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

National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry
Lead Poisoning Prevention Branch

CENTERS FOR DISEASE
CONTROL AND PREVENTION

Advisory Committee on
Childhood Lead Poisoning Prevention
March 21-22, 2006
Houston, Texas

Record of the Proceedings

TABLE OF CONTENTS

ATTACHMENT 1

List of Participants

ACCLPP Members
Dr. Carla Campbell, Chair
Ms. Magaly Angeloni
Dr. Valerie Charlton
Dr. Walter Handy
Dr. Ing Kang Ho
Ms. Valarie Johnson
Ms. Linda Kite
Dr. Jessica Leighton
Ms. Sally Odle
Dr. Catherine Slota-Varma
Dr. Wayne Snodgrass
Dr. Kevin Stephens, Sr.

Designated Federal Official
Dr. Mary Jean Brown,
Executive Secretary

***Ex Officio* and Liaison Members**
Dr. Helen Binns (AAP)
Dr. Duane Bolin (APHL)
Dr. Warren Friedman (HUD)
Dr. Benjamin Gitterman (APHA)
Mr. Steve Hays (AIHA)
Dr. Calvin Johnson (ASTHO)
Dr. Ezatollah Keyvan-Larijani (CSTE)
Ms. Jane Malone (AFHH)
Ms. Jacqueline Mosby (EPA)
Dr. George Rodgers (AAPCC)
Dr. Walter Rogan (NIH/NIEHS)
Mr. Robert Roscoe (NIOSH)
Dr. Phyllis Stubbs-Wynn (HRSA)

CDC Representatives
Dr. Robert Bossarte
Mr. Barry Brooks
Ms. Jeff Jarrett
Ms. Claudine Johnson

Texas State and Local Health Department Representatives
Ms. Robin Anderson
Ms. Kathy Barton
Mr. Emmanuel Enemkpali
Ms. Vivian Gohn
Ms. Anne Harpe
Mr. Ketan Inamdar
Mr. Robert Isaacson
Mr. Bud Karachiwala
Dr. Brenda Reyes
Mr. L.J. Smith
Mr. Richard Williams
Mr. Stephen Williams
Ms. Judy Zoch

Guest Presenters and Members of the Public
Mr. Craig Boreiko (International Lead Zinc Research Organization, Inc.)
Mr. Mark Carlton, Esq.
(Law Office of Mark L. Carlton)
Ms. Sylvia Castillo
(de Madres a Madres, Inc.)
Dr. Kim Dietrich
(University of Cincinnati)
Dr. Polly Ledvina
(Baylor College of Medicine)
Ms. Jane Luxton, Esq.
(King & Spalding)
Ms. Maria Morilla
(de Madres a Madres, Inc.)
Ms. Baby Ruth Nelson
(Gulf Coast Head Start)
Ms. Illiana Romo
(de Madres a Madres, Inc.)
Ms. Margot Tracy
(Harvard School of Public Health)
Mr. Karl Udochukwa
(Texas Southern University)

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

ADVISORY COMMITTEE ON
CHILDHOOD LEAD POISONING PREVENTION
March 21-22, 2006
Houston, Texas

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The proceedings were held on March 21-22, 2006 at the Magnolia Hotel in Houston, Texas.

Opening Session

Dr. Carla Campbell, the ACCLPP Chair, called the meeting to order at 8:40 a.m. on March 21, 2006. She welcomed the attendees to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Mr. Stephen Williams, Director of the Houston Health and Human Services Department, welcomed ACCLPP to Houston. He announced that Houston is now placing more emphasis on children's health overall; the impact of behavioral health issues on children; and the integration of the Women, Infants and Children, Healthy Homes, Maternal and Child Health, and Childhood Lead Poisoning Prevention Programs (CLPPP). Research and data collection components will be incorporated into all of these programs to more closely focus on the epidemiology and health effects of lead and other issues.

ACCLPP applauded the city of Houston in recognition of its extraordinary outreach efforts during Hurricane Katrina.

In the temporary absence of Dr. Mary Jean Brown, the ACCLPP Executive Secretary and Lead Poisoning Prevention Branch (LPPB) Chief, Dr. Campbell announced that

members with a conflict of interest are responsible for identifying these issues and recusing themselves from voting or participating in these discussions.

Update on the ACCLPP Clinical Paper

Dr. Helen Binns is the ACCLPP liaison to the American Academy of Pediatrics (AAP) and served as the primary author of ACCLPP's paper on *Understanding Blood Lead Levels and Primary Prevention*. She reported that the final draft of the paper was resubmitted to *Pediatrics* on March 8, 2006 to reflect comments by *Pediatrics* reviewers, ACCLPP members and liaisons.

The comments resulted in an extensive revision and expansion of the document, but Dr. Binns was pleased to announce that *Pediatrics* accepted the clinical paper for publication. She also reported that the paper was submitted to the *Morbidity and Mortality Weekly Report* (*MMWR*) and may be placed on the September 2006 publication calendar.

ACCLPP applauded Dr. Binns on her outstanding leadership over the past three years in developing and repeatedly revising the clinical paper to reflect ACCLPP's comments and diverse perspectives. The members noted that Dr. Binns' efforts are the primary reason ACCLPP produced a high-quality document.

Improving Model Housing Codes (MHCs) for Primary Prevention

Ms. Jane Malone is the ACCLPP liaison to the Alliance for Healthy Homes (AFHH). She described existing gaps in and ongoing efforts to improve MHCs for primary prevention. States and localities traditionally wrote property maintenance and construction codes based upon model codes developed by Building Officials and Code Administrators International, the International Conference of Building Officials, and Southern Building Code Congress International.

In 1994, the three organizations jointly established the International Code Council (ICC) to serve as the major source for codes on maintaining, building and repairing real estate. The ICC was also formed to foster uniform adoption of a single set of codes, facilitate consistent code enforcement and improve the quality of construction. At this time, ~30 states adopt ICC codes. Any interested individual or group may submit a code change proposal to ICC and participate in the deliberations. Important deadlines

in the 2006-2007 ICC code development schedule are March 24, 2006 to submit current code change proposals and September 20-30, 2006 to attend code development hearings.

At this time, only four model codes contribute to the prevention of lead poisoning. First, the international property maintenance code governs standards for occupancy of units and states that "peeling, chipping, flaking or abraded paint shall be repaired, removed or covered." However, this code only addresses lead safety in a footnote as an option instead of providing specific standards to protect children. Many communities view the language as a "cosmetic" issue that is less important than other housing hazards.

Second, international residential and building codes govern construction, but are unclear. Most notably, some renovations in the United States are not subject to codes, permits or standards. Third, the international existing building code was recently incorporated into ICC codes to address rehabilitation construction when buildings are repaired. However, the code does not mention lead or paint.

Fourth, the hazard abatement for existing building (HAEB) code focuses on correcting hazards in the course of renovation. The HAEB committee drafted a code specifically to address hazards in existing buildings. The public can review and submit comments on the draft code through April 15, 2006 on the ICC web site. Overall, none of the model construction codes cover lead-safe work practices (LSWPs) or renovation.

Other rehabilitation construction codes have been developed by the state of New Jersey, National Fire Protection Association and the U.S. Department of Housing and Urban Development (HUD). The U.S. Environmental Protection Agency (EPA) has a pending renovation and remodeling rule. Similar to the model codes, none of these codes include specific language to protect the health of children, prohibit dangerous work practices, or address LSWPs related to painted surfaces, lead hazards or cleanup. The exclusion of this language is primarily due to building officials rather than health departments having authority for housing codes.

Several actions have been taken at state and local levels to achieve primary prevention through code enforcement activities. The state of New Jersey passed a multi-family housing law and a regulation that requires dust clearance testing after rehabilitation construction. A bill in California specifically addresses lead hazards. New York City and other jurisdictions prohibit lead hazards in rental housing. Some states require LSWP training and several local regulations focus on housing occupied by children <6 years of age. Ten states now prohibit uncontrolled sanding and other dangerous work practices during remodeling and renovation.

AFHH published lead-safe housing policy guidance to assist jurisdictions in developing policies for pre-1970 rental properties, high-risk units and extreme situations. Over the next year, AFHH and its partners will place more emphasis on the decision-making process by code enforcement agencies and accountability for housing health hazards to children beyond health departments.

Ms. Malone proposed several options for ACCLPP to consider in filling existing gaps and improving MHCs for primary prevention.

- A national initiative should be launched with two overarching goals. First, MHCs should be developed with specific language that requires peeling paint to be absent in rental housing and LSWPs to be used when removing peeling paint in older housing. Second, explicit language should be incorporated into construction codes requiring appropriate cleanup of painted surfaces and removal of dust hazards.
- ACCLPP could be extensively involved in the national initiative by expanding the public health legacy related to housing conditions; engaging code enforcement agencies and other groups with responsibility for developing and approving MHCs; and using these collaborations to advance primary prevention beyond state and local health departments.
- ACCLPP could develop a position statement on the need to include lead safety language in MHCs and also provide comments on the draft HAEB code for hazards in existing buildings.
- ACCLPP could support national advocacy efforts to advance primary prevention with MHCs. Public health is often not represented during the decision-making process of developing and changing building codes to voice concerns about childhood lead poisoning and primary prevention. Three opportunities are available to address this issue. First, public health proponents can submit comments on HAEB's draft code for abating hazards in existing buildings. Second, public health can provide ongoing guidance to ICC about lead hazards when policies are developed that focus on housing-related hazards. Third, public health can make strong efforts to incorporate EPA's pending renovation and remodeling rule into MHCs if the language is established as policy in the future.

Ms. Malone reiterated the critical need for ACCLPP's involvement in and support of efforts to advance primary prevention with MHCs. As CDC's advisory committee and outside expert on lead, she believed ACCLPP should take responsibility for communicating with model code entities and emphasizing the importance of including

specific health protection language in MHCs. Her position was that the documents and recommendations ACCLPP has generated to date are generic with unclear messages on this issue.

Ms. Malone further noted that ACCLPP has not produced and disseminated a position statement on specific actions local model code entities should take in developing lead-safe MHCs. She conveyed that ACCLPP's guidance on responding to and addressing the needs of lead-poisoned children has only been directed to health departments and the medical community. Ms. Malone emphasized that ACCLPP's solid expertise in lead will play a significant role in achieving primary prevention with MHCs and supporting ongoing efforts by AFHH and other groups.

ACCLPP extensively discussed its potential role in leading or supporting new and ongoing initiatives to advance primary prevention with MHCs. The voting members and liaisons proposed the following options as ACCLPP's next steps in this effort.

- Establish a new ACCLPP writing group with the following charge. Develop ACCLPP's statement on the importance of lead and its housing-based position on lead. Extract relevant portions from ACCLPP's primary prevention document and compile the text into a letter with succinct bullet points and an appendix. Disseminate ACCLPP's position statement to ICC, the HAEB committee and other code enforcement agencies.
- Establish workgroup 1 with ACCLPP members and liaisons who have experience in MHCs. Charge the new workgroup with developing language that supports states and local agencies in using MHCs to advance primary prevention.
- Establish workgroup 2 with ACCLPP members and *ex officio* representatives for EPA and HUD. Charge the new workgroup with conducting the following activities. Educate other ACCLPP members on definitions and the specific use of terminology in MHCs. Monitor new developments in MHCs and track the ICC code development process. Provide ACCLPP with regular updates on these activities over time. Respond to and support public comments on ICC codes submitted by AFHH and other groups.
- Ask the ACCLPP Chair to contact the ICC committee chair and members by telephone to further emphasize the need to incorporate lead-safe language into MHCs. Mention that ACCLPP's lead expertise will be available to ICC in this effort.

- Explore the possibility of AFHH drafting ACCLPP's position statement due to its experience with and knowledge of MHCs. Circulate AFHH's draft to ACCLPP for review, comment and approval prior to dissemination.
- Submit an ACCLPP comment on the draft HAEB code to change "lead that is present in dangerous amounts." Inform the HAEB committee that this language is unrealistic and the text should be revised to focus on the "condition" rather than the "presence" of lead.
- Attempt to gather evidence or research to demonstrate the role of MHCs in changing practice or improving the standard of care.
- Urge ACCLPP to formally support new initiatives. For example, a national registry could be developed and published with previous and current addresses of children identified with elevated blood lead levels (EBLLs). A policy could be established in which local authorities are given one year to respond to the public registry with a plan to remediate the properties. Local models could be reviewed in this effort. Most notably, the city of Cleveland has identified ~600 properties as sources of lead exposure to children, compiled these addresses into one list, and provided the city council with the list.
- Be mindful of the extensive amount of time and effort involved with the code development and revision process if ACCLPP agrees to become involved with MHCs. For example, stakeholders typically express diverse views about potential changes in costs due to a revised standard or code. Several years may be needed for stakeholders to reach agreement.
- Determine whether ACCLPP will be more effective in providing clear guidance on overcoming barriers to implementing lead-safe MHCs, particularly economic or educational challenges. Use ACCLPP as a mechanism to engage local advocates in the lay community to assist in the implementation of lead-safe MHCs.
- Distribute basic information on lead-safe MHCs to educate providers and increase endorsement, support and advocacy in the medical community.
- Encourage ACCLPP to formally support a policy in which existing LSWP guidance developed by EPA and HUD are uniformly accepted, adopted and incorporated into MHCs. Structure the policy to specifically address LSWPs when a painted surface is disturbed, peeling paint as a potential lead hazard in older housing, lead hazard abatement, and LSWP certification and training of workers.

Dr. Campbell was extremely pleased that the discussion resulted in ACCLPP's interest and willingness to address lead-safe MHCs. She agreed with Ms. Malone that ACCLPP's expertise and involvement in this initiative will play a significant role in the

prevention of lead exposures to children. She urged each member and liaison to submit individual comments on the draft HAEB code by April 15, 2006 because ACCLPP does not have sufficient time to develop a formal position statement by this deadline.

Based on the discussion and general agreement among the voting members, Dr. Campbell summarized ACCLPP's next steps in improving MHCs for primary prevention. A writing group will be formed to draft a letter to ICC with the following key points. ACCLPP's concerns about lead safety and other housing issues that impact children's health will be emphasized. Citations and references for existing recommendations, suggested practices and regulations will be included.

ICC will be encouraged to contribute to the safety of children by following existing guidance and including this language when developing or revising model codes. The writing group will complete the letter in time for ICC's code development hearings in September 2006. All drafts of the letter will be distributed to ACCLPP for review and comment. ACCLPP will revisit the writing group in the future to determine whether its scope should be broadened to monitor new developments in the MHC arena.

Dr. Campbell confirmed that further discussions will be held to more clearly define the charge of the MHC writing group. Ms. Malone will serve as the chair; Ms. Angeloni, Dr. Binns, Ms. Johnson, Ms. Kite, Ms. Odle, Dr. Wynn-Stubbs and ACCLPP's *ex officio* representatives for EPA and HUD will serve as members.

Update on ACCLPP's Communications with HHS

Dr. Campbell reported that ACCLPP has made numerous attempts over a long period of time to engage HHS in primary prevention through written communications, telephone conversations, and invitations to attend and present at ACCLPP meetings. To date, HHS has not responded to ACCLPP's requests.

To advance this effort, Dr. Campbell drafted a letter to the HHS Secretary emphasizing the critical need for HHS to institutionalize primary prevention in all activities throughout the department. The letter provides an example to achieve this goal, such as reviewing the use of federal funding for the Temporary Assistance to Needy Families (TANF) Program. The letter also suggests that HHS review and identify the quality of housing to TANF recipients and determine whether funding is being directed toward lead-safe housing. The draft letter was circulated to ACCLPP for review and comment. Dr. Campbell solicited ACCLPP's input on the need to send the letter to the HHS Secretary and the contents of the document.

ACCLPP's suggestions on next steps in communicating with the HHS Secretary on primary prevention are outlined below.

- Continue to communicate with the HHS Secretary, but shift the focus from "primary prevention" to "child care" because TANF and the Administration for Children and Families Child Care Bureau will be merged in the HHS reorganization.
- Describe non-TANF examples of "institutionalizing primary prevention" throughout HHS, such as safety in child care or Head Start settings.
- Remind the HHS Secretary of the federal rule that requires the use of LSWPs and the removal of lead hazards in any activities supported by federal housing dollars.
- Replace the "EPA Administrator" with the correct title and address for the "HHS Secretary."
- Revise the first paragraph to succinctly and explicitly state ACCLPP's requests to the HHS Secretary. For example, "ACCLPP requests an HHS representative to attend the October 2006 meeting to discuss specific primary prevention issues."
- Minimize HHS's discomfort with potential disruptions in the chain of command by asking HUD to cosign ACCLPP's letter or collaborate in the process.
- Ask CDC to contact HHS to identify reasons for the lack of communication and difficulty in HHS representatives attending and presenting at meetings of an advisory committee to the HHS Secretary.

Dr. Brown announced that she had less success at the CDC level than Dr. Campbell in encouraging an HHS representative to attend an ACCLPP meeting and discuss primary prevention issues. However, she contacted an HHS staff member who is extremely supportive of Medicaid and primary prevention issues. ACCLPP's draft letter will provide Dr. Brown with a solid tool to facilitate further discussions because HHS is embarrassed about the length of time that has passed for the Centers for Medicare and Medicaid Services (CMS) to respond to ACCLPP.

Based on the discussion, Dr. Campbell summarized ACCLPP's next steps in this process. She will revise the draft letter in response to comments made during the meeting, but ACCLPP should feel free to submit additional changes in writing. She will circulate the revised letter to ACCLPP for review and comment. Dr. Campbell will finalize and send the letter to the HHS Secretary so long as ACCLPP does not submit major changes that require a formal vote by e-mail. Dr. Brown offered to convene a

conference call with a subgroup of ACCLPP members and LPPB staff with expertise in TANF issues to facilitate finalizing and sending the letter to the HHS Secretary.

Update on LPPB Activities

Dr. Brown covered the following areas in her report. One, LPPB received a report of the death of a child due to lead poisoning that occurred in February 2006 in Minneapolis. The child was 4½ years of age and had a BLL of 180 µg/dL after swallowing a charm from a bracelet. The child presented with symptoms that were consistent with acute ingestion, nausea and vomiting over a two-week period, agitation and seizures. The child went into respiratory arrest and was declared brain dead before a BLL was available.

No obvious lead hazards were found in the child's home, but the actual source is still pending investigation. The child's sibling is two years of age with a BLL <10 g/dL. By March 24, 2006, the U.S. Consumer Product Safety Commission (CPSC) will issue a consumer recall on the product and LPPB will publish a dispatch on the case in the *MMWR* to notify all CLPPPs and other partners.

The *MMWR* article will strongly emphasize three key messages. Lead poisoning continues to be a part of the differential diagnosis for children with symptoms of increased inter-cranial pressure. Proactive steps are critically needed to prevent further deaths among children due to lead poisoning. Every effort must be made to discourage young children from placing foreign objects in their mouths.

Two, LPPB published an *MMWR* article on March 3, 2006 to report three deaths associated with hypocalcemia from chelation therapy in Oregon, Pennsylvania and Texas. Both children were given disodium EDTA rather than calcium disodium EDTA. The adult case remains under investigation. LPPB made three key recommendations in the *MMWR* article. Healthcare providers who are unfamiliar with chelation therapy should consult with an expert. Hospitals should determine whether continued stocking of disodium EDTA is warranted due to the danger of this drug and the availability of less toxic alternatives. Healthcare providers and pharmacists should ensure that children do not receive disodium EDTA.

The Food and Drug Administration (FDA) is conducting a safety evaluation of disodium EDTA and may issue language that is stronger than LPPB's recommendations. LPPB and the AAP Environmental Health Committee are attempting to jointly publish a paper in *Pediatrics Experience and Reason* on the use of disodium EDTA during chelation

therapy. AAP has received numerous telephone calls from medical toxicologists about this issue, but none from pediatricians. The cases were covered by 66 newspapers.

Three, LPPB finalized two toolkits to educate special populations. The easy-to-use and self-explanatory materials can be distributed to health, social service and other workers who serve high-risk populations. One train-the-trainer toolkit is targeted to state refugee health coordinators, refugee workers and resettlement agencies that serve newly arrived refugee children. The Office of Refugee Health and other federal agencies are extremely supportive of this initiative and will closely collaborate with LPPB to ensure the toolkit is widely distributed. Rhode Island has agreed to pilot the toolkit for refugee children.

LPPB's CLPPP Community Awareness Pilot (CAP) project will be piloted to African American churches to involve grassroots organizations and community residents in lead poisoning prevention. During the pilot, LPPB will evaluate whether the toolkit was useful, helpful and easy to use and will make revisions based on feedback. Georgia has agreed to pilot the toolkit for the CLPPP CAP project. LPPB will widely disseminate both toolkits to state and local partners.

Four, LPPB gathered data on the top 25 communities that reported children with EBLLs from 2000-2005. The data showed that Chicago, New York City, Philadelphia, Cleveland and Detroit were the top five cities with the highest number of children with EBLLs during this time period. However, LPPB acknowledges that low screening rates, a solid lead program and other factors confound these data. LPPB will publicize the data because HUD, EPA and other agencies include the information in grants language. LPPB will also inform grantees and other partners that reporting these data may have a positive or negative impact on lead programs.

Five, LPPB will launch the "Getting the Job Done" project to provide guidance on eliminating EBLLs in children by 2010. The initiative is designed with five major focus areas.

- Intensive efforts to identify and provide services to affected children should be continued, such as screening and case management.
- Primary prevention efforts should be targeted to the top ten communities with the highest risk. LPPB and state and local health departments should collaborate in institutionalizing relationships between health and housing departments; fostering data exchange between local health and housing agencies; and ensuring that HUD resources are targeted to areas with the highest potential of poisoning children.

- Special emphasis should be placed on unserved areas based on housing and socioeconomic indicators of risk. The 2010 objective cannot be achieved without increased efforts in Arkansas and Mississippi.
- Special programs should be developed for refugees, immigrants and other special risk populations to control or eliminate exposures to both paint and non-paint sources of lead in these groups.
- Protective surveillance systems should be developed and maintained to continuously monitor potential exposures to lead among U.S. children. Cost-effective methods should be created to sustain a low level of risk to exposure after elimination is achieved. LPPB hopes to release a proposal in early 2007 for academic institutions to identify appropriate lead surveillance systems.

Six, LPPB received 43 lead poisoning prevention applications and was particularly pleased that Mississippi submitted a proposal. CDC funded 42 state and large-city lead poisoning prevention programs in FY'05, but cut LPPB's budget by $890,000 in FY'06. LPPB will evaluate the applications based on the following criteria:

- Implementation of screening and case management and lead elimination plans that target resources to children at highest risk.
- Enforcement or development of regulations that require elimination or control of lead hazards in housing units occupied by children with EBLLs, including protection to residents and tenants from retaliatory eviction or other lead-related discrimination.
- A current or proposed Medicaid reimbursement methodology for case management services and environmental inspections for Medicaid-eligible children.
- Electronic data collection of unit-specific housing inspection data and a systematic assessment of lead-safe housing status.
- Environmental screening for lead hazards in other high-risk housing.
- Strategic partnerships with child health agencies and organizations at federal, state, local, community and private levels.
- Cooperative state research education and extension services.
- Partnerships with HUD and EPA regional offices in targeting enforcement of the disclosure rule in local jurisdictions.

LPPB will review each application three times in addition to a technical review on March 29-30, 2006. Decisions will be made in April 2006 and the FY'07 grantees will be notified on June 28-29, 2006. Funds will be allocated beginning on July 1, 2006 with individual awards ranging from $50,000-$1 million.

LPPB will also establish contracts in some areas of the country with specific time-lines and deliverables to strengthen and ensure success of CDC's lead grant program. LPPB will soon award the "capacity to build capacity" contract in which non-federal staff with experience in lead poisoning prevention will be hired and placed in lead programs for ~2-3 weeks. These personnel will assist programs in resolving problems related to Medicaid, electronic data collection and other issues.

Seven, LPPB is continuing to provide expertise and support to UNICEF and the World Health Organization (WHO) in response to extremely high BLLs and the deaths of two children due to lead poisoning in Kosovo. Efforts are being made to transfer refugees to a camp. LPPB hopes that a stakeholder meeting will be convened with industry over the next year to explore safer strategies to remove lead from the ground in Kosovo.

Several ACCLPP members made suggestions for LPPB to consider in its ongoing activities related to the deaths associated with hypocalcemia from chelation therapy.

- Inform all state medical boards about the misuse of disodium EDTA during chelation therapy because no state medical board has an advisory group that reviews each physician who performs chelation therapy. Engage Dr. Snodgrass to discuss the possibility of sending a letter to state medical boards and explore other potential strategies. However, acknowledge that state medical boards have no legal basis to address this issue.
- Inform AAP, the American Academy of Nurse Practitioners, and the American Academy of Family Practitioners about the misuse of disodium EDTA during chelation therapy. Use ACCLPP's liaisons to communicate messages and widely distribute information from CDC to the respective memberships of these professional associations.
- Rapidly publish a highlight in *Pediatrics Experience and Reason*. Use this quick mechanism in response to AAP's October 2005 statement that discusses chelation with EDTA without specifying the recommended form of EDTA.
- Ensure that clear and accurate messages are delivered because previous news articles reported "patient deaths caused by chelation therapy" rather than the "use of incorrect drugs."
- Publish an addendum in AAP's weekly news magazine to clarify the title of the *MMWR* article: "Deaths Associated with Hypocalcemia from Chelation Therapy." Delete "chelation" because the use of this word in the title has contributed to the confusion and misunderstanding about the actual cause of death.

Update on Medicaid Screening

Dr. Brown reported that she represented CDC during a recent meeting with HHS and CMS. CMS committed to changing its Medicaid manual if CDC revises its Medicaid screening guidance. CDC will take the following actions to meet CMS's conditions. A former ACCLPP member will be contracted to revise CDC's guidance in collaboration with LPPB staff. The modified guidance will outline a specific process for each state to review its housing, poverty and other types of data; demonstrate the absence of a lead problem; and make a solid case to discontinue universal screening. The specific elements of a targeted screening plan will be clearly defined. CDC will publish its revised guidance on Medicaid screening in the *MMWR*.

Previous recommendations and articles on Medicaid screening developed by ACCLPP and CDC will be used as the foundation to update the guidance. CDC rather than CMS will serve as the reviewer of targeted screening plans submitted by states. CDC will attempt to use cost savings from universal to targeted screening to fund its new role as the reviewer of targeted screening plans.

The National Committee for Quality Assurance permitted CDC to field test a health plan employer data and information set (HEDIS) measure for screening of Medicaid children at least once by two years of age. CDC will soon initiate the field test and expects to obtain results six to eight months after the completion of the project. CDC will attempt to place the revised guidance and HEDIS measure of Medicaid screening on parallel tracks to reasonably target resources.

During the meeting, Dr. Brown received verbal commitments from HHS and CMS to pursue this course of action, but a letter was also drafted confirming that CMS will adopt CDC's revised guidance. The letter will be finalized and signed by the CMS Director within the next month.

Dr. Brown will contact CMS to determine its willingness to adopt and implement CDC's revised guidance as formal policy after the final approval and clearance process is complete, but prior to publication in the *MMWR*. Both the CMS commitment letter and CDC's revised guidance on Medicaid screening will be distributed to ACCLPP for review. However, Dr. Brown clarified that CDC will not solicit ACCLPP's comments and formal consensus because ACCLPP's previous recommendations on Medicaid screening will serve as the basis to revise the guidance.

ACCLPP was extremely pleased about the progress that has been made over the last six months in Medicaid screening. The members commended Dr. Brown on her diligent efforts and long-standing communications with other federal agencies to advance this issue.

Proposal to Restructure CDC's Federal Advisory Committees

Dr. Brown reported that CDC held a meeting on February 13, 2006 with the chairs and designated federal officials of its federal advisory committees. A new organizational structure was proposed to align advisory committees with CDC's 21 goals for healthy people, healthy places, preparedness and global health. Key changes proposed for the existing structure are highlighted below.

Boards of scientific counselors (BSC) will be formed to provide advice at the center level on research agendas, programs, peer reviews and technical issues. Advisory committees will be formed to provide guidance at the coordinating center level on strategies and priorities, collaborations and partnerships, resources, health impact, the balance between research and science, and the collection, analysis and dissemination of information. Additional subcommittees will be formed under the Advisory Committee to the CDC Director. A new study section will be established to conduct initial merit reviews of applications throughout CDC.

No decisions have been made on the proposed reorganization at this time, but efforts will be made to quickly establish a BSC for each center and an advisory committee for each coordinating center. Decisions will then be made on the disposition of existing committees. Mandated committees can only be dissolved by an act of Congress, but discretionary committees are retained at the discretion of the CDC Director. The three options proposed for the disposition of CDC's discretionary committees are disbanding, retaining or restructuring the groups as coordinating center subcommittees. ACCLPP is one of CDC's discretionary committees.

Several members and liaisons suggested actions ACCLPP should take in responding to the proposed restructure of CDC's advisory committees.

- Communicate three key principles to emphasize the need to retain ACCLPP. First, the dissolution of ACCLPP is premature at this point. The current momentum to achieve the *Healthy People 2010* goal for the elimination of childhood lead poisoning must be continued. Second, ACCLPP is extremely interested in integrating its focus on childhood lead

poisoning with the efforts of other committees that address other hazards in homes. Third, cost-effective methods can be identified to maintain ACCLPP.

- Conduct a critical review to support the retention of ACCLPP as an advisory committee. For example, identify specific gaps that may arise without ACCLPP's input, expertise and leadership as the federal government's only external advisory committee on childhood lead poisoning prevention. Highlight activities that ACCLPP conducted in direct response to requests by CDC and the HHS Secretary. Describe ACCLPP's future plans to achieve the *Healthy People 2010* goal for the elimination of childhood lead poisoning. Compile and distribute the results of the critical review to the Directors of CDC and the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR).
- Ask the ACCLPP Chair to send a letter to the Directors of NCEH/ATSDR and the Coordinating Center for Environmental Health and Injury Prevention (CCEHIP). Use the letter to highlight ACCLPP's products, achievements, publications, guidance and role as a national forum for childhood lead poisoning prevention since 1989.

Dr. Campbell summarized ACCLPP's next steps based on the discussion and general agreement among the members. Dr. Campbell, Ms. Kite and Ms. Malone will serve on a writing group to draft a letter outlining ACCLPP's future as a CDC advisory committee. Formal recommendations and other documents ACCLPP has produced since 1989 will be distributed to the writing group to assist in developing the draft. The letter will be circulated to ACCLPP for review and comment and will contain places for each voting member to sign. The final letter will be distributed to the CDC, CCEHIP and NCEH/ ATSDR Directors with a copy to Dr. Brown.

Update on the Lead and Pregnancy Workgroup (LPWG)

Dr. Jessica Leighton, the LPWG Chair, covered the following areas in her report. Since the previous ACCLPP meeting, LPWG has focused on developing an outline for the lead and pregnancy report. The report will be organized into the following ten chapters. Chapter 1 will serve as the introduction. An overview will be provided on the health effects of lead poisoning. The need to guide clinical decisions, inform public health policy, and address state legislation on pregnancy and lead poisoning will be highlighted as the rationale for the report.

Chapter 2 will serve as the background section with a review of the following areas: the physiology and kinetics of lead and pregnancy and lactation; recent data on the effects of low-level lead exposure; LPPB's experience with immigrant pregnant women and cases of lead exposure; and measurement issues. Chapter 3 will address environmental and biological measures of lead, including bone, blood, dust, air, soil, plasma, hair, placenta, meconium and the reliability of a single measurement.

Chapter 4 will address the epidemiology of lead in women of child-bearing age in the United States. The distribution of BLLs, trends and high-risk populations will be discussed. Chapter 5 will address exogenous and endogenous sources of lead exposure in pregnant women, including leaded gas, occupational exposures, lead paint, personal products, cultural uses, ceramics, and past maternal exposure. Chapter 6 will address biochemical, sub-clinical and clinical health effects of lead to the mother, fetus and infant.

Chapter 7 will contain recommendations on screening for exposure, such as appropriate groups, time during pregnancy, methodology and level of concern for screening. Specific guidance will be given on whether universal or targeted screening to high-risk groups is best and if a BLL measurement or questionnaire is the optimal strategy. Chapter 8 will address management of lead poisoning in pregnant women, including prevention and intervention, the role of occupational health, and follow-up testing of mothers and infants. Guidance will be provided on eliminating lead sources, reducing lead absorption through nutrition, and using chelation to decrease retention and increase excretion of lead.

Chapter 9 will provide recommendations on breast-feeding and lactation issues, including the benefits of breast-feeding versus the risk of an EBLL and the possibility of lead in infant formula. Chapter 10 will address research and policy gaps and provide recommendations on future research and policy.

Dr. Leighton announced that LPWG will hold two meetings in May and July 2006 to develop the first draft of the report, identify gaps, review recommendations, and determine future research and policy. From July-December 2006, LPWG will circulate drafts to ACCLPP for review and comment and revise each iteration of the report based on comments received. LPWG will submit the lead and pregnancy report to CDC in December 2006 to initiate the clearance process.

ACCLPP made several suggestions for LPWG to consider in developing the first draft of the lead and pregnancy report.

- Distribute each completed chapter separately to ACCLPP for review and comment rather than the entire report at one time.
- Develop an executive summary with ten key points from the report, such as "prevention begins long before pregnancy."
- Chapter 1: Describe the methodology in developing the report. Explain that some recommendations are based on existing evidence, while others are based on expert opinion in the absence of data.
- Chapter 2: Describe pharmacokinetics and pharmacodynamics models of lead.
- Chapter 5: Include other sources of lead, such as water as a source for infant formula and BLL measurements and enhanced lead exposure of smokers.
- Chapter 6: Rename the title to "Adverse Health Effects."
- Chapters 8 and 10: Provide guidance on removing housing risks to eliminate lead sources to pregnant women and women of child-bearing age.
- Chapter 10: Describe research priorities, gaps and areas that will be most important in future lead and pregnancy studies.
- Chapter 10: Provide guidance on lead and pregnancy to federal, state and local agencies.

Dr. Leighton encouraged ACCLPP to provide her with additional information on lead and pregnancy to support or expand LPWG's recommendations and other sections of the report. For example, Dr. Snodgrass has reviewed case reports of imported skin creams containing lead that the mother applies on the breast to relieve skin irritation. The infant then ingests the cream while breast-feeding.

Update on CDC's August 2005 Lead Poisoning Statement

Dr. Brown reported that the statement was mailed to CLPPPs and other partners and is now available on the LPPB web site. LPPB did not conduct a mass mailing due to the large size of the document. CDC did not issue a press release because the statement was distributed immediately before Hurricane Katrina. Public health officials and clinical providers submitted numerous comments to CDC on the document. CDC's rationale for not lowering the BLL of concern below 10 µg/dL continues to serve as a major source of controversy in the document. Dr. Brown welcomed ACCLPP's suggestions on additional venues and organizations to distribute the 2005 lead poisoning statement.

Several ACCLPP members and liaisons expressed concerns that CDC did not inform AAP, the National Institutes of Health (NIH) and other key partners about the 2005 lead poisoning statement. The pediatric community is still largely unaware of the existence of the document. Drs. Campbell and Rogan asked LPPB to consider the following strategies to address these concerns.

LPPB should notify key partners and constituencies during the early development phase when formulating new lead poisoning statements in the future. LPPB should send a letter to organizations on the *MMWR* mailing list and other professional associations represented by ACCLPP liaisons to announce the availability of the statement on the LPPB web site and the ability to request paper copies from CDC. LPPB should publish a similar notice in the *MMWR*.

Update on the Federal Task Force on Other Sources of Lead

Dr. Brown reported that the federal interagency task force has not made tremendous progress to date because regulatory agencies are constrained by the limitations of existing statutes. For example, CPSC is prohibited from conducting pre-market testing of consumer products. U.S. Customs and Border Protection is not required to test all products that enter U.S. borders. A radical shift must be made in federal policy for the task force to take a more proactive approach in addressing other sources of lead. The task force may be able to take advantage of upcoming opportunities to advance this effort.

Child health advocacy groups are expected to bring strong public attention to the recent death of a child due to lead poisoning that occurred in Minneapolis. The U.S.-Mexico Border Health Commission has agreed to address lead in candy and will discuss this issue at the next task force meeting. FDA posted draft guidance on lead and candy on its web site, but will issue the guidance as recommendations rather than enforcement actions. AAP, CDC, state health departments and several other groups submitted comments to FDA about the critical need to release the guidance as regs. CDC and EPA are currently testing ayurvedic medicines for lead. During the next task force meeting in May 2006, EPA will provide an update on its Toxic Substances Control Act (TSCA) regulations and FDA will make a presentation on ayurvedic medicines.

Ms. Jacqueline Mosby is the ACCLPP *ex officio* representative for EPA. She announced that EPA drafted an action plan to clearly define its federal role, methodology and resources to address other lead sources. EPA will solicit feedback from its federal partners to refine and finalize the draft action plan by the end of 2006.

The document will also be distributed to ACCLPP, representatives of non-governmental organizations and other stakeholders for review and comment. In the interim, however, EPA will continue its ongoing activities to address other sources of lead, such as outreach, education, regulatory actions and voluntary approaches to remove consumer products containing lead.

Ms. Mosby added that some of the limitations within the interagency task force may be resolved if EPA's action plan is expanded to define the roles of other federal agencies in addressing non-paint sources of lead. For example, a flowchart could be developed to illustrate regulatory authority for each federal agency to react to a specific problem; the appropriate chain of command for each agency to initiate and discontinue a response; and gaps among the missions, mandates and jurisdictions of each agency. The flowchart could play a significant role in fostering federal support because the agencies do not become involved after a consumer product containing lead is under CPSC's authority. However, EPA's TSCA regulations can prevent the manufacture and future use of a lead product after a CPSC ban.

Dr. Warren Friedman is the ACCLPP *ex officio* representative for HUD. He announced that the latest edition of HUD's guidelines for the evaluation and control of lead-based paint hazards in housing is now undergoing departmental clearance. HUD may use the guidelines as an opportunity to focus on non-housing sources of lead because the document emphasizes that environmental investigations are broader than a lead-based paint risk assessment. HUD also intends to convey its support of wider investigations by local health departments. HUD expects to release the guidelines over the next several months.

Dr. Friedman fully supported Ms. Mosby's proposal of a broader interagency action plan and suggested that the existing interagency Lead-Based Paint Task Force be used in this effort. This group could provide an additional forum for federal agencies to more clearly define roles, missions and responsibilities in addressing non-housing sources of lead.

Several members and liaisons proposed actions that ACCLPP can take in supporting and advancing the activities of the federal interagency task force on other sources of lead.

- Form an ACCLPP workgroup on other sources of lead and charge the new workgroup with conducting the following activities. Collect solid data and review the literature to quantify the problem. Review the interagency action plan proposed by Ms. Mosby to identify gaps in existing mandates

and regulatory authorities of federal agencies. Formulate creative strategies for federal agencies to change current enforcement policies and models. Provide external support and guidance to the federal interagency task force. Develop evidence-based guidelines for CLPPPs to address other sources of lead while implementing lead poisoning elimination plans. Obtain diverse perspectives and expertise by engaging state and local health departments, members of EPA's National Pollution Prevention and Toxics Advisory Committee, child health advocacy groups, grassroots organizations and industrial hygienists.

- Urge the federal task force to review lessons learned and duplicate the success of the long-standing EPA/HUD collaboration in developing the new interagency action plan.
- Develop and issue a formal ACCLPP statement to cover three key areas: the magnitude of the problem, the statutory limitations of federal agencies, and strategies for agencies to establish a new regulatory threshold for consumer products containing lead.

Discussion on New ACCLPP Workgroups

Dr. Brown asked ACCLPP to review and provide input on EPA's draft action plan and the new interagency road map for other sources of lead if the federal task force decides to undertake this effort. ACCLPP's comments on these documents would be more pragmatic, helpful and useful to LPPB than the formation of a new workgroup on other sources of lead.

Dr. Brown pointed out that resources must be considered as well. Most notably, LPPB expended >$1 million to support the <10 Workgroup report and other activities. She also reminded ACCLPP of its charter to provide advice and recommendations on childhood lead poisoning prevention efforts. Suggestions for ACCLPP to address the relationship between exposures to lead and other heavy metals are beyond the purview of both LPPB and ACCLPP. Moreover, EPA and other agencies focus on heavy metals other than lead.

Dr. Brown was absent during the morning session of the meeting when ACCLPP agreed to form a writing group on improving MHCs for primary prevention. She returned to this issue to provide her perspective. MHCs are not limited to lead and are beyond the purview of both LPPB and ACCLPP. HUD is the most appropriate agency to obtain external guidance and recommendations on MHCs.

Dr. Campbell and Ms. Kite clarified that the new ACCLPP writing group would be charged with identifying effective strategies and supporting ongoing efforts to incorporate language on primary prevention, lead hazard identification and LSWPs into MHCs. The writing group will also draft a letter to outline ACCLPP's concerns about lead safety and other housing issues that impact children's health. The writing group will not formulate recommendations on MHCs.

ACCLPP made several remarks in response to the suggestion to form a new broad-based workgroup on other sources of lead with multiple stakeholders. Dr. Campbell proposed tabling this activity until EPA completes and distributes its action plan at the end of 2006. Dr. Leighton raised the possibility of holding a series of "subject matter" ACCLPP meetings in which guest speakers would make presentations on other sources of lead. The guest speakers would represent diverse perspectives and interests, including child health advocacy groups, grassroots and community-based organizations (CBOs), and state and local health departments.

Drs. Binns and Keyvan-Larijani recommended forming a short-term interest group with only a few ACCLPP members and a simple charge. The small interest group would catalogue the most critical issues, gaps, needs, priorities and next steps related to other sources of lead and circulate the document to ACCLPP for review, comment and approval. Dr. Brown would then distribute the document to the federal task force for the agencies to use as a checklist while developing the interagency action plan.

Dr. Charlton placed a motion on the floor for ACCLPP to form a small and short-term interest group to catalogue the most critical issues, gaps, needs, priorities and next steps related to other sources of lead. The motion was properly seconded by Dr. Kang Ho and **unanimously approved** by ACCLPP. Dr. Binns will chair the other sources of lead interest group; Mr. Hays and Drs. Charlton, Gitterman, Handy, Keyvan-Larijani and Leighton will serve as members.

Overview of the Lead Policy Statement (LPS)

Dr. Benjamin Gitterman is the ACCLPP liaison to the American Public Health Association (APHA). He reported that a group of stakeholders from Washoe, Nevada submitted the LPS to APHA's governing council in June 2005. The LPS is entitled "Protecting Children from Overexposure to Lead in Candy and Protecting Children by Lowering the Blood Lead 'Level of Concern' Standard." APHA's governing council approved the LPS in December 2005 and its executive committee will establish an

action plan to either support or call on other agencies to respond to 12 recommendations.

Dr. Gitterman explained that the best approach for ACCLPP to express its concerns about the LPS or correct inaccuracies would be to send a letter to the Chair of the APHA Executive Board with a copy to the APHA President. APHA could use ACCLPP's letter to identify factual errors and then amend or archive the LPS. Dr. Gitterman committed to providing ACCLPP with a status report on whether APHA has recently released other policy statements on lead.

ACCLPP was in favor of sending a letter to APHA about the LPS. On the one hand, several members suggested positive, diplomatic and constructive language to include in the letter because this approach may increase APHA's willingness to archive or amend the LPS.

- APHA is a respected and reputable professional association with a huge membership.
- APHA should make every effort to ensure that its policy statements are accurate, fully vetted and released as consensus because the guidance has tremendous implications for the broad public health field.
- Some areas of the LPS are solid and accurate. ACCLPP is pleased that APHA adopted these issues as policy and supports most of the 12 recommendations outlined in the LPS.

On the other hand, several members emphasized the need for ACCLPP to highlight specific errors in the LPS and express its concerns about APHA's overall process of developing and finalizing the LPS.

- APHA did not provide Dr. Gitterman, the ACCLPP liaison to APHA, with the draft LPS before finalizing and releasing the document to the public. This approach would have given Dr. Gitterman an opportunity to circulate the draft LPS to ACCLPP for review, comment and correction of factual errors. This process may have also minimized perceptions that the LPS offends the diligent efforts of ACCLPP, state health departments and other groups involved in lead and child health.
- The LPS should not jointly address lead in candy and the BLL of concern because these two issues are distinct and unrelated.
- Lines 7-11: The text does not capture the tremendous outreach efforts by local CLPPPs in California to inform the public and media about lead in imported candies, candy wrappers and seasonings.

- Lines 143-146: ACCLPP's 2004 draft of the <10 Workgroup report is referenced rather the final document that was published in August 2005. The draft report did not contain ACCLPP's detailed explanation about its position on 10 µg/dL as the BLL of concern.
- Lines 152-155: The characterization of ACCLPP's membership as "lead industry-connected scientists" is inaccurate. The composition of ACCLPP has dramatically changed since 2002 and is much more diverse in terms of race, ethnicity and disciplines. ACCLPP's current membership includes pediatricians and other clinicians, advocates for children's health and healthy homes, parents, lead abatement experts, academicians, and state and local health department officials. Advocates originally expressed concerns about ACCLPP's membership and should take responsibility for communicating with APHA about this issue.
- Lines 238-240: ACCLPP should provide APHA with language on primary prevention to clarify this text.
- Lines 242-246: The goal for laboratories to operate with a total allowable BLL error of ±1 µg/dL will negatively impact the availability of lead testing. Many local laboratories do not have advanced equipment that is necessary to perform lead analyses with this level of specificity.

Based on the discussion, Dr. Campbell summarized ACCLPP's next steps in response to the LPS. She will draft a letter to APHA to highlight the points ACCLPP raised during the meeting, but the members and liaisons should provide her with additional comments by April 14, 2006. The draft letter will be circulated to ACCLPP for review and input and revised based on any comments submitted. Dr. Campbell will also ask Drs. Gitterman and Stubbs-Wynn to review the letter from an APHA organizational perspective. The final letter will be sent to the APHA Executive Board Chair and President.

Public Comment Period

Dr. Friedman announced that HUD recently published notices of funding availability (NOFAs) for healthy homes and lead grants, including lead hazard control, lead technical studies and lead outreach activities. Each state or local governmental agency can increase its application score by demonstrating collaborations with CBOs and faith-based organizations in conducting activities and research under HUD's lead programs. State and local grantees are required to integrate activities under HUD's lead programs with activities under CDC's lead strategic plans in local jurisdictions. The NOFAs can be viewed on the HUD web site.

With no further discussion or business brought before ACCLPP, Dr. Campbell recessed the meeting at 5:29 p.m. on March 21, 2006.

Changes to the ACCLPP Membership

Dr. Campbell reconvened the ACCLPP meeting at 8:33 a.m. on March 22, 2006 and yielded the floor to the first presenter. Dr. Brown announced that the terms of the ACCLPP Chair and a member will soon expire. She acknowledged and thanked Drs. Campbell and Slota-Varma for their outstanding service to ACCLPP and CDC; valuable contributions to the health of children in the United States; and tremendous efforts to prevent lead poisoning at local, state and federal levels. Dr. Brown presented the outgoing members with plaques and letters signed by the CDC Director. Dr. Campbell was presented with an additional plaque in recognition of her eight-year service as both the ACCLPP Chair and a member.

Dr. Brown made additional announcements about changes in ACCLPP's membership. Ms. Kite's original one-year term was extended to a full term. A voting member needs to soon volunteer to serve as the new ACCLPP Chair. The ACCLPP Chair has traditionally been a pediatrician, but the charter does not outline specific requirements for this position. Two new members will greatly contribute to ACCLPP's deliberations. Dr. Deborah Cory-Slechta, of the University of Medicine and Dentistry of New Jersey, has expertise in psychology, bench science and the developmental effects of lead. Dr. Sherry Lynn Gardner is the Chief of Pediatrics at Grady Memorial Hospital in Atlanta, Georgia and has a wealth of clinical expertise.

New Data on Concurrent BLLs and Neuropsychological Outcomes

Dr. Walter Rogan is the ACCLPP *ex officio* representative for NIH. He presented data from a clinical trial that focused on IQ and BLLs in children 2-7 years of age to determine whether effects in older children are residual of high BLLs in children 2 years of age. BLLs in U.S. children tend to peak at 2 years of age and then decline. A meta-analysis of four prospective studies that was conducted in 1994 did not show a relationship between the mother's BLL measured around birth and IQ measured at school age. However, the peak BLL at around 2 years of age and the postnatal mean BLL showed an association with IQ measured at $\geq$5 years of age.

Children 2 years of age should be recruited and followed until 5 years of age to analyze the peak lead effect and determine its impact on IQ. However, lead poisoning screening has traditionally focused on children 1-2 years of age and clinical trials have historically treated children 2 years of age. Previous prospective studies conducted in Boston, Cincinnati and Rochester did not include a detailed analysis of the association between IQ and the peak BLL at 2 years of age.

In an effort to fill this gap, data from the Treatment of Lead-exposed Children (TLC) study were used to identify the strength of the association between BLLs and IQ at various time points and determine whether cross-sectional associations observed in school-age children represent residual effects from peak BLLs. The TLC trial served as a solid data source for the new study due to its large sample size, rigorous degree of testing, quality control measures, longitudinal design and high retention rate. However, no home observations for measurement of the environment (HOME) score were conducted for the TLC cohort.

TLC was a randomized placebo-controlled clinical trial of succimer with the primary outcome focusing on IQ measured at 5 and 7 years of age. The cohort included 780 children 12-33 months of age with BLLs ranging from 20-44 µg/dL. Of the entire cohort, 396 children were in the succimer group, 384 were in the placebo group, 77% were African American, 56% were male, 95% were English speaking, 40% had parents with less than a high school education, 72% had single parents, and 97% were on public assistance. The cohort was followed up to 60 months after treatment until 7 years of age.

TLC was conducted at multiple centers in Baltimore, Cincinnati, Newark and Philadelphia. BLLs were measured at baseline, frequent intervals over the course of treatment and follow-up. IQ was measured with standardized instruments at 2, 5 and 7 years of age. The IQ of the mother or other care giver was measured as well. A statistical analysis was performed with TLC data using general linear models, untransformed BLLs and important covariates. The succimer and placebo groups were combined because no treatment effect on IQ was observed.

In the new longitudinal study, BLLs were measured at baseline, at 2 years of age, at the 36-month follow-up at 5 years age, and at the 60-month follow-up at 7 years of age. The mental development index and IQ were measured to determine relationships among the three different age periods. Results of the model are outlined below.

A ~3-point IQ deficit was observed for every 10 µg/dL change in BLL at 2 years of age. A 2-point IQ deficit was observed at 5 years of age for every 10 µg/dL change in BLL at

2 years of age. A 1-point IQ deficit was observed at 7 years of age for every 10 µg/dL change in BLL at 2 years of age, but this result was not statistically significant. A 5-point IQ deficit was observed at 7 years of age cross-sectionally for every 10 µg/dL change in BLL at 2 years of age.

A larger response was seen in older children than younger children per unit change in BLLs. The concurrent BLL and IQ at 5 years of age were larger than the BLL and IQ at 2 years of age. This result was statistically significant. BLLs at 5 years of age showed a larger effect on IQ at 7 years of age than BLLs at 2 years of age.

Children with BLLs below the median at both 2 and 7 years of age had an IQ of 89. A 3.6-point IQ deficit was seen in children with BLLs below the median at 2 years of age and above the median at 7 years of age. No effect on IQ was seen in children with BLLs above the median at 2 years of age and below the median at 7 years of age. No additive effects on IQ were seen in children with BLLs above the median at both 2 and 7 years of age. Similar results were seen with IQ at 5 years of age.

The following conclusions were reached based on the findings of the new longitudinal study. A stronger association was observed between BLLs and IQ at 7 years of age than between the higher BLL at 2 years of age and IQ at 7 years of age. The strength of the cross-sectional association increased over time. The results support the theory that lead exposure continues to be toxic to children as they reach school age, but not all of the damage occurred by the time the child was 2-3 years of age. Lead exposure near school age may affect cognition. Difficulties in preventing lead exposure are greater, but the potential increases.

Dr. Kim Dietrich, of the University of Cincinnati, presented data to demonstrate the potential importance of later BLLs on periods of enhanced developmental susceptibility to central nervous system (CNS) effects of environmental lead. AAP's 2005 policy statement strongly recommended that all Medicaid-eligible children receive at least two screenings at 1 and 2 years of age. The policy further noted that a "low" BLL in a school-age child does not rule out earlier lead poisoning.

The Boston prospective study was published in 1992 and found that BLLs at 24 months of age were exclusively associated with neurodevelopmental deficits. The study also showed that 2 years of age is the critical period of exposure and when the most damage occurs. These findings had a tremendous impact on CDC recommending lead screening at 2 years of age. More recent data have been collected to support the results of the Boston prospective study, but stronger emphasis should now be placed on the implications of BLLs beyond 2 years of age.

Blood lead is often considered to be merely a measure of recent exposure, but late BLLs represent exposures from both exogenous and endogenous sources. Blood lead reflects an equilibrium between body burden and ongoing exposure to environmental sources at any given point in time, such as a young school-age child. Blood lead measured concurrently with measures of neurodevelopmental outcomes may be better predictors of deficit. Blood lead measured concurrently with an assessment of outcome may be a better indicator of biologic levels of exposure to the CNS or other target organ. Higher BLLs in later life may represent individual differences in absorption, retention and vulnerability.

A study was published in 1995 comparing findings from the Boston prospective study and more recent data. The impact of certain sensitive periods on neurocognitive development was analyzed in the study. Covariate adjusted regression coefficients for BLLs on performance IQ by year of serial BLLs assessment were measured. The analysis showed that the regression coefficients became statistically significant after 3 years of age in terms of predicting deficits in performance IQ. The results suggested that late measures of lead exposure are important and may be better indicators of the effects of toxicants on target organs. The most significant relationship between BLL and IQ was observed at 6 years of age rather than assessments at 1 or 2 years of age.

Evidence from five studies conducted from 1996-2005 did not clearly demonstrate that only the period of peak BLLs at 2 years of age is important in terms of risks for neurodevelopmental vulnerability. These five studies showed similar results as the 1995 study in which later BLLs were found to be more predictive of neurodevelopmental deficits in children beyond 2 years of age. Data from the National Health And Nutrition Examination Survey (NHANES) on >1,400 children 6-16 years of age were analyzed in 2000 and showed a highly significant relationship between reading scores and concurrent BLLs <10 µg/dL.

An international pooled analysis of data from seven prospective studies was conducted in 2005 focusing on low-level environmental lead exposure and children's intellectual function. The analysis was designed with three major objectives. The relationship between IQ and BLLs in children followed prospectively from infancy through 5-10 years of age was examined. Evidence of lead-associated decrements in IQ scores at BLLs <10 µg/dL was tested. A determination was made on whether lead-associated IQ deficit was greater for a given change in exposure for children with lower peak BLLs.

Four different BLL measures were defined for the analysis. The "peak BLL" was the maximum BLL of blood lead tests taken at 6 months, 1 year or 15 months, and 2-7

years of age. The "early childhood BLL" was the mean BLL from 6-24 months of age. The "mean lifetime average" was the mean BLL from 6 months of age to the concurrent value. The "concurrent BLL" was the blood lead value at the age concurrent with IQ testing or otherwise closest to IQ testing for each site. The data were adjusted for the following covariates: the child's gender, birth order and birth weight; HOME score; and maternal IQ, education, age at delivery, marital status, prenatal smoking and alcohol use.

An adjusted log-linear model and a restricted cubic spline function were used to examine the following areas: (1) the relationship between IQ and selected blood lead indices adjusted for all available covariates; (2) the relationship between full-scale IQ and selected blood lead indices; (3) the relationship between concurrent BLLs and children's intellectual function; (4) estimated lead-associated IQ deficits by concurrent BLLs; and (5) the relationship between concurrent BLLs and children's intellectual function at BLLs above and below 10 µg/dL.

The log BLL, HOME score, birth weight, and maternal IQ and education showed the most significant associations to IQ. Estimates of a 9.2-point IQ deficit with concurrent BLLs ranging from <1-30 µg/dL and a 6.2-point IQ deficit with concurrent BLLs ranging from <1-10 µg/dL were found to be clinically strong. The key findings and conclusions of the international pooled analysis are highlighted below.

The data support the hypothesis that lead-associated intellectual deficits occur at BLLs <10 µg/dL. This threshold is the current action level established by CDC and WHO. The decrease in IQ per unit BLL was greatest at BLLs <10 µg/dL. No evidence was seen of a threshold of lead-associated intellectual deficits. The data strongly suggest the need for continued risk assessment beyond 2 years of age. The pooled analysis and other data provide sufficient evidence to launch an aggressive campaign to eliminate childhood lead exposure. Overall, findings from pediatric lead studies do not indicate any particularly critical period of vulnerability. The current focus on screening for EBLLs in children only through 2 years of age may be insufficient.

Dr. Brown was pleased that the data presented by Drs. Dietrich and Rogan strengthen the current national focus on primary prevention by ACCLPP, CDC, state and local CLPPPs, and professional organizations. However, she was concerned about the potential for the data to be used to support widespread screening of school-age children. The most recent NHANES data show that the geometric mean BLL of school-age children is ~0.9 µg/dL.

Dr. Campbell pointed out that the data raise the issue of the extent to which aggressive efforts should be made to lower EBLLs at 2 years of age to eliminate continued damage to cognition. Dr. Slota-Varma recommended publishing the data in *Pediatrics* and other venues that are targeted to providers and public health officials. Dr. Rogan clarified that the data are too technical and dependent on models for publication in journals targeted to providers. Dr. Binns reminded ACCLPP that the clinical paper will soon be published in *Pediatrics* and the *MMWR* and contains a paragraph on the data.

Overview of the Wisconsin State Lead Elimination Plan (LEP)

Dr. Catherine Slota-Varma is an ACCLPP member and an Associate Clinical Professor in the Department of Pediatrics at the Medical College of Wisconsin. She described current efforts to eliminate lead poisoning in Wisconsin by 2010. The state formed a planning group for the LEP in 2003 and engaged a broad range of stakeholders representing rental property owners, healthcare, housing agencies, state and local governments, businesses, public health and child advocacy organizations. The planning sessions resulted in the identification of four categories of concern for the LEP: providing education, correcting lead hazards in housing, allocating funding and resources, and targeting high-risk populations.

The LEP was developed with strategies, objectives, performance measures and time-lines for each category of concern. Four subcommittees were formed to focus on each category. An Implementation and Oversight Committee was established to monitor the activities of the subcommittees. CDC responded favorably to the Wisconsin LEP, particularly its comprehensiveness and emphasis on the depth of the childhood lead poisoning problem in the state. The LEP, state statutes, lead-free and lead-safe housing registry, and other lead poisoning resources throughout the state can be accessed on dhfs.wisconsin.gov.

The LEP extensively defines the scope of the childhood lead poisoning problem in Wisconsin. In 2004, ~3,300 children were lead poisoned. The lead poisoning rate in Wisconsin of 3.9% is more than twice the national average of 1.6%. Milwaukee has an overall lead poisoning rate of 9.2%, but two zip codes in the city have rates of ~25% each. Data collected from Milwaukee showed that the screening rate of children 1-2 years of age only increased from 46.9% in 1999 to 53% in 2004. High-risk populations in the state are characterized by <6 years of age and residence in a home older than 1950 or 1978 with renovation. Of Wisconsin's high-risk population, 82% are on Medicaid.

Of Wisconsin's 600,000-660,000 dwellings, 120,000 are occupied by children <6 years of age. The state uses geographic information systems to pinpoint zip codes, streets and individual addresses of high-risk dwellings. Based on a cost analysis of cleanup for 120,000 homes, $240 million would be needed for window abatement at $2,000 per home and $1.32 billion would be needed for full abatement at $11,000 per home. Wisconsin receives $6-$7 million annually from federal and private sources to address childhood lead poisoning, but another cost analysis showed that the state can save ~$14 million by eliminating lead poisoning. The savings would be based on costs for special education, medical care, juvenile justice and loss of future income.

Despite the magnitude of its childhood lead poisoning problem, Wisconsin has achieved success with the LEP. Milwaukee established a national reputation in primary prevention, developed a citywide LEP, obtained several HUD grants, and integrated the local health department and public housing agencies to strengthen enforcement activities. Milwaukee now only needs 30-40 days to repair old homes after receiving a report compared to ~260 days in other areas of the state. Other local successes include an expansion of home visitation programs with health department nurses, a dramatic decrease in lead levels with an exterior inspection model, and improved enforcement capacity.

Wisconsin implemented a new rule in 2005 requiring inspectors to check for deteriorated or flaking paint in potentially new day care centers. Educational efforts are now directed to day care providers because the state disapproved several applications for new day care centers based on the 2005 inspection rule. The day care "child health report" form was revised to include mandates for testing of Medicaid-eligible children and a new question requiring physicians to provide the date of the child's last blood test. A lead test will be incorporated into Wisconsin's electronic immunization registry. The state Medicaid program has made a commitment to fully fund the cost of software that will be required to make this change.

Physician report cards are mailed annually to all providers in the state who screened >50 children for lead poisoning in the previous year. The report cards provide physicians with their individual testing rates based on the number of children seen, tested and not tested at 1-5 years of age. The report cards also contain a bar graph comparing the physician's adherence to Medicaid testing requirements and the best compliance rates of ten other providers. A cover letter accompanies the report card offering to provide the physician with the names of children who were seen, but not tested. The local health department will administer a follow-up survey to the report cards in Milwaukee to obtain feedback from and offer lead screening assistance to physicians.

Wisconsin continues to receive funding from CDC, HUD and private sources to support the LEP and primary prevention efforts. A housing trust fund was established in Milwaukee to provide low-interest loans and rebates to persons who perform lead hazard control activities. Efforts will be made in the future to expand the housing trust fund throughout the state. Wisconsin's other funding sources for lead hazard control include fees from the transfer of real estate and a redirection of state general funds.

The Wisconsin Senate and Assembly Committees recently passed a window replacement bill. Report cards with maps of addresses where children have been lead poisoned in each legislative district are being hand-delivered to state senators and representatives of these districts. National legislation was introduced to provide tax credits for abatement and renovation. Wisconsin hosted a "Lead Poisoning Prevention Week" in October 2005 with local community events, press conferences and media coverage. The state's educational activities and other efforts have tremendously increased advocacy, support and awareness of Wisconsin's childhood lead poisoning problem at both governmental and non-governmental levels.

Dr. Brown invited Dr. Slota-Varma to attend a future ACCLPP meeting and provide an update on the physician report cards and Wisconsin's other lead elimination activities. She raised the possibility of LPPB compiling the lead strategic plans of all grantees to highlight the similarities and individual differences. While this activity is being considered, Dr. Brown encouraged ACCLPP to review the lead screening and strategic plans of all grantees on the LPPB web site.

Overview of the Houston CLPPP

Ms. Margot Tracy is a master's student at the Harvard School of Public Health. She and another student collaborated with the Houston CLPPP to implement the "Building the Evaluation Framework" project. The Children's Environmental Health Bureau (CEHB) houses the Houston CLPPP and a lead-based paint hazard control program. However, CEHB provides clinical management, but does not offer environmental services to children living in public housing identified with EBLLs. Multi-family housing (MFH) remediates properties, but does not have the infrastructure to identify and refer children with EBLLs to CEBH for clinical management. This system does not enable health and housing agencies to share data, collaborate and communicate in childhood lead poisoning elimination.

The project was designed to bridge gaps between primary and secondary prevention by integrating CEHB's clinical services and MFH's remediation services. A memorandum

of understanding (MOU) was developed to clearly define collaborative efforts between CEHB and MFH and improve coordination of lead poisoning prevention activities. A logic model was also created with objectives, specific activities and measurable indicators to illustrate the sequence of events that should occur to achieve the goals of the project.

For example, the objective of increased information sharing between CEHB and MFH would be achieved by providing the lead certification status of all MFH properties and exchanging data on properties that may have poisoned children. MFH's quarterly updated list to CEHB of all MFH properties, all properties exempt from lead certification and the lead status of non-exempt properties would serve as an indicator on the housing side. CEHB's quarterly updates to MFH on properties that were identified as non-certified and may have poisoned a child would serve as an indicator on the health side.

Ms. Tracy thanked CDC and the Houston CLPPP for educating her on evaluation and providing an invaluable opportunity to apply this knowledge in actual practice. She hoped that the "building the evaluation framework" model could be broadened to strengthen relationships between health and housing departments throughout the country. She was extremely pleased that the implementation of the project fostered collaboration and coordination between CEHB and MFH.

Dr. Brenda Reyes, the Houston CLPPP Director, described the current status of the "building the evaluation framework" model. The project was completed in January 2006, but the logic model is not being formally implemented at this time. The legal, housing and health departments have not completed the clearance and approval process for the MOU. However, the Houston CLPPP is informally conducting some of the activities described in the logic model. Children with EBLLs who reside in MFH properties are being identified. The draft logic model was distributed to state and local health departments, the broader housing community and HUD grantees. Each partner agency and organization has made a commitment to adopt the logic model after the clearance and approval process is complete.

Dr. Reyes also summarized the extremely positive impacts of the project on Houston CLPPP staff. The focus on lead was strengthened and knowledge of the evaluation process was enhanced. Collaborative efforts were undertaken with students from the nation's leading public health school to develop a logic model. The "building the evaluation framework" model is a living document that can be changed to meet the different needs of the partner agencies over time. MFH's high level of support and interest in the project facilitated coordination and collaboration with CEHB. Positive

feedback about the project was expressed at all levels of the Houston CLPPP from leadership to program staff.

Dr. Brown hoped EPA and HUD would develop similar programs with schools of public health. Each CLPPP that has participated in the program has provided CDC with extremely favorable, supportive and positive feedback of its experience.

Issues Regarding the Use of Instruments for Blood Lead Screening

Dr. Robert Bossarte of CDC described the public health impact in the United States of misclassifying or using defective sensors with the LeadCare blood lead testing instrument. Previous comparisons of results obtained with LeadCare and graphite furnace atomic absorption spectrometry (GFAAS) supported the use of portable testing units for onsite screening. In May 2005, proficiency testing revealed a negative bias in BLLs that were obtained with the LeadCare portable blood lead testing device. In response to these results, the LeadCare manufacturer launched a recall of defective BLL testing sensors on May 19, 2005.

The eight lots of recalled testing sensors were distributed from September 2004-May 2005 with expiration dates from February 2005-July 2006. The distribution and use of recalled sensors may have resulted in the misclassification of BLLs among ~500,000 persons. CDC conducted a study to quantify the public health impact of the recall and answer two research questions. First, did the average BLL decrease compared to the average BLL before the defective sensors were placed on the market? Second, did the bias adversely affect any individual by not providing medical, worker or environmental protection in a timely manner?

CDC requested laboratory data from 15 high-volume LeadCare facilities in the United States and all data from January 1, 2003-June 30, 2005. These data included the test date, sample type, result, sensor lot number, patient's age and retest results when available. Of the 15 clinical sites, 53% contributed 26,883 patient records. Of the 26,883 records, 47% contained a lot number identification. All results were obtained using capillary samples. The eight contributing facilities represented the Northeast, Midwest and West geographic regions and the states of California, Massachusetts, Michigan, Missouri and New York.

Data supplied by the facilities were stratified to analyze the following areas: (1) the availability of defective sensors and mean differences in BLLs before and after the recall in age groups of 0-6, 7-15 and >16 years; (2) mean differences in the three age groups

and the recall status with known lot numbers; and (3) differences in test and retest results with and without defective sensors. The limitations of the study include a small geographical area and sample of laboratories, a minimal number of retested patients, limited demographic information, and the sole use of capillary samples.

The analyses of the data showed the following results. A significant negative bias among BLLs was seen when defective sensors were available or used. Older children and adults may have been more severely impacted by the recall. The misclassification may have affected the treatment of >50% of persons tested with defective sensors. Poor techniques may have resulted in a misclassification.

CDC made three key recommendations based on these findings. Proficiency testing should be continued to identify defective testing systems. Persons tested between September 2003 and May 2005 with BLLs $\geq$5 µg/dL should be retested. The LeadCare field testing unit should not be used for confirmatory testing.

Mr. Jeff Jarrett of CDC announced that the LeadCare II instrument for blood lead screening is certified for use in the field, but is not commercially available. A Clinical Laboratory Improvement Amendments waiver has not been approved at this time because the instrument is still classified as "moderately complex" and proficiency testing issues have not been resolved.

The manufacturer claims that the accuracy of the LeadCare II instrument will be within 95% of GFAAS results based on measures of 14.4% at 5.35 µg/dL and 9.95% at 28.5 µg/dL. The error rate of the LeadCare II instrument is expected to be <$\pm$2. The FDA closed the recall on the lots of previous LeadCare testing sensors.

New ACCLPP Business

Ms. Johnson noted that federal housing dollars should be consistent with the regulatory language of Section 8, but this policy is not routinely followed in Rochester, New York. Perceptions of a reduction in Section 8 funds may be contributing to an increase in lead hazards to families at the local level. Ms. Johnson questioned whether other ACCLPP members have noticed this trend in other areas of the country.

Ms. Odle reported that Connecticut strictly adheres to lead-safe housing rules requiring the identification of chipping and peeling paint in Section 8 housing. The state has seen an increase rather than a decrease in compliance to these regulations. Dr. Campbell mentioned that the city of Philadelphia engaged health and housing agencies in 2002 to

make drastic changes in improving inspections of Section 8 housing and enforcing remediation of identified lead violations.

Dr. Handy emphasized the need to engage local health departments and other groups outside of HUD to address primary prevention in Section 8 housing. The amount of funds currently offered to property owners for reimbursement of Section 8 tenants is diminishing. The number of property owners who are willing to rent units to persons in Section 8 and other federally-subsidized housing programs is also decreasing. Organizations and agencies outside of HUD can provide information on the number of dwellings cited for housing children with EBLLs and property owners who receive no federal assistance.

Ms. Malone announced that AFHH has initiated dialogues with Fannie Mae, Freddie Mac and other government-sponsored enterprises to incorporate language on housing conditions into mortgage materials developed by these groups. She strongly encouraged ACCLPP to become involved in this initiative.

Drs. Brown and Friedman made a commitment to determine whether the federal interagency Lead-Based Paint Task Force is willing to address primary prevention in Section 8 housing. In the interim, however, Dr. Brown challenged ACCLPP with broadly defining "federally-assisted housing." She clarified that federal agencies other than HUD and quasi-governmental agencies also own or provide funding for federally-assisted properties. Dr. Brown confirmed that ACCLPP will revisit primary prevention in Section 8 housing at a future meeting. Dr. Friedman's update on HUD's Title X housing assistance regulations will be included in this agenda item.

Public Comment Period

Ms. Judy Zoch, of the Harris County, Texas Department of Environmental Public Health, reported that the agency sees more cases of EBLLs in children than many urban health departments. Of 20 children with EBLLs ranging from 20-48 µg/dL reported to Harris County over the last two years, 18 were Hispanic and two were African American. Of these cases, 12 were caused by non-paint sources and six were caused by lead paint. At least three of the mothers of the children had pica during pregnancy and persistent EBLLs.

Closing Session

The next ACCLPP meeting will be held on October 17-18, 2006 in Atlanta, Georgia. Dr. Campbell acknowledged the diligent efforts of Ms. Claudine Johnson in organizing and making the logistical arrangements for the meeting.

With no further discussion or business brought before ACCLPP, Dr. Campbell adjourned the meeting at 12:34 p.m. on March 22, 2006.

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

5/25/06
Date

Carla C. Campbell, M.D., M.S.
ACCLPP Chair