspective.

Assessing Children for Educational Needs (Section 7) is in progress and will cite AAP practices, describe quality measures for developmental screening of children, and emphasize the need for assessments in transitional years for children in grades 4-5. Educational Resources (Section 8) are in progress and will describe resources and interventions that are currently available in schools for the target children (e.g., specialists). EIWG is still compiling existing data for this section.

Individual Regulations (Section 9) are in progress and will reference existing laws in IDEA Parts B and C, Section 504 that protect the target children. EIWG has extensively discussed the need to inform the public of these existing laws because many parents are unaware that their children already qualify for certain IDEA services (e.g., assessments, interventions and other benefits). Under each IDEA law, guidance will be provided on the same set of questions (e.g., Who needs this service? Why is this service needed?). This section will be directed to all persons who are responsible for the care of the target children (e.g., teachers, providers, school nurses and parents).

Advocacy Opportunities (Section 10) are incomplete and will provide guidance on including advocacy efforts in existing models and policies and mobilizing additional grassroots efforts. Specific Recommendations (Section 11) are nearly complete, but modifications will be made after the other sections are finalized. Recommendations for Policy Change (Section 12) are incomplete. EIWG currently is identifying gaps in this section (e.g., other populations of eligible children, additional services, ineligible children from a legal perspective, and opportunities to recommend policy changes to cover ineligible children).

Research Needs (Section 13) are incomplete and will include an evaluation of the impact of the interventions following implementation. Action Steps (Section 14) are complete and will provide practical, feasible and meaningful guidance for specific categories of caretakers. Although many of the sections are incomplete or in progress at this time, Dr. Gardner believed that EIWG would complete the draft Educational Intervention paper by March 2012.

Kim Nelson Dietrich, PhD
Professor of Environmental Health
University of Cincinnati College of Medicine
ACCLPP Member & Educational Intervention Workgroup Member

Dr. Dietrich provided additional comments on EIWG's ongoing activities. The overarching purpose of the paper will be to educate pediatricians, family physicians and general practitioners on the critical role of EBLLs in the educational development of children. Providers will be encouraged to view lead exposure as an important component of the child's medical record.

Dr. Dietrich noted that EIWG's draft guidance will need to be revisited after ACCLPP's formal vote on lowering the BLL of concern to <10 µg/dL. Similar to LWG, ACCLPP's decision will have implications for EIWG's recommendations.

ACCLPP made several comments and suggestions for EIWG to consider in its ongoing efforts to complete the draft Educational Intervention paper.

- Section 6 should analyze the cost of developmental evaluation or neuropsychological testing, particularly for the high-risk Medicaid population. This section should include a strong recommendation on the need for Medicaid children to have access to EIS in all states.
- Section 10 should address advocacy opportunities for both public policy and specific children. Advocacy for children will be particularly important to ensure eligible children receive their entitled benefits and services.
- Section 10 or 11 should address existing capacity and gaps in the current infrastructure at the system level. The new language will be important to determine whether the recommendations can be realistically implemented to evaluate children who need EIS.
- Section 13 must be given a great deal of consideration to ensure appropriate data are collected. Most notably, the study design (e.g., no, non-specific or specific interventions) will be critical in determining research needs based on an evaluation of the impact of the interventions. Different types of study designs could confuse results of the evaluation due to confounders that have no relevance to lead.
- EIWG should give careful consideration to the implications of lowering the BLL of concern to <10 µg/dL. Most notably, the number of children who will be characterized as "lead exposed" and will need EIS will dramatically increase. School systems across the country might be overburdened by referring and taking other actions on a much larger population of lead-exposed children. However, other ACCLPP members emphasized the need to take caution in publicizing that the population of children with EBLLs will tremendously increase if the BLL of concern is lowered to <10 µg/dL. Based on data collected through 2008, current estimates show that the number of children with BLLs ≥5 µg/dL in the United States has decreased to 442,000. Capacity to assess the target children at more regular intervals most likely will need to be increased with a lower BLL of concern, but a dramatic change in the delivery of interventions is not anticipated.
- CDC should expand ACCLPP's membership to include representation by ED. ED's ongoing input will be invaluable in helping ACCLPP to determine the most effective educational interventions for lead-poisoned children. ED representation also will serve as a strong linkage between ACCLPP and teachers.

Update by the Lead in Consumer Products Workgroup (CPWG)

Michael Kosnett, MD, MPH
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ACCLPP Member & Lead in Consumer Products Workgroup Chair

Dr. Kosnett covered the following topics in his update to ACCLPP on CPWG's activities. CPWG's initial focus was on lead in toys, particularly those that were produced in and imported to the United States from China. The Consumer Product Safety Improvement Act of 2008 stated that recalled toys could not be exported to other countries. CPWG recognized that interventions for lead in consumer products only would be effective with international outreach.

The vast majority of consumer products that have been recalled due to lead originated from international countries outside of the United States.

CPWG focused on products from China due to its role as the second largest trading partner to the United States outside of Canada. CPWG formulated a strategy to interact with colleagues in China. Most notably, a U.S. group with representation by ACCLPP and CDC traveled to China in 2010 to describe the domestic experience of addressing lead from multiple sources. The Chinese colleagues were open to collaborating with the United States in reducing the use of lead in consumer products.

CPWG initially advised HHS/CDC to convene conferences or workshops in China to address this issue in further detail, but funding constraints prohibited this approach. As a result, CPWG raised the possibility of colleagues in China attending conferences in the United States. To facilitate this effort, CPWG drafted the "Model Curriculum for Short Courses in U.S. Approaches to Lead Poisoning Prevention." The model curriculum is designed for and targeted to Chinese public health professionals and scientists who would visit and learn from U.S. programs in a variety of formats.

Dr. Kosnett noted that the draft outline of the model curriculum was distributed to ACCLPP for review and comment. He summarized the 4 modules of the draft model curriculum.

Module I: Childhood Lead Poisoning Prevention

1. Overview presentations
    a. Sources and epidemiology of childhood lead poisoning
    b. Clinical diagnosis and medical management
    c. Discussion of similarities and differences in U.S. and Chinese populations
2. Pediatric Blood Lead Registries
    a. Presentation on state and regional registry operation
    b. Information technology components and privacy concerns
    c. Demonstration of database utilization
    d. Discussion of strategies to enhance childhood blood lead screening
3. Pediatric Case Management
    a. Presentation regarding case management protocols (including case ascertainment, data collection, family interviews, record keeping, and follow-up)
    b. Site visit to a child's residence with demonstration of interview techniques, wipe and bulk sampling, handheld XRF measurement technology, lead swabs, etc.
    c. Review and discussion of multimedia lay language educational materials
    d. Strategies for integration of lead poisoning prevention with other maternal-child health initiatives (WIC clinics, etc.)
4. Manpower and Budget Requirements for a Regional CLPPP

Module II: Laboratory Aspects of Blood Lead Testing

1. Overview Presentations
    a. Laboratory technology for blood lead analysis: modalities, accuracy, precision, limits of detection, quality assurance and quality control
    b. Laboratory certification regimes

c. Optimizing information technology for lead poisoning prevention programs
2. Site visit to a clinical laboratory with a demonstration of instrumentation and QA/QC methods
3. Presentation and Demonstration of Point of Care Testing Equipment (e.g., LeadCare II)

Module III: Environmental Methods in Lead Poisoning Prevention

1. Overview presentations
   a. Lead in environmental media (soil/dust, air and water) as a source of childhood and adult lead exposure
   b. US approaches to assessing, measuring, and remediating lead hazards posed by contaminated soil, water, and air (including state and federal programs, clean-up standards, CERCLA, etc.)
2. Site visit to a lead remediation project (including presentations from an on-scene coordinator or contractor regarding methods to control exposure to remediation workers, disposal of lead contaminated waste, etc.)
3. Site visit to a lead-safe "renovation, remodeling, and painting" project at residence
4. Demonstration of sampling techniques for lead in environmental media
5. Presentation on lead in consumer products, with demonstration of product screening using wipe sampling and x-ray fluorescence (XRF) instrumentation

Module IV: Occupational Lead Poisoning Prevention

1. Overview presentations
   a. Sources and epidemiology of adult lead exposure
   b. Health concerns of low level lead exposure and recommendations for medical management (including medical removal protection)
   c. Discussion of similarities and differences in U.S. and Chinese workplaces
2. Adult blood lead registries
   a. Presentation on state adult blood lead registries
   b. Information technology components and privacy concerns
   c. Demonstration of database utilization
3. Occupational lead poisoning case management
   a. Presentation regarding case management protocols (including case ascertainment, data collection, worker and employer interviews, record keeping, and follow-up)
   b. Presentation on "take-home" exposure (child exposure from parental occupation)
   c. OSHA regulations and recommendations regarding lead safe work practices
   d. Review of lay language worker and employer educational materials
   e. Discussion of strategies for prevention of adult lead exposures
4. Lead industry site visit, with demonstration of state-of-the-art industrial hygiene practices (personal protective equipment, engineering controls, work practices, air sampling and wipe testing)

CPWG believes that a delegation of 10-15 Chinese public health professionals and scientists could be accommodated for each of the 4 modules over a 4- to 5-day period. A certificate would be awarded to each Chinese colleague who completes a module. China would support the majority of the costs for the U.S. site visits. CPWG's next steps are to present the draft

model curriculum to various groups (e.g., the Shanghai Municipal Center for Disease Control and Prevention) for input, endorsement and support.

CPWG's other priority is to expand the CDC.gov website to include programs and resources that are available to public and private agencies at state and local levels to better understand, identify and report problems on lead in consumer products to domestic and international governments. CPWG believes that the new web page will promote outreach to overseas peer institutions and other colleagues. The U.S. Department of State (DOS) and Food and Drug Administration (FDA) will be key partners in this effort.

Carla Campbell, MD, MS
Associate Teaching Professor, Drexel School of Public Health
ACCLPP Liaison, American Academy of Pediatrics

Dr. Campbell provided additional details on CPWG's website project. The CDC.gov website will be updated with a new "one-stop-shop" web page that will provide links to other websites. The links will allow parents, healthcare providers, regulators and other groups to access information from a variety of sources (e.g., DOS, FDA, USDA, U.S. Consumer Product Safety Commission (CPSC) and U.S. Department of Commerce) on consumer products that have been recalled or are a subject of concern.

The new web page also will provide more explicit and specific guidance to individuals or groups with an interest in reporting problems related to consumer products. CPWG currently is gathering information that will be helpful to web page users. The contents of the draft web page will be presented to ACCLPP for review, comment and formal approval. CPWG welcomes input from ACCLPP at this time on other potential resources to include on the new web page.

ACCLPP applauded and expressed support for CPWG's plans to implement the model curriculum modules for China and develop a new web page for lead in consumer products. The members made several comments and suggestions for CPWG to consider in shifting from a vision of these efforts to concrete action steps.

- The entity with responsibility for supporting the maintenance of the lead in consumer products web page over time should be identified at the outset. This approach will be critical because information on lead-containing products and regulations rapidly changes and will need to be quickly updated for the public. However, CPWG clarified that the web page will only serve as a portal to other resources (e.g., CPSC and FDA) and will not need frequent updates.
- Ms. Lori Michaelson is the ACCLPP *ex-officio* to DOS. She volunteered to serve as a conduit to provide DOS Desk Officers with information on lead-containing products to facilitate notification to other countries.
- Participation in the model curriculum modules in the United States should be expanded to include public health professionals and scientists from countries other than China that have similar interests and needs in reducing lead poisoning.

- Some modules in the model curriculum should be incorporated over time rather than at the outset. For example, capacity and expertise on POC testing, the use of XRF, environmental testing and other laboratory-based techniques need to be strengthened in the United States before training can be offered to China and other countries. APHL could serve as an important partner in enhancing laboratory expertise in the United States and refining the proposed modules related to laboratory-based techniques.
- The Society of Toxicology should be engaged as an important partner in implementing the model curriculum modules due to its strong interest in environmental issues at the global level. Moreover, Society of Toxicology members who represent China and other countries are continuing to grow.
- Consideration should be given to expanding ACCLPP's sole focus on lead to include arsenic, mercury, cadmium, and other non-essential, highly-toxic elements that play an important role in ayurvedic medicines, jewelry and other consumer products. This approach would be consistent with CDC's expanded scope to focus on other threats in addition to lead.

Public Comment Session

Marissa Scalia Sucosky, MPH
Epidemiologist, NCEH/EEHS/HHLPPB
Centers for Disease Control and Prevention

Ms. Sucosky reported that CDC subscribes to CPSC and FDA recalls on consumer products to update its website within 24 hours. CDC currently is revising its recall website to be more user-friendly. FDA recalls on consumer products will be included on the CDC website in the near future. Strategies are being explored to determine the feasibility of including and maintaining alerts issued by states on the CDC website. CDC's ability to sort product recalls on its website by country might be helpful to ACCLPP in identifying countries other than China with a critical need to participate in the model curriculum modules in the United States.

Craig Boreiko
Environment and Health Manager
International Lead Zinc Research Organization

Mr. Boreiko advised CDC and its partners to contact the Secretariat of the Basel Convention in Geneva to obtain additional expertise on the battery recycling investigation in Puerto Rico. The Basel Secretariat restricts trans-boundary movement of hazardous wastes, including used lead-acid batteries, and has been making efforts in the Caribbean and Latin America to structure regional recycling regimens for used lead-acid batteries.

The Basel Secretariat has developed web-based guidance documents, assessment tools and other materials to assist in evaluating the performance of facilities. Based on these tools, for example, EPA has grossly underestimated the magnitude of the problem at the battery recycling

plant in Puerto Rico. The plant produces ~500 tons of lead product each month from ~600 tons of spent batteries each month, but the disposal of the remaining 100 tons of contaminated material each month is not addressed. Mr. Boreiko offered to provide Dr. Brown with links to the Basel Secretariat's resources for review by CDC and its partners.

Cynthia Driscoll, PhD, JD
Jones Day

Dr. Driscoll reported that the U.S. government maintains a website at www.recalls.gov to provide the public with up-to-date information on recalled products in numerous categories (e.g., foods, medicines, consumer products, motor vehicles and boats).

Carolyn Grossman
Communications and Public Affairs Consultant
Magellan Biosciences

Ms. Grossman reported that Magellan has a long history in encouraging PT participation. To reduce barriers to this effort, Magellan offers a free test kit to PT participants who report their results. The cost of the test kit is $260. Magellan has been exploring strategies to offset costs to the California and Wisconsin PT Programs. However, Wisconsin needs the full PT protocol (e.g., a $50 registration fee plus $490 per year) and will not be eligible for the less expensive model of 2 PT tests.

Public health laboratories are the major source of opposition to participation in the new PT program, particularly because small, rural clinics do not have sufficient volume. Magellan currently is collaborating with public health laboratories, WIC clinics and Federally Qualified Health Centers to overcome these challenges.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 4:52 p.m. on November 14, 2011.

Opening Session: November 15, 2011

George Rhoads, MD, MPH
Interim Dean, University of Medicine and Dentistry of New Jersey, School of Public Health
ACCLPP Chair

Dr. Rhoads opened the floor for introductions to determine the ACCLPP voting members, *ex-officio* members and liaison representatives who were in attendance. He confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for ACCLPP to conduct its business on November 15, 2011 and reconvened the meeting at 9:14 a.m.

Dr. Rhoads reminded the ACCLPP voting members of their responsibility for recognizing and publicly disclosing their individual conflicts of interest identified by the CDC Committee Management Office and recusing themselves from participating in or voting on these matters.

Update on 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 covered the following topics in his update to ACCLPP on national performance measures of blood lead in children. NHANES data have shown a dramatic reduction in the prevalence of BLLs ≥10 µg/dL in children 1-5 years of age from 88.2% in 1975 to 0.8% in 2010. The prevalence of BLLs ≥10 µg/dL has decreased in the U.S. population for all ages from 2.2% in 1991 to 0.34% in 2010. The current prevalence of BLLs ≥10 µg/dL has not been stable since 1999, but an overall downward trend has been observed from ~2.2% to 0.37%.

NHANES is a national, representative program of studies to determine the health and nutrition status of non-institutionalized adults and children in the United States. NHANES was initiated as a periodic survey in the early 1960s and was changed to a continuous survey that has been conducted every two years since 1999. NHANES includes home-based interviews and medical evaluations to collect demographic, socioeconomic and dietary data. The examination includes medical, dental and physiological measurements and laboratory tests.

The NHANES methods include a complex multi-stage survey design and a probability sampling frame. The sampling frame for the Primary Sampling Unit is all U.S. counties or a cluster of counties with small populations. Within each selected county, a certain number of households are selected. Within each selected household, ≥1 persons are selected after all members of the household have been screened.

This methodology allows NHANES to produce estimates of medical conditions for the entire civilian non-institutionalized U.S. population, quantify sampling areas associated with the sampling design, characterize the precision and make estimates. NHANES serves as a more efficient approach to obtain a simple random sample.

Of all household members interviewed and screened, ~80% are selected for participation in NHANES. Of 15 Primary Sampling Units (e.g., counties) that are selected each year (or 20-30 per cycle), ~5,000 persons are selected for NHANES participation (or 10,000 per cycle). NHANES over-samples populations that have health characteristics of particular importance or interest. If over-sampling was not performed, stable estimates could not be generated in smaller groups to yield meaningful data. For example, Hispanics, non-Hispanic blacks and persons >60 years of age were over-sampled in the 2007-2008 NHANES cycle.

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.

Based on 2009-2010 NHANES data, 77,100 children 1-5 years of age currently have BLLs $\geq$10 µg/dL. However, these estimates are unstable due to wide confidence intervals. In the current NHANES cycle, the geometric mean of BLLs is 1.17; the 95th percentile is 3.34; and the 97.5th percentile is 4.46. These estimates account for all sampled children and have no problems with stability. Geometric means of BLLs based on 4-year data are 1.33; 3.83 at the 95th percentile; and 5.18 at the 97.5th percentile.

The Blood Lead Level of Concern Workgroup has proposed to identify a reference value based on 2 NHANES cycles (or 4 years of NHANES data) rather than use the cutoff of 10 µg/dL. The reference level for the 1999-2002 NHANES cycle was 6.2 for the 95th percentile and 8.5 for the 97.5th percentile. The reference level for the 2003-2006 NHANES cycle was 4.6 for the 95th percentile and 6.4 for the 97.5th percentile.

Mr. Wheeler summarized estimates using the reference value. The proportion of BLLs in children above the reference point at the 95th percentile would be 6.2 in the 1999-2002 NHANES cycle and 4.6 in the 2003-2006 NHANES cycle. The proportion of BLLs in children above the reference point at the 97.5th percentile would be 8.5 in the 1999-2002 NHANES cycle and 6.4 in the 2003-2006 NHANES cycle. Calculations of the reference level using 2007-2010 NHANES data showed that the geometric mean would be 1.33; the 95th percentile would be 3.83; and the 97.5th percentile would be 5.18.

The number of children with BLLs 4-5 µg/dL would be substantial based on 2005-2008 NHANES data. The number of children with BLLs equal to or greater than a reference level of 4 µg/dL would be ~686,000 based on 2009-2010 NHANES data. The number of children with BLLs >10 µg/dL would be 5 in the 2009-2010 NHANES cycle and 9 in the 2007-2008 NHANES cycle. The reference level identified 30 children with BLLs >10 µg/dL. Based on a reference value, the number of children estimated to have BLLs >5 µg/dL at the 97.5th percentile would be 442,000.

A similar number of children 1-2 and 3-5 years of age were well represented in the sample for the 2007-2010 NHANES cycle (e.g., 615 versus 590 children). However, more samples from children 1-2 years of age were submitted for blood testing. The total number of children 1-5 years of age sampled was 860 in the 2007-2008 NHANES cycle and 890 in the 2009 NHANES cycle.

In response to ACCLPP's questions, Mr. Wheeler provided additional details in two areas: (1) the rationale for selecting NHANES data beginning in 1999 to compare reference levels and (2) the systematic approach to randomly select 15 counties for NHANES from ~3,000 counties in the United States.

Dr. Brown confirmed that Mr. Wheeler's modified slides and all other slide sets presented during the meeting would be available to the public on the CDC/ACCLPP web page at: www.cdc.gov/nceh/lead/ACCLPP.

PANEL PRESENTATION: UPDATE BY THE BLOOD LEAD LEVEL OF CONCERN (LOC) WORKGROUP

A series of ACCLPP members presented overviews of specific sections that would be included in the draft LOC Report. The presentations are set forth below.

Introduction

Perry Gottesfeld, MPH
Executive Director, Occupational Knowledge International
ACCLPP Member & Blood Lead Level of Concern Workgroup co-Chair

Mr. Gottesfeld presented an overview of the "Introduction," including the background and justification of the LOC document and issues the LOC Workgroup considered in developing the document. Millions of children had BLLs >10 µg/dL when CDC established this threshold in 1991. The number of children with BLLs <10 µg/dL currently is ~400,000. This dramatic decrease underscores the tremendous progress that has been made over the past 20 years. The LOC Workgroup strongly believes that lowering the BLL of concern also addresses budget issues related to CDC's LPP activities.

HHS established a Healthy People 2010 goal to reduce childhood BLLs to <10 µg/dL. Based on the national performance measures of blood lead in children presented by Mr. Wheeler, the HHS goal has been met. However, ACCLPP should now make efforts to establish and meet a new goal by lowering the BLL of concern. The LOC Workgroup is aware of the urgency of this action. Despite the reassurances Dr. Brown made on the previous day, Mr. Gottesfeld's personal belief was that ACCLPP would not be maintained in 2012 to continue addressing the BLL of concern.

ACCLPP charged the LOC Workgroup with recommending a new approach, terminology and strategy for EBLLs among children. The LOC Workgroup identified specific strategies to best replace the LOC. BLLs related to adverse effects would be evaluated. Consideration would be given to laboratory quantification for lead in blood as a possible limitation. Decisions would be made on an appropriate terminology to replace "LOC." Increases in BLLs over time would be interpreted. Guidance would be provided on screening and re-screening intervals, notification procedures and other interventions (e.g., chelation). Possible actions to lower exposures would be outlined. Research recommendations would be provided.

To fulfill its charge, the LOC Workgroup convened 6 face-to-face meetings and teleconferences with >20 members, experts and CDC staff. Options for replacing the LOC were reviewed and a decision was made not to conduct a comprehensive risk assessment or literature review. Several drafts of the document were circulated among the LOC Workgroup members and a final draft was distributed to the full ACCLPP membership.

The LOC Workgroup considered additional issues during its deliberations. CDC has extensive guidelines and recommendations covering a wide range of topics that are all based on the BLL of 10 µg/dL. Federal, state and local governments all use the LOC to trigger actions. Decisions on abatement versus interim control measures currently are linked to the BLL of 10 µg/dL. Some local and state housing codes use BLLs >10 µg/dL to trigger enforcement. Pediatricians use the BLL of 10 µg/dL to inform parents whether their children do or do not have problems. Efforts to eliminate the LOC must replace outdated advice.

Mr. Gottesfeld highlighted the next steps in the process. The LOC Workgroup members would present brief overviews of the sections of the document. The floor would be opened for a focused discussion on the particular section only. Ideally, these sessions would be limited to questions and clarifying comments because a much broader discussion would be held on the entire document after all of the sections had been presented.

During the broader discussion, a revised draft would be presented based on comments the ACCLPP members submitted to the LOC Workgroup after the deadline. Comments submitted by individuals and organizations outside of ACCLPP have not been incorporated because ACCLPP has not yet formally voted to approve the document.

Based on ACCLPP's comments made during the meeting, the current draft would be revised overnight and presented for ACCLPP's vote during the business session on the following day. If approved, CDC would forward the document to the HHS Secretary within 3 days. The HHS Secretary would have 30 days to review and acknowledge receipt of the document.

Mr. Gottesfeld thanked the ACCLPP members, external consultants and CDC staff for their extensive participation, input and assistance in helping the LOC Workgroup to develop and revise the draft document over the past year.

Scientific Rationale

Deborah Cory-Slechta, PhD
Professor, University of Rochester School of Medicine
ACCLPP Member & Blood Lead Level of Concern Workgroup co-Chair

Dr. Cory-Slechta presented an overview of the "Scientific Rationale" section. In 2005, an ACCLPP Workgroup evaluated extant evidence and recommended against changing the LOC at that time for various reasons. Data available on IQ in association with BLLs <10 µg/dL relied on <200 children at that time. No effective clinical or public health interventions exist to reliably

and consistently lower BLLs that already were <10 µg/dL. Poor housing, poverty, lead exposure and cognitive impairment often occur together. The ability to isolate the role of any specific component with certainty is difficult, particularly socioeconomic status (SES). Uncertainties exist related to laboratory testing precision.

Based on its review of data that are relevant to BLLs <10 µg/dL following activities by the 2005 Workgroup, the LOC Workgroup made the following recommendations. The term "level of concern" should be eliminated because no BLL without deleterious effects in children has been identified. Primary prevention should be reemphasized. Recognition should be given to the fact that a biological "threshold" or "effect level" is not synonymous with a BLL at which intervention is required or effective. The science should be separated from actions taken with respect to medical management and community intervention.

The Scientific Rationale section is not intended to serve as a full-blown risk assessment or a comprehensive review of the scientific literature. Numerous other bodies have recently produced papers on the effects of BLLs <10 µg/dL (e.g., EPA in 2006, Health Canada in 2010-present, German Human Biomonitoring Commission in 2010, ATSDR in 2007, state of California, and the National Toxicology Program (NTP)).

The Scientific Rationale section considers the weight of the evidence related to BLLs <10 µg/dL that is now available. A brief summary is provided on new scientific literature that was published after the 2005 Workgroup document was released. The new data cover reductions in IQ and academic achievement, impairments of specific cognitive functions, and adverse effects on other organs and systems (e.g., cardiovascular system, development of reproductive systems and growth). Supportive animal data are cited in terms of biological plausibility.

Several issues formed the basis of the LOC Workgroup's recommendations. The weight of the evidence is critical. All studies on lead or other epidemiological parameters are not of equal merit. Prospective studies are considered to be stronger than cross-sectional studies due to the lack of a full exposure history in these designs. Children's BLLs are highly correlated over time. The overall weight of the evidence is much more critical than findings from a single study. The shape of the dose-effect curve at BLLs <10 µg/dL, particularly in relation to IQ, is irrelevant. Greater effects at BLLs <10 µg/dL compared to BLLs >10 µg/dL are not reported for all outcomes and were not a component of the LOC Workgroup's deliberations.

The impact of concurrent BLLs is critical and is among the strongest predictors of many negative associations. Concurrent BLLs are more consistent for many outcomes than maternal or neonatal exposure metrics. This finding is reported in the draft NTP monograph. No evidence has been produced to date to demonstrate that lead effects can be reversed after being imposed. This finding is reported in the Treatment of Lead-Exposed Children clinical trial and also is supported by toxicokinetics data.

Evidence related to reductions in IQ at BLLs <10 µg/dL has been gathered from populations in North America, Australia, Europe and Asia with a range of IQ tests. The 2005 Lanphear, *et al.* pooled analyses included 1,333 children from 7 international population-based longitudinal cohort studies. Additional studies have been produced since the 2005 Workgroup's review: the

2005 Chen, *et al.* study, the 2007 Chiodo, *et al.* study, the 2009 Kim, *et al.* study, and two Jedrychowski, *et al.* studies in 2009.

Although the average BLL is lower at school age, most prospective studies show stronger associations between concurrent BLLs and IQ reduction at school age. Since 2003, data from a much larger and more diverse group of children have informed effect levels. The NTP draft monograph cites "sufficient" evidence of an association between concurrent BLL and IQ reduction and only "limited" evidence of an association with prenatal BLLs.

Evidence related to reductions in academic achievement has been gathered from prospective and cross-sectional studies in children with BLLs 2-10 µg/dL from North America, Europe and Africa. The studies reported negative associations between BLLs and scores in tests of academic performance, class rank, or end-of-grade testing. The body of evidence includes the 2007 Surkan, *et al.* study, the 2001 Al-Saleh, *et al.* study, the 2002 Wang, *et al.* study, the 2009 Min, *et al.* study, and the 2009 Chandramouli, *et al.* study.

Evidence related to impairments in specific cognitive functions has been gathered from prospective and cross-sectional studies of children 3 months to 16 years of age from multiple, different populations. These studies used both general and specific measures of cognitive function. Multiple studies reported negative associations between Mental Development Index (MDI) scores and BLLs 2-10 µg/dL.

The majority of prospective studies reported an association between prenatal exposure in cord or maternal BLLs <10 µg/dL and decreased MDI scores in children through 3 years of age. Multiple studies reported impaired attention-related behaviors at mean BLLs <5 µg/dL. Since 2000, >10 publications have reported an association between concurrent BLLs at mean values of 1-11 µg/dL and a diagnosis of attention deficit hyperactivity disorder (ADHD)/decreased attention or hyperactivity in children 3-18 years of age.

Evidence related to adverse effects on other organs and systems has been gathered from multiple studies. An association between BLLs <10 µg/dL and delayed onset of puberty in children 8-17 years of age was reported by 8 cross-sectional studies and one prospective study from 7 different populations in North America, Europe and Africa. The studies were adjusted for factors known to influence puberty (e.g., race, SES and body mass index).

An association between BLLs <10 µg/dL and stunted postnatal growth in children was reported by prospective studies of a negative association between maternal BLLs <10 µg/dL and head circumference. Multiple cross-sectional studies and findings from three relevant prospective studies supported growth retardation. A prospective study reported two key findings: (1) an association between a mean cord BLL of 3 µg/dL and blood pressure changes in children 9.5 years of age and (2) an association between a mean early childhood BLL of 4.6 µg/dL and increased blood pressure in response to acute stress. These findings were highly consistent with animal studies.

The LOC Workgroup has extensively discussed and thoroughly considered input submitted on the Scientific Rationale section. Concerns were raised about residual confounding with low

SES. The LOC Workgroup's response is that the Bellinger and Needleman study defined the Boston prospective cohort as a "socioeconomically advantaged population." The Yugoslavia prospective cohort reported an inverse association between BLL and IQ. Only BLLs, not SES, differentiated the two towns in the cohort. IQ was reduced only with EBLLs in comparison to an SES-equivalent population without EBLLs.

The Health Canada document concluded that the pattern of results did not appear to be dependent on cohort demographics (e.g., SES) or range of exposure. Significant associations were reported among groups with both relatively low and high SES.

The following specific comments were submitted to the LOC Workgroup: "Despite reductions in BLLs, reading and math scores have not increased." "Even though BLLs have declined, ADHD diagnoses have risen." The LOC Workgroup's response is that these are multifactorial outcomes and are not dependent upon changes in BLLs alone. No published studies could be identified to support the comments. Moreover, IQ scores, math scores and reading scores have actually increased in the United States over the past century.

In terms of the greater magnitude of effects at lower BLLs, an argument was made that in a lower lead environment, the same differences in developmental outcomes are now associated with small differences in BLLs and magnify the apparent effect of each microgram of blood lead on various developmental outcomes.

The LOC Workgroup's response is as follows. The fact that IQ scores are reduced to a greater extent at BLLs <10 µg/dL as opposed to reductions at BLLs >10 µg/dL is not the sole determinant in the context of the weight of the evidence and does not provide evidence of no effects at BLLs <10 µg/dL. Moreover, the shape of the curve at low BLLs has been described for IQ. Even if the shape of the curve is confounded, no explanation can be given on the effects of BLLs <10 µg/dL on other outcomes and organs/systems where the shape has not been reported.

In terms of multiplicity of lead effects, one commenter noted that the lack of specificity implied by multiple endpoints suggests the need for more study of these outcomes. The LOC Workgroup's response is that the biology of lead is completely consistent with an impact on multiple organs, systems and endpoints. Lead is a calcium mimetic. In some studies, lead has been shown to be used preferentially by the body over calcium.

Calcium is the most important metal in the body from a physiological perspective and is used in a wide variety of cellular processes that generalize across organs (e.g., basic neurotransmission through the central or peripheral nervous system). Lead also substitutes for other essential metals in the body, including zinc, copper and iron.

Dr. Cory-Slechta summarized the bases for the LOC Workgroup's recommendations. Many uncertainties associated with BLLs <10 µg/dL have been minimized or eliminated by research published since the health effects review conducted by the 2005 Workgroup. The weight of evidence supports associations of BLLs <10 µg/dL with a variety of endpoints in children,

including reductions in IQ and academic achievement and impairments in attention-related behaviors.

Less extensive, but supporting evidence shows an association with retardation of growth and delayed puberty. The weight of evidence underscores the importance of concurrent exposures of children in many of these outcomes. The LOC Workgroup's position is that epidemiological approaches should be retired if the studies cited in the document do not constitute a sufficient weight of evidence.

The LOC Workgroup emphasized primary prevention in the document. Children currently serve as "canaries in the coal mine" because EBLLs are used to identify lead sources. The current strategy of identifying EBLLs does not prevent damage already incurred. Economic analyses of reducing or eliminating lead always have a positive dollar benefit.

The need for primary prevention was first suggested by CDC in 1970 and is underscored by the success of regulatory policies that control or eliminate sources of lead in the environment; the lack of proven methods to reverse negative impacts after identifying children with EBLLs; and the lack of a clear "threshold" or "safe" BLL without deleterious effects. This focus would allow for resources to be redirected to evidence-based primary prevention strategies to reduce exposures.

Dr. Cory-Slechta provided additional details on the Scientific Rationale section in response to ACCLPP's questions. These topics included:

- reasons why the shape of the dose-effect curve is irrelevant;
- the breadth and scope of studies on concurrent BLLs and the definition of "concurrent BLLs;"
- the clinical importance of changes in blood pressure in children with BLLs <10 µg/dL; and
- the extent to which the quality of blood lead measurements in the studies were reviewed.

ACCLPP proposed specific suggestions for the LOC Workgroup to consider in revising the Scientific Rationale section.

- The lack of changes in learning outcomes over time in the context of the tremendous decrease in BLLs may warrant more attention in the Scientific Rationale section.
- Studies on learning, cognitive and behavioral outcomes are much more extensive than those that address other outcomes. Studies on other outcomes have not been reviewed and examined for possible confounding factors to the same extent as the body of evidence on learning, cognitive and behavioral outcomes.
- The Nevin study should be cited in the LOC document. Other studies that have tracked the use of lead in gasoline and BLLs to determine associations with teen pregnancy, IQ and other important social outcomes are quite remarkable and should be referenced as well.

- The LOC document cites numerous studies that reported an association between BLLs <10 µg/dL and a specific adverse health effect. These statements might need to be clarified with qualifying language (e.g., the lower limit of detection for a particular study).

In response to ACCLPP's questions, Dr. Brown provided additional details on next steps and procedural issues related to the LOC document. ACCLPP members, liaisons and *ex-officios* will be provided opportunities to make comments on the draft document throughout the meeting. A public comment session will be opened after ACCLPP's deliberations for members of the public to provide commentary.

If ACCLPP votes to adopt the draft, the document will be forwarded to the CDC Office of the Director for "information only." The Office of the Director will forward the document to the HHS Secretary within 3 days after receipt. The HHS Secretary will have 30 days to acknowledge receipt of and review the document. After the 30-day period, ACCLPP will be free to make the document publicly available through websites or other venues. CDC could decide to implement all, some or none of the recommendations. CDC's decision-making process will occur at the level of NCEH leadership.

After ACCLPP publishes the document and before CDC begins implementing the guidance, ACCLPP liaisons and their organizations, ACCLPP *ex-officios* and their federal agencies, and other groups or individuals in the public will have an additional opportunity to make public comments.

Dr. Brown emphasized that the LOC document is not a CDC product with the weight of a CDC manual, guidance document or set of recommendations. The LOC document is an ACCLPP product. As a result, CDC will review the document and determine the extent to which all, some or none of the recommendations will be implemented.

Reference Value Approach to Evaluate BLLs

Perry Gottesfeld, MPH
Executive Director, Occupational Knowledge International
ACCLPP Member & Blood Lead Level of Concern Workgroup co-Chair

Mr. Gottesfeld presented an overview of the "Reference Value Approach to Evaluate BLLs" section. 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 are derived from large population studies (e.g., NHANES) and can be used to classify individuals or populations as "elevated" or "not elevated."

Various scientific bodies and authorities define "reference values" differently. The Clinical Laboratory and Standards Institute and the International Union of Pure and Applied Chemistry have published definitions for reference values. In 1996, the German Human Biomonitoring

Commission defined reference values as "usually the 90th or 95th percentiles." The 2009 Schulz, *et al.* study defined the reference value as within the 95% confidence interval of the 95th population percentile of the distribution of concentrations of a specific compound or element in a body fluid of a reference population.

The 2010 Boyd study reported that 95% reference intervals often are derived by splitting the most outlying 5% of observed values, but all of the 5% are considered in cases where only low or high values are of concern and result in a one-sided reference interval. To inform its approach, the LOC Workgroup reviewed a German model that was used by an advisory group of the Federal Environment Agency in Germany.

The 2010 Wilhelm, *et al.* study concluded that a reassessment of critical lead effects by the German Human Biomonitoring Commission should result in suspension of human biomonitoring values for lead in blood of children and adults. The study recommended a reference value for children 3-14 years of 3.5 µg/dL.

Reference values identify persons with increased exposure, but are not toxicologically-derived or health-based. If the 95th percentile is applied to a combination of the two most recent NHANES cycles, the reference value would be ~4 µg/dL in the United States. Reference values identify children in the upper range of BLLs in a population and must be periodically updated. The LOC Workgroup's recommendation is for CDC to update the reference value every 5 years. This approach would yield a long-term and robust measure. Geographical subgroups or other subpopulations also could be used if the sample size was sufficient.

Overall, a "reference value" unifies ACCLPP's message that a "safe" or "acceptable" level of exposure for children has not been determined. A reference value also provides a clearly defined approach to establish a public health action level based on surveillance data that should be regularly updated over time.

ACCLPP proposed specific suggestions for the LOC Workgroup to consider in revising the Reference Values section.

- NHANES is conducted every 2 years, but the LOC Workgroup has recommended updating the reference value every 5 years. The reference value should be updated every 4 or 6 years to correspond to the 2-year NHANES cycles.
- Some ACCLPP members did not agree with the LOC Workgroup's statement that a reference value unifies the message of "no safe or acceptable level of exposure for children has been determined." The members noted that "safe" is a risk management term. The Reference Value section should use the same language as the Scientific Rationale section: "No BLL without deleterious effects in children has been identified."
- The reference value should not be limited to 2.5% at the 97.5th percentile or 5% at the 95th percentile because these figures are arbitrary.

In response to ACCLPP's question, Mr. Wheeler confirmed that he would provide data on the distribution of BLLs in children 1-5 years of age in increments of 1 µg/dL for the 2007-2010 NHANES cycle.

Laboratory Methods

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

Dr. Parsons presented an overview of the "Laboratory Methods" section for blood lead testing and analytical performance at BLLs <10 µg/dL. Blood lead testing was associated with three false myths in 1991 at the time CDC lowered the BLL of concern to 10 µg/dL. Capillary blood obtained by fingerstick cannot be used for a blood lead test because of lead contamination from the skin and a small sample volume. Analytical techniques are not sufficiently sensitive to measure lead at the lower action level. Most clinical laboratories cannot accurately measure lead at the lower action level.

Analytical methods for blood lead testing have dramatically improved from 1965 to 2001. The need for 7 mL of venous blood has been eliminated. The introduction of ASV and Delves Cup Flame Atomic Absorption Spectrometry in the 1970s allowed for reliable measurements of capillary blood and established opportunities to conduct mass screening. These techniques evolved into Graphite Furnace Atomic Absorption Spectrometry (GFAAS) in the 1980s, Inductively Coupled Plasma Mass Spectrometry (ICP-MS) in the 1990s, and the LeadCare I and II POC devices in the 2000s.

GFAAS is an automated and highly complex technique with a limit of detection (LOD) of ~1 µg/dL and a limit of quantitation (LOQ) of 2-3 µg/dL. GFAAS is used in a large number of U.S. laboratories for routine clinical blood lead measurements. A GFAAS unit can be purchased for $30,000-$50,000 and still can be used to make reasonably solid measurements at BLLs 5 µg/dL with a certain level of confidence.

ASV bench-top is a non-automated and highly complex technique with an LOD of ~2-3 µg/dL and an LOQ of ~10 µg/dL. ASV is no longer available for purchase, but the manufacturer still supports current users. In the past, an ASV unit could be purchased for $10,000-$15,000. ASV is not expected to have good performance in measuring BLLs at lower levels.

ICP-MS is an automated and very highly complex technique with an LOD of 0.05-0.20 µg/dL and an LOQ of 0.30-0.70 µg/dL. ICP-MS is a multi-element technique that has capacity to simultaneously measure different metals (e.g., lead, mercury, manganese and cadmium). An ICP-MS unit can be purchased for $180,000-$250,000. Sector Field ICP-MS has an LOD of 0.016 µg/dL and an LOQ of 0.055. The cost of this unit is $500,000 and is used for special

projects rather than routine blood lead measurements, including those that require isotope ratios. Due to its cost, Sector Field ICP-MS is not widely available.

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

Routine blood lead measurements depend on the performance of these devices. The current CLIA standard for total laboratory errors is ±4 µg/dL/±10%, but a recommendation has been made for a more stringent standard of ±2 µg/dL/±10%. Based on available data, most U.S. laboratories should be able to meet the recommended standard. The New York State Department of Health used its 2006 PT reports to determine the inter-laboratory standard deviation (SD) at 11 µg/dL and 6 µg/dL. The analysis showed that at the concentration of 6 µg/dL, the SDs were 1.5 with ASV bench-top, 1.4 with the handheld ASV LeadCare device, 0.7 with GFAAS, and 0.6 with ICP-MS.

The same data set was used to determine the inter-laboratory relative SD (RSD) for each of the 4 devices. At concentrations <10 µg/dL, ASV bench-top began to poorly perform and had quite large relative uncertainty. The RSD was well above 20%. If the BLL of concern is lowered to 5 µg/dL, ASV could not be used for routine blood measurements.

GFAAS had an RSD of better than 20% at a concentration of 5 µg/dL and could be used for routine blood measurements based on an analytical perspective, current laboratory performance, and use of the 97.5th percentile. However, GFAAS could not be used if the BLL of concern is lowered to 4 µg/dL due to misclassification issues. The performance of GFAAS and the LeadCare device was nearly identical, while the performance of ISP-MS was quite respectable.

Dr. Parsons provided additional details on the Laboratory Methods section in response to ACCLPP's questions. These topics included (1) the rationale for recommending a more stringent standard for laboratory errors of ±2 µg/dL/±10% and (2) the effect of contamination errors at a lower capillary BLL of 4 or 5 µg/dL.

Ms. Cynthia Ruff is the ACCLPP *ex-officio* for the Centers for Medicare and Medicaid Services (CMS). She would approach her colleagues in the CLIA Section to determine the status of CMS's decision on the recommendation to lower the standard for laboratory errors from ±4 µg/dL/±10% to ±2 µg/dL/±10%. Ms. Ruff confirmed that she would report her findings to ACCLPP.

Health Management

Megan Sandel, MD, MPH
Assistant Professor, Boston Medical Center
ACCLPP Member

Dr. Sandel presented an overview of the "Health Management" section for primary prevention, management and treatment of lead exposure in children. The section reemphasizes the need for a discussion of risks of lead exposure prior to testing. Language on risk questionnaires was extracted from the 2007 Binns, *et al.* study. Language on risk factors for lead exposure in pregnant and lactating women was extracted from a table in the ACCLPP Lead in Pregnancy Workgroup document. Language on nutrition and iron was extracted from a statement published by the AAP Pediatrics Committee.

If the LOC document is approved, the Health Management section will include revisions to 3 tables in the 2002 ACCLPP publication, *Managing Elevated Blood Lead Levels Among Young Children*. In Table 3.1, the column heading of "10-14 µg/dL" would be replaced with "≤ [Reference Value]." New guidance would be included in this column to conduct an environmental investigation for children who live in pre-1978 housing.

The column headings of "15-19 µg/dL and 20-44 µg/dL" would be combined into one column and replaced with "≥[Reference Value] to ≤45 µg/dL." The guidance would be merged, but not changed. Guidance in the <45-69 µg/dL column would not change. Guidance in the >70 µg/dL column would change from "chelation therapy" to "intravenous (IV) chelation therapy."

In Table 3.3, "10-19 µg/dL" would be changed to "[Reference Value] to 9 µg/dL. The time to confirmation testing would be changed from "3 months" to "1-3 months." The second BLL category would be changed from "20-44 µg/dL" to "10-45 µg/dL." The time to confirmation testing for BLLs ≥70 µg/dL would be changed from "emergently" to "urgently as an emergency test."

In Table 3.4, the first two categories of venous BLLs for follow-up testing would be changed from "10-14 µg/dL and 15-19 µg/dL" to "[Reference Value] to 9 µg/dL and 10-19 µg/dL." The footnotes on the seasonal variation of BLLs and decisions by some case managers or primary care providers to repeat blood lead tests within a month will be retained in the table. For early follow-up testing (2-4 tests after identification), the ≥45 µg/dL column would be changed from "as soon as possible" to "consider chelation."

ACCLPP proposed specific suggestions for the LOC Workgroup to consider in revising the Health Management section.

- Table 3.1: The language on abdominal x-ray should be should be removed from the > [Reference Value] to ≤45 µg/dL" column and placed in the text of the document.

Abdominal x-ray should be recommended at these BLLs in exceptional circumstances only or with a rising or problematic BLL in a child.

- Table 3.1: The recommendation to perform free erythrocyte porphyrin (FEP) testing in the 45-69 µg/dL column should be removed.
- Table 3.1: The recommendation to conduct an environmental investigation for children who live in pre-1978 housing at BLLs <[Reference Value] will have huge implications for public health resources.
- Table 3.1: "Chelation therapy" should not be changed "IV chelation therapy" in the >70 µg/dL column. A reference should be given to the 1995 and 2002 CDC documents on different types of chelation.

Community Interventions

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

Ms. Malone presented an overview of the "Community Interventions" section, but she welcomed input from ACCLPP on potentially changing the title of this section to engage a broader group of stakeholders. The section relies on ACCLPP's key publication, *Preventing Lead in Young Children: A Housing-Based Approach to Primary Prevention*. HUD data were used to develop a table of U.S. homes with lead-based paint (LBP) or hazards, but the LOC Workgroup has not made a decision on whether the table will be included in the document.

The subsections cover essential points in 3 major categories. The "Controlling and Preventing Lead-Based Paint Hazards" subsection explains that abatement is a common response to a lead-poisoned child and requires specialized work to eliminate lead. Guidance is provided on actions every property owner can and should take: maintain paint in an intact condition; check for and repair deteriorated paint; insist that contractors follow EPA's Renovation, Repair and Painting (RRP) Rule to ensure poor renovation work does not poison children; and follow lead-safe work practices on "do-it-yourself" projects.

The "Policies to Advance Lead-Safe Housing" subsection outlines key guidance in several areas. Resources should be focused on high-risk homes and communities. Surveillance data will play a critical role in this effort. Many entities should be engaged in a continuum of strategies (e.g., housing and financial approaches) to reach a variety of homes, programs and activities. RRP capacity and compliance should be assured. Housing codes and lead laws should be enforced with a "zero tolerance" for LBP hazards.

The "Local and State Government Roles" subsection describes activities that should be conducted by these agencies. Properties at highest risk should be targeted for priority action. Health and housing agencies and their data should be linked to easily identify properties with lead-poisoned children. Preventive standards for rental housing should be enacted (e.g.,

essential maintenance practices, proactive inspections, intact paint, turnover treatments, clearance following high-risk work, and a response to multi-family properties in which one unit has poisoned a child).

Standards should be established for owner-occupied housing. The use of exterior deteriorated paint could be used as an indicator of problems in the interior of the property. Financing through loans, grants and tax credits should be offered for remediation of properties. Families should be given assistance to undertake self-protective actions through lead and tenant education, home visiting programs and legal support.

Overall, medical professionals, educators, parents, employers, advocates, public health officials and other groups should distribute "public health prescriptions." The "patient" would be a child <6 years of age. The "address" would be a home at risk of lead hazards. The "age of home" would be pre-1978. The "medication" would be a lead-safe home with zero tolerance of hazards.

ACCLPP proposed specific suggestions for the LOC Workgroup to consider in revising the Community Interventions section.

- A new recommendation should be added to address proactive window replacement.
- The language on "standards for owner-occupied housing" should be changed to "preventive standards."
- The guidance on financing for remediation of properties should be expanded to include the private sector in addition to federal, state and local governments. Moreover, this language should make a distinction between tenant-occupied and owner-occupied housing. Low-income owner-occupants may have fewer resources than landlord-owned properties. Financing options and resources should be referenced in the document.
- Guidance should be provided on common reporting formats and language for housing interventions to facilitate implementation at the local level.
- The term "lead-poisoned child" should be removed from the "Controlling and Preventing Lead-Based Paint Hazards" subsection to be consistent with the other sections of the LOC document.

Dr. Brown announced that the November 16-18, 2010 meeting minutes were distributed to the ACCLPP membership in March 2011. However, hard copies of the minutes were available on the table of meeting materials. She asked ACCLPP to review the minutes in preparation of the business session on the following day.

Environmental Interventions

Perry Gottesfeld, MPH
Executive Director, Occupational Knowledge International
ACCLPP Member & Blood Lead Level of Concern Workgroup co-Chair

Mr. Gottesfeld presented an overview of the "Environmental Interventions" section for lead hazards in housing. The goal of primary prevention is to reduce environmental exposures from soil, dust, paint and water before their contribution to a child's exposure. This approach is in contrast of just lowering a child's BLL.

The new approach emphasizes that the only strategy to solve childhood lead poisoning is to control potential lead exposures in a child's environment before damage is caused. Multiple risk factors and exposures contribute to BLLs <10 µg/dL. Capacity does not exist to identify a single source of exposure in many cases that require source identification and reduction.

Several actions can be taken to prioritize housing. Specific addresses often are linked to repeated cases of EBLLs. Neighborhoods based on census tracts predict rates of EBLLs. Rental status and other housing characteristics can be used as indicators. Environmental testing is a useful strategy to focus limited hazard control resources. However, environmental assessments in housing still will be triggered by the presence of an EBLL.

CDC's current guidelines recommend (1) considering environmental investigations for BLLs >15 µg/dL and (2) eliminating environmental lead sources for BLLs >20 µg/dL. Proposed changes to CDC guidelines by the LOC Workgroup are to (1) consider environmental investigations for all pre-1978 homes where children live and (2) conduct environmental investigations for all homes where children live with BLLs greater than the reference value. The LOC Workgroup proposed no changes to the following language in the current CDC guidelines: "The extent of an environmental intervention (e.g., abatement) is based on identifying lead hazards during investigations."

The LOC Workgroup also formulated new recommendations. Environmental investigations are a necessary first step to primary prevention and should be encouraged in as many homes as possible. Environmental remediation should be triggered by the presence of lead hazards in soil, dust or paint that exceed EPA's current guidance. If environmental testing uncovers lead hazards that trigger a response in a single unit in multi-family housing, environmental remediation should be performed on all units in the property.

Mr. Gottesfeld provided additional details on the "Environmental Interventions" section in response to ACCLPP's questions. These topics included:

- existing data on the efficacy of identifying remediable environmental lead sources at a BLL of 4 or 5 µg/dL;
- the interchangeable use of the terms "environmental assessments" and "environmental investigations" throughout the document;
- guidance in the LOC document to address the 2.7% of LBP hazards in U.S. homes built between 1978 and 2005; and
- the need to assess state and local capacity to serve a larger number of children who will be referred for environmental interventions due to the lower BLL of concern.

Research Needs

Walter Rogan, MD
Epidemiologist Branch, National Institute of Environmental Health Sciences
ACCLPP Ex-Officio

Dr. Rogan presented an overview of the "Research Needs" section. Research area 1 is an evaluation of interventions to reduce exposure. The reduction of exposures from lead or other toxic substances is known to prevent effects. A ban on lead-painted toys or lead in cosmetics does not need to be evaluated *per se*. Children who are not raised in leaded neighborhoods have low BLLs. Opportunities to evaluate programs should be identified and leveraged. Data are limited on the quality that a home, neighborhood, or other facilities in a child's social network should have (e.g., homes of other family members and daycare centers). This issue warrants further research.

Research area 2 is secondary prevention. Data have shown that at least in infancy, higher dietary calcium, iron and zinc are associated with lower BLLs. A study conducted with NHANES data showed that children with higher BLLs had lower vitamin C levels. The study concluded that vitamin C may enhance excretion of lead. Children should at least be replete for calcium, iron and zinc, but AAP specifically warns about iron supplementation in children with BLLs $\geq$25 µg/dL. Children with cognitive or behavioral problems that are associated with lead should respond to the same educational interventions as other children. EIWG will address this issue in the Educational Intervention paper.

Research area 3 is sources and routes of exposure in older children. Prospective studies have reported stronger associations with lower BLLs achieved by older children. Cross-sectional associations in older children may be causal because this population of children is more mobile, live in a "bigger world," and likely differ from toddlers in their exposure sources. A systematic review of the existing literature on older children would help to guide further analyses, but new data also may need to be produced.

Research area 4 is other uses of the results from screening programs. Results from screening programs need to be validated. These findings do not produce true prevalence, are not comparable across jurisdictions, and do not provide guidance on stable actions that can be taken over time or performed by various clinical professionals.

A population-based survey was conducted in Chicago and compared to results from a screening program. Unweighted results from the Chicago statistical sample were similar to the frequency of positives identified in the screening program. The availability of a reliable strategy to avoid true surveys by using screening data would be extremely helpful as a planning tool and a resource to evaluate the success of screening programs. Additional paired data sets of large U.S. cities and screening programs would help to demonstrate whether or not this approach is effective.

Research area 5 is better POC lead analyzers. POC technology is needed that is accurate to ±1 µg/dL or better to conduct primary prevention at this time. In the future, mass spectrometry on a chip, µMXRF machines, or combined lead/mercury/arsenic/cadmium devices could be useful for both clinical and research purposes. LWG is addressing this issue for the LOC Workgroup.

Research area 6 is the epigenetic mechanism of lead action. Delayed effects at lower levels are observed, but are difficult to explain. Epigenetic changes (e.g., stable changes in DNA that alter gene expression) are a new and plausible approach for an epigenetic mechanism of lead action to occur.

Open Discussion on the LOC Document

Dr. Rhoads initiated the open discussion on the LOC document by presenting a series of slides on secular trend data. Observational studies, which account for the vast majority of the published literature on lead effects, are subject to confounding. RCTs and secular improvements in health following environmental and preventive interventions are two approaches that are useful to confirm that observed associations are likely to be causal.

ED conducts the National Assessment of Educational Progress (NAEP) to follow educational outcomes in children over time. The nearly 1 SD difference in reading scores between black and white children 9 years of age is consistently demonstrated in NAEP reports. Applying regression coefficients published by Lanphear, *et al.* to the 90% reduction in BLLs that has occurred since the 1970s yields an expected improvement in reading scores that is of similar magnitude to the black/white difference and should be easily seen in the NAEP 9 year-old data. Surprisingly, there has been no change. Reading scores of children at other ages as well as high school graduation rates also have remained flat over time.

There are two competing explanations for this disconnect. The first possibility is that the failure to detect the predicted improvement in learning outcomes is due to other adverse secular changes that have canceled the favorable effects of the 90% reduction in lead exposure. The very smooth, flat reading scores that persisted while lead levels fell so dramaticaly argue against this interpretation since it would be unlikely that these countervailing influences (if operative) would so exactly cancel the favorable effects of declining lead exposure so as to avoid swings in reading scores in the successive birth cohorts of children.

A second, much simpler explanation is that the strength of the relationship between lead and learning outcomes that is reported in newer observational studies of BLLs <10 µg/dL is substantially exaggerated.

Support for explanation 1 is based on the consistency of observational studies in showing an association between BLLs and a variety of learning and cognitive outcomes. Cohort studies of good quality have been done with adjustment for many potential confounders.

Support for explanation 2 is based on the well-known vulnerability of observational studies to confounding even in carefully planned and well-executed cohort studies. The difficulty in measuring SES, its close nexus with blood lead and academic performance makes these studies particularly vulnerable. A stronger association at low levels is compatible with both explanations 1 and 2, but is predicted only by explanation 2.

Non-food ingestion is known to be exaggerated with very low IQ and probably is facilitated in rambunctious, active and unsupervised children who may not perform as well in school settings. The association between lead and ADHD has been observed more in hyperactive than in inattentive children.

Concurrent BLLs in school years was not found to be important in the early Needleman studies, but appear to be more important than toddler BLLs in recent studies. The reason for this finding is unknown, but would be logical if less academic children ingested more substances. In early studies, air would have dominated exposures to school-aged children and obscured the effect of ingestion on BLLs. However, air is now much less important as a source. Presumably, ingestion now dominates exposures to school-age children providing a possible explanation for the association.

In summary, very large effects on developmental outcomes are predicted by the 90% reduction in blood lead, but are not observed. The LOC Workgroup should acknowledge this gap in the document and be more circumspect in its assertions that low-level effects are causal.

ACCLPP made several remarks in follow-up to Dr. Rhoads' comments.

- Some LOC Workgroup members were not persuaded by the secular trend data Dr. Rhoads presented. Large increases in IQ are unaccompanied by large increases in reading. The rationale for this finding is unknown, but does not demonstrate evidence against an effect of lead on IQ or reading. The interpretation of secular trends in these measurements might be more difficult than counting outcomes year-by-year. Moreover, other factors are included in educational outcomes (e.g., reading) that are not captured by IQ. To select one outcome over the other and conclude that increases are or are not due to lead is "cherry-picking." This approach is not the result of a comprehensive analysis across a variety of outcomes that should be equally considered.
- Hyperactivity or ingestion answered all cross-sectional associations in the studies. The secular trend data Dr. Rhoads presented should not be acknowledged in the LOC document.
- The Boston study found that BLLs peaked at 2 years of age, while the Cincinnati study observed a cross-sectional association. These studies were conducted simultaneously and their outcomes were due to different findings and cohorts rather than a disconnect between air and dust lead.
- The stable trend in reading scores is not surprising due to the collapse of the educational system in the United States and factors other than lead.

- The graph Dr. Rhoads presented on “expected” and “actual” NAEP reading scores has statistical variation, uncertainty and questionable power because the SD from one measure was extrapolated and applied to another measure.
- The LOC document does not include statements on “causal” associations. However, other ACCLPP members believed that the term “causal associations” should be included in the document because lead is known to directly cause adverse health effects.
- The LOC document will include a paragraph on the weight of evidence to acknowledge that not all studies are equal.

To guide the open discussion, Dr. Cory-Slechta displayed the current draft of the LOC document on a screen for ACCLPP to review in preparation of its vote. She explained that this version reflected written comments ACCLPP submitted to the LOC Workgroup after the deadline as well as comments and suggestions ACCLPP made over the course of the November 2011 meeting up to the point of the open discussion.

Dr. Cory-Slechta highlighted two key points related to the current draft displayed on the screen. First, the current draft had a new title: *Low Level Lead Exposure Adversely Impacts Child Health: A Renewed Call for Primary Prevention*. Second, hard copies of the current draft were not distributed to ACCLPP in advance of the open discussion due to time constraints.

In general, ACCLPP commended the LOC Workgroup on displaying an up-to-date draft of the document. This effort was particularly impressive because the current draft reflected key comments and suggestions ACCLPP made during the meeting. In particular, ACCLPP was extremely concerned that the current draft was displayed on the screen only and was not distributed to the membership. The members noted that ACCLPP was expected to vote on a document that would have significant policy implications, but a hard copy was not provided.

ACCLPP’s comments and suggestions on the LOC document are outlined below. (*Editor’s Note*: The feedback summarized below reflects both the November 8, 2011 draft and the most recent version of the document displayed on the screen.)

General Comments

- The extensive review of primary prevention, therapeutic strategies and other data from the lead literature dilutes the impact and focus of the document on BLLs <10 µg/dL. The LOC document should solely focus on this issue and emphasize that no safe level for lead has been determined. Primary prevention, treatment and other lead-related issues should be addressed in smaller companion documents.
- Consideration should be given to replacing “elevated BLLs” with “BLLs above the reference value” throughout the document.

Scientific Rationale

- The section should be refined by first making a strong case for primary prevention and then documenting the scientific rationale.
- A statement should be made to acknowledge that IQ as a measurement does not have the same level of quality and accuracy as other indices (e.g., height and weight) due to

disparities in lead exposures based on culture, SES and other factors. Dr. Friedman will provide citations to the LOC Workgroup to support this suggestion.

- More data should be provided on the association between BLLs and ADHD in the context of criminal behavior. A statement should be added to clarify that some studies on delinquency and crime used bone lead rather than blood lead as a marker.
- A reference was previously included in the document regarding the efficacy of chelation in reducing BLLs and their adverse effects. This text should be reinserted based on data that demonstrate the ability of chelation to reduce BLLs.
- The 2004 Dietrich, *et al.* study described chelating agents for BLLs 20-44 µg/dL, but specific BLLs of children who were chelated in the study should be specified. These data are needed because chelation doses given to children in the study were not traditionally recommended. The safety and efficacy of chelation at lower BLLs need to be assessed.

Reference Value

- The reference value should be updated every 4 years rather than every 5 years as proposed by the LOC Workgroup. The date of the first review should be staggered to coincide with the 2-year NHANES cycle. A staggered approach still will provide CDC with one year to collect and review NHANES data from the last year that will be included in the review. **[Accepted]**
- The term "reference value" as used in the document actually refers to a "reference limit" (e.g., the upper limit of the reference interval).
- The reference value should be more clearly outlined and prominently featured. A table should be developed to highlight the reference value and the supporting NHANES data. This format would be particularly helpful to clinicians. **[Accepted if CDC provides technical assistance]**
- In general, many AAP members were in favor of the proposal to lower the BLL of concern to establish a more solid goal toward prevention. In particular, AAP supported 5 µg/dL because this reference value may lead to less misclassification errors. A value of 4 µg/dL at the 95th percentile may result in more misclassification errors and uncertainty.
- The reference value should be based on the 97.5th percentile rather than the 95th percentile. This value is well established in clinical laboratories in the United States. Moreover, the 97.5th percentile for a 4-year estimate (e.g., the combination of two 2-year NHANES cycles) is stable. **[Accepted]**

Health Management/Primary Prevention

- The reference value has serious implications and proposes approaches in Table 3.1 that are not feasible for health departments to implement. Table 3.1 recommends environmental investigations for children with BLLs below the reference value and lead hazard control for children with BLLs above the reference value. The LOC Workgroup estimated that the reference value would be ~4 µg/dL if the two most recent NHANES cycles were combined and the 95th percentile was applied. Based on this estimate, the projected costs of interventions in this population of children would range from $5 to $20 billion annually. The federal government does not and will not have this level of funding now or in the future for the management and treatment of lead-exposed children. The

reference value must be effectively translated into priority actions. Because costs will prohibit compliance to the recommendations, the credibility of public health will be damaged at federal, state and local levels.

- The term "environmental investigation" should be replaced with "environmental assessment" in the table, "Recommended action according to blood lead measurement." Alternatively, a footnote could be added to clarify that health departments will not be expected to conduct a full-blown environmental investigation for children with the lowest BLLs. However, other ACCLPP members were not in favor of this suggestion because the term "environmental investigation" establishes a goal for health departments and programs in the field. The language should not be softened due to limited resources.
- The primary prevention documents that CDC/ACCLPP published in 2004 and 2005 should be more prominently featured and referenced in the document. The LOC document should clarify that the focus on primary prevention is not new and has been a longstanding issue for CDC/ACCLPP.
- The text should be revised as follows: "Over the last 22 years, federal and state agencies have adopted requirements for lead safe work practices …". The LOC document inaccurately states that these actions have occurred over the last "10" years. The requirements include HUD's interim guidelines for public and Indian housing in 1990; OSHA's requirements in 1993; and EPA's Training and Certification Rule in 1996. Dr. Friedman will provide citations to support this revision. **[Accepted]**
- The LOC document does not acknowledge the enormous accomplishment by HUD's Lead Hazard Control Grant Programs of making >130,000 units lead safe. However, some ACCLPP members were not in favor of adding this language because the overarching purpose of the document is to provide fairly concise messages to pediatricians and clinicians. A suggestion was made to reference the HUD infrastructure at a later point in the document to inform clinicians of existing resources.
- The existing language should be revised and clarified as follows: "An elevated capillary blood lead test should be repeated using venous blood." **[Accepted]**
- The word "small" should be deleted from "small variations of $\pm$2 µg/dL." The document should acknowledge that federal regulations allow laboratory errors up to $\pm$4 µg/dL.
- In the "Summary of medical interventions" table, the basis for the recommendation to measure hemoglobin or hematocrit in children with a BLL of 4 or 5 µg/dL is unclear. Lead-induced anemia does not occur in children until BLLs are at least $\geq$25 µg/dL. The recommendation should be changed for clinicians to "consider" measuring hemoglobin or hematocrit. **[Accepted]**
- The word "IV" should be deleted from "hospitalize and commence IV chelation therapy for BLLs $\geq$70µg/dL" in the table. This revision would allow a medical toxicologist or Pediatric Environmental Health Specialty Unit (PEHSU) to decide whether to administer IV or oral chelation.
- The 45-69 µg/dL column should include new text to "consider hospitalization if a lead-safe environment cannot be secured for the child." The text can be added after "oral chelation therapy" in the table. **[Accepted]**
- "Environmental investigation" should be changed to "environmental assessment" in the first column of the table. **[Accepted]**

- A new recommendation should be included: "Chelation should not be initiated until confirmatory venous blood lead testing is conducted." **[Accepted]**
- FEP testing is not justified and should not be recommended in a policy document. However, other ACCLPP members were in favor of new language: "Consider FEP paired with blood lead testing."
- "Packed red cells in saliva" should be added to the matrices of hair, teeth and fingernails to test for lead. New language should be added: "Stimulated urine testing or provocative chelation prior to testing is not recommended." "There is no medical indication for diagnostic testing using the following: lead lines, testing of neurophysiologic function …". "K-XRF" should be deleted.
- The guidance should be categorized by specific recommendations for clinicians, public health officials and government agencies.
- Standard terminology should be established and uniformly used throughout the document (e.g., "lead level above the reference value" or "elevated blood lead level"). However, the term "lead-poisoned" should not be used. The word "management" should be used rather than "treatment" to refer to the clinical management of children.
- AAP expressed concern over the increased clinical load for public health departments, PEHSUs and clinicians and the lack of resources to manage the new population of children with BLLs at or above the reference value.
- The document should provide links to solid patient education materials for clinicians and encourage public health educational campaigns.
- The table illustrating risk factors for pregnant women is confusing because risk factors are different for pregnant women/fetuses and young children 9-12 months of age through 3-6 years of age who are screened. The table should be revised with more details on specific risk factors for children.
- The document calls for universal screening to occur at least once for children 12-24 months of age. The document should acknowledge that this recommendation is a departure from CDC's 1997 policy. The document provides latitude to localities in choosing different screening guidelines, but many state and local health departments have already created universal or targeted screening recommendations based on CDC's 1997 policy. This guidance needs to be clarified in the document.
- Universal screening is used to collect data to determine reference values in the future, but other strategies should be explored in this effort (e.g., population-based surveys). Pediatricians have previously rejected universal screening.
- Any recommendations in the LOC document that differ from previous CDC policy should be highlighted in a bulleted format at the beginning.
- The recommendation to "test siblings of children with EBLLs, even those above age 6" does not provide sufficient guidance (e.g., the age to stop testing and the circumstances under which to conduct testing).
- Dr. Sandel is a member of the AAP Committee on Environmental Health and will be responsible for ensuring comments submitted by this group are included in the LOC document. However, the inclusion of AAP's comments in the document will be limited to only those that relate to the LOC Workgroup's charge.

Community Interventions

- Interim controls are intended to correct LBP hazards. The document should cite 24 CFR 35.10 to define interim controls. Lead-safe paint repairs should be deleted from the list of interim controls.
- ACCLPP was not in favor of the suggestion to revisit the definition of "lead-based paint" because this guidance would be for EPA rather than CDC. Moreover, HUD and EPA currently are undertaking this effort.
- Community sources of lead other than housing, screening of these sources and preventive measures should be described in the document. Agreement was reached to provide references to other CDC documents that address these issues.

Environmental Interventions

- The phrase, "there is no acceptable level of risk," should be deleted. The phrase implies that any detectable level of lead in paint and dust in the home is unacceptable. This implication is inconsistent with public policy in the United States. EPA and HUD are undertaking a deliberative process at this time to assess levels of lead in dust and paint in the home. However, other ACCLPP members did not agree with this suggestion. The following compromise was reached: "Given the involuntary nature of lead exposures associated with housing and other sources and the risks associated with lead exposure, all exposures should be kept as low as possible." **[Accepted]**
- The document should provide less radical guidance than assessing all units in multi-property housing based on lead hazards identified in only one unit. Dr. Friedman will provide the LOC Workgroup with HUD guidelines that describe the scientific and statistically-based protocol for assessing all units without the need for testing.

Research Needs

- The research need for "better POC lead analyzers" should be expanded with more details.

The LOC Workgroup made several follow-up remarks to some of ACCLPP's comments and suggestions.

- The Scientific Rationale section clearly states that the recommendations are resource-dependent.
- The term "reference value" is not consistently used by any agency or authority. Based on a review of existing data, the LOC Workgroup's use of the term "reference value" is appropriate and refers to only one tail rather than an entire interval.
- The suggestion to first address primary prevention in the Scientific Rationale section is not an effective approach. With this format, the charge to the LOC Workgroup would begin on page 10 or 11 and would dilute the overarching purpose of the document. However, the LOC Workgroup will determine if this suggestion can be accommodated in the executive summary that will be developed.
- The LOC Workgroup did not identify any studies that demonstrated an association between criminality and BLLs <10 µg/dL. However, the LOC Workgroup welcomes citations of studies from ACCLPP on this issue to consider for inclusion in the document.

- Pediatricians routinely measure hemoglobin or hematocrit in children as part of blood lead testing. This recommendation is consistent with normal clinical practice.
- FEP remains a valuable biochemical marker of lead intoxication.
- The term "universal screening" has been removed from the LOC document.

Dr. Brown provided additional details on next steps and procedural issues. ACCLPP has three options to take formal action on the LOC document: (1) accept the document, (2) accept the document with revisions for the LOC Workgroup to make, or (3) reject the document. If ACCLP approves option 2, the members must submit their comments on the current draft of the LOC document by December 1, 2011. The LOC Workgroup will consider and review additional comments made during the meeting and up to the December 1, 2011 deadline. A revised draft will be circulated to the ACCLPP voting members in early January 2012. ACCLPP will vote on the document during a teleconference that will serve as an official ACCLPP meeting.

If CDC adopts the recommendations in the LOC document, a more specific, "operational" document will be developed similar to the Blue Book. The purpose of this document will be for CDC to implement the recommendations. However, the process to obtain public comment on CDC's operational document has not been determined at this point. In response to the suggestion to create multiple companion documents, Dr. Brown clarified that a robust executive summary most likely would address this issue.

A motion was properly placed on the floor by Drs. Sandel and Reyes, respectively, for ACCLPP to agree to the following approach. ACCLPP will accept the document pending changes on the following day during the business session. The LOC Workgroup will distribute the revised version of the document reflecting comments made during the meeting and additional comments up to the December 1, 2011 deadline. A teleconference will be held in January 2012 for ACCLPP to vote on the final draft. **ACCLPP unanimously approved the motion.**

Public Comment Session

Richard Gragg III, PhD
Associate Director & Associate Professor, Environmental Sciences Institute
Florida A&M University School of the Environment

Dr. Gragg announced that he was attending the meeting by teleconference and had no access to the LOC document displayed on the screen. Because he could not make public comments on the document, he questioned whether the relationship between blood lead and bone lead was taken into account. Research has shown links between lead and hypertension when lead is stored in the body and bone. This health disparity and disproportionate levels of lead are especially prevalent in low-income and minority populations, particularly African Americans.

Dr. Gragg also questioned whether the document discusses the long-term effects of lead, accumulation of lead in the bone and its relationship to hypertension. These relationships are

important to consider in determining the actionable level for blood lead. BLLs are indicators of present or short-term exposure. Dr. Gragg asked the LOC Workgroup to consider the following citation for potential inclusion in the document: Hicken, Gragg, Hu. "How cumulative risks warrant a shift in our approach to racial health disparities: The case of lead, stress, and hypertension." *Health Affairs* 2011; 30:1895-1901.

Dr. Brown confirmed that an additional opportunity for public comment would be provided after CDC develops a process to operationalize the LOC document. All members of the public would be notified of this process. In the interim, she confirmed that Dr. Gragg would be e-mailed the current version of the LOC document displayed on the screen. Ms. Carolyn Grossman, of Magellan Biosciences, would provide Dr. Gragg's contact information to CDC. However, Dr. Brown clarified that the draft document is a product of the LOC Workgroup at this time. If ACCLPP votes to approve, the document then becomes public.

Dr. Rhoads confirmed that the LOC document discusses both the association between BLLs and hypertension and the accumulation of lead in bone. Dr. Cory-Slechta clarified that the association of lead and stress is beyond the scope of the LOC Workgroup's charge. However, she asked Dr. Gragg to provide the reference in writing for the LOC Workgroup to consider for possible inclusion.

Craig Boreiko
Environment and Health Manager
International Lead Zinc Research Organization

Mr. Boreiko announced that his agreement with the LOC document was limited to the title only. He also was dismayed with ACCLPP's process to revise an important public policy document. The LOC has been viewed as a practical level and never has been regarded as an absolute level of safety. The effects of BLLs <10 µg/dL are well known. The 2005 ACCLPP Workgroup publicly stated that BLLs <10 µg/dL cause effects, but voted to maintain the LOC to ensure children with EBLLs continued to be prioritized and societal resources were preserved.

The LOC Workgroup should carefully re-review efforts by other countries that are described in the document to ensure the accuracy of this language. The Health Canada guidelines are not in the public domain. The German guidelines are more reflective of its cancer policy. The National Health and Medical Research Council maintained the LOC at 10 µg/dL in the Australian guidelines.

The LOC Workgroup's re-review also should focus on factually inaccurate content. For example, the document states, "There was no difference in maternal IQ and home scores." However, the referenced study actually concluded: "There was a statistically significant difference." The content on SES appears to make no association with residual confounding based on the Lanphear pooled analysis. Other studies that did not show effects were cited in the document.

The document ignores the published Jesco, *et al.* study that analyzed the Rochester data used in the Lanphear analysis and found uncontrolled confounding. The study further noted that

when the Rochester data were corrected for SES or income level, a marked attenuation of the superlinear dose-response reported by Lanphear or Canfield was observed. The LOC document cites the Chandramouli, *et al.* study that found effects at BLLs <10 µg/dL, but the threshold was 5 µg/dL. Overall, Mr. Boreiko was bothered by the factual inconsistencies in the document and uncertainty related to the LOC Workgroup's approach of addressing some issues and completing ignoring others.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 5:00 p.m. on November 15, 2011.

Opening Session: November 16, 2011

George Rhoads, MD, MPH
Interim Dean, University of Medicine and Dentistry of New Jersey, School of Public Health
ACCLPP Chair

Dr. Rhoads opened the floor for introductions to determine the ACCLPP voting members, *ex-officio* members and liaison representatives who were in attendance. He confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for ACCLPP to conduct its business on November 16, 2011 and reconvened the meeting at 9:06 a.m.

Dr. Rhoads reminded the ACCLPP voting members of their responsibility for recognizing and publicly disclosing their individual conflicts of interest identified by the CDC Committee Management Office and recusing themselves from participating in or voting on these matters.

Update on the Lead Poisoning Outbreak in Zamfara State, Nigeria

Mary Jean Brown, ScD, RN
Chief, Healthy Homes/Lead Poisoning Prevention Branch, NCEH, EEHS
Centers for Disease Control and Prevention
ACCLPP Designated Federal Official

Dr. Brown presented an update on the ongoing investigation of the lead poisoning outbreak in Zamfara State, Nigeria. In May 2010, Doctors Without Borders/Médecins Sans Frontières (MSF) contacted CDC in response to children who were dying of seizures and coma. Children who MSF empirically treated for malaria and meningitis did not respond to treatment.

Blood samples taken from 6 children showed an average BLL of ~175 µg/dL with a range of 100-400 µg/dL. These BLLs are unheard of in modern times. During the investigation in May-June 2010, the childhood mortality rate for children <5 years of age in two villages in Zamfara State was ~12/10,000 per day. The childhood mortality rate of >2/10,000 per day in a refugee camp is an indicator of poor health outcomes and emphasizes the need for immediate action.

Artisanal gold ore processing was determined to be the cause of the outbreak during the first site visit to two villages. The villagers purchase sacks of gold ore from miners, ground and process the gold ore to eliminate lead, and sell the gold. In June-September 2010, CDC collaborated with several non-profit organizations (e.g., clinical care by MSF, cleanup by TerraGraphics Environmental Engineering and Blacksmith Institute, and Federal and State Ministries of Health and Environment Rapid Response Team (RRT)).

CDC and New York City provided high-level training to 4 RRT members in New York City on comprehensive lead poisoning prevention. During the training course, one RRT member received certification from New York City to process blood lead samples with GFAAS.

The Nigerian government granted CDC's request for expedited approval of oral DMSA. WHO funded MSF to provide DMSA to treat >350 children <5 years of age. The case fatality rate in MSF field hospitals decreased from ~43% at the start of the outbreak to <1% after 3 days of administering chelation therapy. However, BLLs in a large number of chelated children have plateaued in the range of 45-60 µg/dL. CDC and its partners will convene a meeting in January 2012 in Nigeria to discuss potential reasons for this outcome (e.g., re-exposure, body burden or nutrition status). Treatment also was provided to breastfeeding women who were tested.

The RRT traveled to 7 other villages and identified >100 additional cases of symptomatic lead poisoning. Experts in the field (e.g., CDC, ACCLPP, MSF and WHO) developed a protocol in which only children who lived in villages that had undergone cleanup or those who were symptomatic would be chelated. Of children who were lead poisoned in Zamfara State, ~200 are blind. Cases of spastic paralysis, serious seizure disorders and major mental retardation effects have been reported as well.

The cleanup of Zamfara State is complicated because villagers are fundamental Muslims. Women are not allowed to leave their family compounds from the age of puberty to menopause. However, religious leaders have been extremely supportive of the cleanup efforts and have lifted some of the restrictions. Women are allowed to leave the compound and men who are non-family members are permitted to enter the compound for the cleanup. Gold ore processing was performed in common areas of the compound. After the compounds were remediated, children were treated as outpatients.

The United Nations Environmental Program and the RRT tested soil samples from the gold ore processing areas in the 7 additional villages. All of the samples showed levels that exceeded the EPA standard of 400 ppm. Some samples had levels that were higher than the capacity of the handheld XRF of 100,000 ppm. The lead-contaminated surface soil was replaced with clean soil and dust inside lead-contaminated compounds was removed. TerraGraphics hired local villages to manage and conduct the cleanup.

UNICEF led the social mobilization and advertisement campaigns. Key messages that were conveyed included "move gold ore processing from the villages," "clean up before returning home," "wash your hands," and "keep children away from gold ore processing sites." Most of the gold ore processing sites have been moved from the villages. Dr. Brown presented a series

of photographs illustrating adults and children in villages who were grinding ore rock, mixing mercury by hand, and drying ground ore.

In October-November 2010, CDC visited 75 villages in Anka, Bukkuyum and Maru to characterize the outbreak. CDC is still operating on an emergency response and does not yet have population-based estimates of the extent of the outbreak. CDC's focus is on intentional screening to identify very sick children. The CDC laboratory is continuing to analyze 20 clinical samples per month for lead and other metals. These analyses have shown that the manganese levels of children who were chelated in Zamfara State have not decreased.

A plan was developed with multiple strategies to mitigate the effects of artisanal gold ore processing. Sustainable public health programs will be created to identify lead-poisoned children and provide needed medical interventions. To achieve this goal, CDC plans to conduct population-based sampling to estimate exposure. Efforts are underway to develop a cluster sampling protocol. In villages that will serve as randomized cluster samples, children 1-5 years of age, soil and house dust, and livestock will be tested. Discussions have been held to pilot a program to integrate blood lead testing into other medical services (e.g., immunization). MSF is continuing to dedicate its individual resources and efforts to developing local treatment capacity.

High-priority contaminated areas will be identified and remediated. CDC is using Google Maps to achieve this goal. The remediation plan for village compounds will cover surface soil, particularly sleeping and cooking areas where children frequent; surface soil in ore processing areas; drinking water wells near contaminated areas susceptible to contamination from surface runoff; drinking water wells with elevated lead levels; and food preparation areas and equipment that have been contaminated with lead or suspected of having been used in gold ore processing. Dr. Brown recently learned that 10-18 additional children have died from a village that was not remediated.

The remediation plan for areas outside village compounds will cover ore processing areas in the vicinity of surface water or drinking water sources; areas only accessible to young children and livestock; ore stockpiles and processing waste storage areas; and sediment in the vicinity of processing operations. Safe mining and ore processing practices will be promoted as part of worker safety and health. A remediation plan must be built into each license that is granted to a corporation to work in Zamfara State.

Economic sustainability of better mining practices will be improved. The *Daily Sun* reported 4 deaths in Zamfara State from a mining pit that collapsed on October 28, 2011. Efforts are underway to locate secure facilities to lock the gold ore. The Artisanal Gold Mining Council has made recommendations to improve mining practices. The "crushing" process can be improved by reducing dust through the use of a hammer mill and jaw crusher rather than a flour grinder. The "grinding" process can be improved by adding water to eliminate dust as the main exposure pathway. This improvement is more efficient and profitable.

The "sluicing" process can be improved by using Vortex and centrifuge. This improvement is a step toward eliminating mercury use. The use of a retort can capture mercury smoke and is believed to reduce air pollution by 95%, but this approach needs to be tested. Reprocessing of

tailings centralizes waste and is more profitable. Dr. Brown showed photographs of the recommended improvements in workflow.

Several areas of the plan to mitigate the effects of artisanal gold ore processing need to be addressed. The randomized cluster sample design may allow CDC to determine the relative contribution from drinking water, livestock and other foods. The use of ore processing waste as play material for young children needs to be addressed. The contribution of lead-contaminated house bricks, alternative ore processing methods and worker training need to be evaluated. The child labor laws need to be considered from both political and cultural perspectives. Technical expertise needs to be deployed in the field in Zamfara State.

Other significant lead sources in Nigeria include mines, lead paint, and eyeliner with 85% of lead used on children <5 years of age. The Nigerian Minister of Environment is extremely receptive to banning lead paint in this country.

During her 10-day tour of Nigeria, Dr. Brown had discussions with local and national Miner Association members, physicians, Ministers of Health, Environment Mines and Steel, and the U.S. Ambassador to Nigeria. She was pleased to announce that these groups were extremely engaged and interested in information from CDC. She also pointed out that many other parts of CDC outside of NCEH have been extensively involved in the investigation.

ACCLPP commended CDC and its global partners on the outstanding and rapid response to the unprecedented lead poisoning outbreak in Zamfara State, Nigeria. ACCLPP particularly applauded Dr. Brown for applying her international expertise and providing leadership in mobilizing the CDC team. ACCLPP emphasized the need to widely publicize CDC's response to this international disaster.

ACCLPP made two suggestions for CDC and its global partners to consider in its ongoing investigation of the outbreak. First, MSF should examine the incidence of "bruising" or "trauma" as a side effect of succimer among children in Zamfara State. Second, efforts should be made to measure bone lead levels in the children in Zamfara State. CDC should approach NIEHS to fund future research projects in this population of children.

ACCLPP Business Session

Dr. Rhoads led ACCLPP in a review of items that would require formal action or discussion.

ISSUE 1: Dr. Cory-Slechta proposed the following resolution for ACCLPP to adopt.

> ACCLPP resolution on *Low Level Lead Exposure Adversely Impacts Child Health: A Renewed Call for Primary Prevention*:
>
> Based on its conclusions of adverse effects at BLLs <10 µg/dL, ACCLPP recommends elimination of the use of the term "level of concern." ACCLPP recommends the use of a

reference value based on the 97.5th percentile of the NHANES-generated blood lead distribution in children (currently ~5 µg/dL) to identify children with elevated BLLs. These lower levels currently impact ~450,000 U.S. children. The inability to identify BLLs without deleterious effects underscores the critical importance of primary prevention. For these reasons, ACCLPP believes that restoration of full funding to the Healthy Homes/Lead Poisoning Prevention Program of the Centers for Disease Control is critical to protect children from exposure to lead in their homes and by other sources. The ACCLPP document summarizing these recommendations will be finalized in January 2012.

ACCLPP suggested several revisions to the proposed resolution.

- Change the title to: "*Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention*."
- Change the text to: "Based on its conclusions that blood lead levels (BLLs) <10 µg/dL harm children, the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommends elimination of the use of the term 'blood level of concern.'"
- Change the text to: "ACCLPP recommends the use of a reference value based on the 97.5th percentile of the NHANES-generated blood lead distribution in children 1-5 years of age (currently 5 µg/dL) to identify children with elevated BLLs."
- Change "Centers for Disease Control" to "Centers for Disease Control and Prevention."
- Change the text to: "The ACCLPP document summarizing these recommendations will be finalized and voted upon in January 2012."

A motion was properly placed on the floor by Mr. Gottesfeld and Mr. Williams, respectively, for ACCLPP to approve the resolution with the changes noted for the record. **ACCLPP unanimously approved the motion.**

Dr. Parsons announced that LWG would convene a conference call over the next month to revisit its draft recommendations based on ACCLPP's approval of the resolution, particularly those related to the POC practice standards. He emphasized the need for the LWG members to review the LOC document, submit comments and vote on the document. Dr. Brown clarified that only ACCLPP voting members can vote on documents. As a voting member, Dr. Parsons serves as the liaison between ACCLPP and LWG in terms of consolidating and presenting credible comments on the LOC document from the laboratory community.

Dr. Brown and Mr. Gottesfeld summarized the LOC Workgroup's next steps. The current version of the document that was displayed on the screen and edited on the previous day will be distributed to ACCLPP. All comments must be specific, reference a line number, and submitted in writing to the LOC Workgroup no later than December 1, 2011. Issues that the LOC Workgroup should include in the new 1-page executive summary should be submitted in bullet form.

The LOC Workgroup will hold a 3-hour teleconference on December 16, 2011 from 12:00-3:00 p.m. EST in preparation of distributing the revised document to ACCLPP by December 21,

2011. Dr. Parsons will participate on the teleconference to present LWG's laboratory comments on the document to the LOC Workgroup. A 2-hour teleconference will be held on January 4, 2012 from 1:00-3:00 p.m. EST for ACCLPP to vote on the document. The teleconference will serve as an official ACCLPP meeting that will be announced in the *Federal Register*. The teleconference will be open to the public and will include a public comment session.

Although ACCLPP unanimously approved the resolution, Dr. Brown explained that ACCLPP's charter does not provide authority for the membership to recommend funding levels for CDC/ HHLPPB. ACCLPP is chartered to advise the HHS Secretary and Director of CDC on the science of childhood lead poisoning prevention. The language in the resolution related to funding is outside the scope of the ACCLPP charge. However, Dr. Brown clarified that ACCLPP could express its concerns regarding continued funding of the CDC LPP Program in a follow-up letter to the HHS Secretary.

ACCLPP extensively discussed whether the following sentence should be modified, deleted or moved to a separate resolution: "For these reasons, ACCLPP believes that restoration of full funding to the Healthy Homes/Lead Poisoning Prevention Program of the Centers for Disease Control is critical to protect children from exposure to lead in their homes and by other sources."

A motion was properly placed on the floor and seconded by Drs. Cory-Slechta and Sandel, respectively, to delete the sentence from the resolution. **ACCLPP unanimously approved the motion.**

ISSUE 2: Dr. Brown presented tokens of appreciation to two outgoing ACCLPP members whose terms would expire in May 2012. Mr. Dana Williams has honorably served on ACCLPP for the past 5 years and is only the second member in ACCLPP's history who has represented a parent of a lead-poisoned child. The participants joined Dr. Brown in applauding Mr. Williams' participation on ACCLPP and his outstanding service to CDC.

Dr. George Rhoads has been professionally and personally supportive of ACCLPP and CDC for a number of years. He has made tremendous accomplishments as both an ACCLPP member and the Chair. The participants joined Dr. Brown in applauding Dr. Rhoads' leadership as the ACCLPP Chair and his excellent service as a member.

Mr. Williams noted that he was honored to serve on ACCLPP with his colleagues. His reports to parents, schools and other groups on ACCLPP's activities have been extremely informative and helpful to families and communities. He encouraged ACCLPP to continue its course toward elimination of childhood lead poisoning in the United States.

ISSUE 3: Dr. Rhoads entertained a motion for ACCLPP to approve the draft minutes of the November 16-18, 2010 meeting. **ACCLPP unanimously approved the minutes with no changes.**

ISSUE 4: Dr. Kosnett raised the possibility of ACCLPP revisiting recommendations that were made during the November 2010 meeting in response to the "State of the Science of Lead in Water Panel Presentation." A key recommendation was for ACCLPP and CDC to provide

guidance on lead in water. Dr. Kosnett expressed his interest in ACCLPP focusing on this issue in the future. To guide this effort, Ms. Mosby confirmed that she would provide CDC with ongoing and future plans by the EPA Office of Water for distribution to ACCLPP.

Dr. Brown announced that CDC has formally and informally made recommendations to the EPA Drinking Water Group. This input primarily focused on the need to halt the practice of partial LSL replacement and become more prescriptive in sampling procedures. Dr. Brown was confident that EPA would welcome ACCLPP's input on these and other issues related to lead in water, including current efforts to revise the Lead and Copper Rule.

Ms. Malone added that ACCLPP could play an important role by applying its expertise to ensure water is well reflected in risk assessments, particularly in the instructions, protocols and training provided to lead programs to integrate water issues into environmental investigations.

ISSUE 5: Ms. Norton reminded ACCLPP that actions are being taken in the House and Senate to eliminate CDC's LPP Program. She reiterated the urgent need for individuals to contact their Congressional representatives to stop this effort. The resolution that ACCLPP passed regarding the LOC document should be included in these communications.

Strong support also should be expressed to increase HUD's budget for primary prevention with hazard control and abatement. NCECLP, NCHH and other organizations are available to help individuals and groups with their advocacy efforts. The elimination of CDC's LPP Program would be a dramatic loss, particularly in light of ACCLPP's approval to lower the reference value to 5 µg/dL.

The LOC document should be cross-checked with the interagency "Healthy Homes Strategy for Action" document that is being developed. The agencies hope to release the document early in 2012. Dr. Friedman offered to present an overview of the document to ACCLPP at a future meeting.

ISSUE 6: Dr. Reyes announced that the cities of Houston and Nevada were successful in their two-year effort to address lead in pottery. A chain store voluntarily recalled its pottery. CDC helped Houston draft a letter to FDA with recommendations regarding the use of the term "lead-free" on pottery imported to the United States. Dr. Reyes planned to send the FDA letter to the ACCLPP members for their individual support and expertise. The letter would be accompanied by a list of organizations and individuals who support this effort. Houston expects to send the letter to FDA by November 30, 2011.

ISSUE 7: Mr. Barry Brooks, of CDC/HHLPPB, announced that all ACCLPP voting members are required to receive new or refresher training from the CDC Management Analysis and Services Office on their duties and responsibilities as Special Government Employees. The 1-hour training course will be held via teleconference or webinar.

ISSUE 8: Mr. Dignam returned to the meeting to respond to ACCLPP's previous questions on the investigation of take-home lead exposures from employees of a battery recycling plant in Puerto Rico. These topics covered CDC's point of contact at EPA, the fate of battery cases,

funding for Puerto Rico-OSHA, results of environmental soil samples at the plant, owners of the plant, and the range of BLLs ≥10 µg/dL among 27 children.

Public Comment Session

Dr. Rhoads opened the floor for public comment; no participants responded.

Closing Session

Dr. Rhoads received a motion and a second from ACCLPP voting members to adjourn the meeting at 11:40 a.m. on November 16, 2011.

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

1/30/12
Date

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