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
October 17-18, 2006
St. Louis, Missouri

Record of the Proceedings

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List of Participants

ACCLPP Members
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Ms. Magaly Angeloni
Dr. Valerie Charlton
Dr. Deborah Cory-Slechta
Dr. Walter Handy
Ms. Valarie Johnson
Ms. Linda Kite
Dr. Jessica Leighton
Dr. Wayne Snodgrass
Dr. Kevin Stephens, Sr.

Designated Federal Official
Dr. Mary Jean Brown,
Executive Secretary

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Dr. Duane Bolin (APHL)
Mr. William Davis II (AANP)
Dr. Benjamin Gitterman (APHA)
Mr. Steve Hays (AIHA)
Dr. Ezatollah Keyvan-Larijani (CSTE)
Ms. Jane Malone (AFHH)
Dr. George Rodgers, Jr. (AAPCC)
Dr. Walter Rogan (NIH/NIEHS)
Mr. Robert Roscoe (CDC/NIOSH)
Ms. Darlene Watford (U.S. EPA)

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Mr. Penn Jacobs
Dr. Jeffrey Jarrett
Ms. Claudine Johnson
Dr. Robert Jones

Missouri State and Local Agency Representatives
Ms. Jeanne Arraghe
Ms. Patricia Ausbon
Ms. Colleen Beckwith
Mr. Joseph Benbyodal
Ms. Carol Braun
Ms. Patricia Curtis
Mr. Bradley Hall
Dr. William Kincaid
Ms. Christy Inskip
Ms. Shirley Scatcherd
Ms. Christine Silva
Ms. Tara Robinson
Mr. Raymond Sheld
Ms. Jane Tarlow
Ms. Sharon Taulken
Ms. Susan Thomas
Ms. Heather Wheaten
Mr. Wayne Wilhem
Ms. Judy Wider-Jones
Mr. Michael Zlatic

Guest Presenters and Members of the Public
Mr. Rick Clemens (Missouri Governors Advisory Board for Lead Poisoning Prevention)
Ms. Ruth Ann Henry (Public)
Ms. Kimberly Maloney (Public)
Dr. Leland McClure (Governor's Lead Poisoning Advisory Committee & Quest Diagnostics Corporation)
Dr. Patrick Parsons (New York State Department of Health)
Mr. Robert Putnam (CITE, Inc.)
Dr. Felicia Rabito (Tulane University School of Public Health and Tropical Medicine)
Dr. Noel Stanton (Wisconsin State Laboratory of Hygiene)

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ADVISORY COMMITTEE ON
CHILDHOOD LEAD POISONING PREVENTION
October 17-18, 2006
St. Louis, Missouri

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 October 17-18, 2006 at the Hilton Ballpark Hotel in St. Louis, Missouri.

Opening Session

Dr. Mary Jean Brown, the ACCLPP Executive Secretary and Lead Poisoning Prevention Branch (LPPB) Chief, called the meeting to order at 8:55 a.m. on October 17, 2006. She welcomed the attendees to the proceedings and particularly recognized the new ACCLPP members: Dr. Deborah Cory-Slechta and Drs. Sherry Lynn Gardner and Megan Sandel *in absentia*. Dr. Brown opened the floor for introductions; the list of participants is appended to the minutes as Attachment 1.

Dr. Brown announced that voting members with a real or perceived conflict of interest related to any item on the October 17-18, 2006 ACCLPP would be responsible for identifying these issues and recusing themselves from voting on these topics or participating in these discussions.

Update on LPPB Activities

Dr. Brown covered the following areas in her report. LPPB held a conference with its 41 state and local cooperative agreement grantees. The 250 participants represented diverse groups, including advocacy organizations, state and local health departments, non-funded lead poisoning prevention programs (LPPPs), the U.S. Department of Housing and Urban

Development (HUD), the U.S. Environmental Protection Agency (EPA), and parents of lead poisoned children.

"Reaching Elimination and Stretching Beyond" was established as both the conference theme and LPPB's FY'07 theme due to the most recent data from the National Health and Nutritional Examination Survey (NHANES). NHANES data from 2003-2004 indicated that 1.2% or ~240,000 children had elevated blood lead levels (EBLLs) in the United Sates. Although the current data represent a 6% decrease since the 2001-2002 NHANES, the reduction is slow.

The nation established a goal to eliminate EBLLs as a public health problem in the United States, but this goal will not be achieved if existing tools and strategies continue to be inadequate in preventing lead exposure. Unless efforts are increased, the 2010 goal will not be achieved.

HUD data estimated that the number of houses in the country with lead paint hazards decreased by 40% from 1995-2005. Of >900 children tested in the most recent NHANES, EBLLs were detected in only 14. No statistical differences were observed between the percentage of African American and white children with EBLLs. However, data on lower BLLs showed that white children were more likely to have BLLs <1 µg/dL, while African American children were more likely to have BLLs $\geq$2 µg/dL. Disparities based on race, poverty status and older housing were seen between the two groups at the lower BLLs.

LPPB awarded 41 cooperative agreements in the current five-year cycle, including two new grantees in Mississippi and Clark County, Nevada. Alabama, South Carolina and Tennessee were not re-awarded, but LPPB will make efforts to develop contractual agreements with high-risk areas in these states. The five-year cooperative agreements will not be re-competed until 2010. LPPB will ensure that each grantee adheres to and includes ten essential services in its respective elimination plan.

Grantees will be required to comply with mandatory laboratory reporting of all blood tests. LPPB distributed a letter to clinical laboratories to encourage laboratory reporting of all blood lead tests even in states that do not have this requirement. The letter outlined minimum data elements that should be collected, such as the child's name, address, date of birth, provider, test results and sample type.

The LeadCare II handheld instrument for blood lead screening recently received a waiver from the requirements of the Clinical Laboratory Improvement Program. This raises concern that BLLs analyzed using the LeadCare II instrument will not be reported. However, software will be provided to grantees free of charge to facilitate electronic reporting.

Grantees will be required to provide lead hazard professionals and firms with the EPA-authorized licensing, certification and accreditation program. Other persons who perform

renovations will be required to receive training in lead poisoning and proper cleanup of abatement. Dust wipe testing after lead hazard abatement will be mandatory as well.

Grantees will be required to develop and maintain formal partnerships with housing and children's service agencies, community groups, policymakers, parents, health professionals and other groups. Data will be shared between HUD and EPA and quarterly reports will be submitted to housing authorities for federally subsidized housing. The data sharing approach is a solid strategy to ensure that properties with a history of poisoning multiple children over a certain period of time are corrected.

HUD data estimated that its lead paint abatement grants and demonstration projects made 80,000 units lead-safe in the United States over the past ten years. HUD also caused the abatement of 184,000 units over the past four to five years by enforcing the Lead-Based Paint Disclosure Rule under Section 1018 of the Residential Lead-Based Paint Hazard Reduction Act of 1992.

LPPB recently awarded a contract to the National Center for Healthy Housing (NCHH) to identify other federal housing subsidy programs that can be aligned with the HUD requirement. After NCHH completes an inventory with the Rural Housing Improvement Program, the Low Income Tax Equity Program and other federal housing subsidy programs, training materials will be developed and disseminated to these programs and state and local partners.

Grantees will be required to develop, implement and evaluate a written plan to achieve elimination of childhood lead poisoning by 2010. All grantees have developed elimination plans and ~60% have completed at least one of the tasks outlined in their respective plans. The public can review the childhood lead poisoning elimination plans of all grantees on the LPPB web site.

Grantees will be required to develop targeted screening plans that identify areas at highest risk in their respective jurisdictions and design screening programs to ensure children in these areas are tested.

LPPB recently published a case study in the State Medicaid Director's newsletter on four Women, Infant and Children's (WIC) programs that leveraged Medicaid dollars to test low-income children. However, LPPB acknowledges that WIC programs must be reimbursed for providing these services through a fee-for-service structure, state set-asides or contracts with managed care organizations. The New York State Senator is extremely interested in expanding the WIC pilot project and the U.S. Department of Agriculture hired an intern to assist LPPB in replicating the pilot in other parts of the country.

Grantees will be required to develop and maintain viable data management systems that contain both medical and environmental records of children with EBLLs. The environmental records would include two or three x-ray fluorescence (XRF) readings, one dust wipe

sample and other sources. LPPB will urge grantees to include laboratory tests of BLLs <10 µg/dL in the viable data management systems.

CDC is developing the National Electronic Disease Surveillance System (NEDSS) as a comprehensive public health database with asthma, HIV, immunization and other data elements. LPPB is creating a lead program area module (PAM) to be linked to NEDSS. The lead PAM is currently being beta tested in Ohio and is expected to be launched in January 2007.

Grantees will be required to develop case management protocols for children with any BLL that fits the case definition. States and local partners will be strongly encouraged to have regulatory authority requiring abatement of lead hazards in households of children with EBLLs. In 2006, only 22 of 41 grantees or 54% had regulatory authority to clean up housing that had a known history of poisoning children. States that develop lead hazard abatement laws would be required to include mandatory dust wipe testing and statutory language to protect families against retaliatory eviction, rent increases and discrimination.

LPPB acknowledges the challenges in passing and enforcing lead hazard abatement laws, particularly in areas where local agencies rather than states have authority. Training of the judiciary can help address this. For example, Indiana recently passed a lead paint abatement law and received CDC funding to develop and distribute a *Bench Book* to judges as a resource on this type of legislation. LPPB hopes to replicate the book for use by other states. The public can review the Indiana *Bench Book* on the LPPB web site.

Overall, LPPB will continue its strong focus on primary prevention by targeting the ten essential services to children with EBLLs. Primary prevention activities will be conducted for all children regardless of their BLLs, but LPPB is not considering providing individualized interventions to children with BLLs <10 µg/dL at this time.

Current estimates show that EBLLs in 240,000 children in the United States will affect their academic and life performance over time. As a result, LPPB will continue its efforts to launch the "Getting the Job Done" project to provide guidance on eliminating EBLLs in children by 2010. LPPB designed the initiative with the following activities.

- Intensive efforts to identify and provide screening and case management services to affected children will be continued.
- Primary prevention efforts will be targeted to the top ten communities with children at highest risk.
- Special emphasis will be placed on underserved areas through a "Capacity to Build Capacity" program. Experts from the Alliance for Healthy Homes (AFHH), NCHH and other organizations will provide an intensive two- or three-week onsite training and education program to struggling grantees or non-funded states and cities. Topics covered in the capacity building

program will include case management and effective collaborations with advocacy groups.

- Special programs will 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. LPPB will use the programs to train refugee resettlement workers in lead poisoning and will also evaluate the training programs.
- LPPB's initiative to engage faith-based organizations in its activities is being piloted in Georgia. An evaluation is underway to determine the effectiveness of the project in the target audience.
- Protective surveillance systems will be developed and maintained to continuously monitor potential exposures to lead among U.S. children after 2010. LPPB hopes to allocate funding to an academic partner to conduct this activity.

LPPB is continuing its international lead activities. LPPB is responding to an Epi-Aid request in an area in Peru where a town is located near a lead mining facility. Nearly all residents in this area would fit the U.S. definition of "lead poisoning."

LPPB is continuing activities in Kosovo in partnership with UNICEF, the World Health Organization (WHO), and Ministries of Health in Albania and Serbia. A Kosovo refugee camp reported two deaths and BLLs $\geq$65 in all children. However, BLLs of children began to decline following their relocation to safe facilities. Ministries of Health approved use of a chelating agent in Albania and Serbia and the manufacturer provided the drug free of charge. Two Serbians received training at CDC's facilities in Atlanta on laboratory methods. A CDC staff member will be deployed to Kosovo to provide EPA-certified training to environmentalists on analyzing and testing the environment.

Discussions are underway at CDC about reorganizing LPPB as a "Healthy Homes" operational unit with a lead surveillance program. LPPB is applying WHO's expansive definition of a "healthy home" that extends beyond the lack of disease or disability as a model in this effort. A healthy home is one that is sited, designed, built, maintained and renovated to support the health of occupants.

CDC is considering this effort for alignment and coordination with federal partners, advocacy groups, and state and local lead programs that have already initiated healthy homes activities. However, CDC recognizes the need to preserve the existing expertise, experience and resources of state and local programs while expanding the current lead poisoning prevention focus.

Data from the longitudinal American Housing Survey indicated that 6 million housing units in the United States have both severe and moderate problems in terms of peeling paint, unclean water, rodents, insufficient plumbing and other hazards. These data also

suggested that the *Healthy People 2010* objective for a 52% decrease in the number of substandard units in the United States will not be met.

In response, LPPB is developing a Surgeon General "Call to Action" to assist architects, low-income property developers, community-based organizations and mortgage holders in better understanding their respective roles in a public health program. The Call to Action will focus on several basic principles, such as keeping housing dry, clean, safe, contaminant-free, pest-free, properly ventilated and well maintained; accessible to persons with disabilities and other special needs; and able to allow persons to age in place.

ACCLPP commended LPPB on its diverse activities to address and eliminate the childhood lead poisoning problem in the United States. The members made two key comments for LPPB to consider in its ongoing efforts. First, "green" housing should be considered as an additional basic principle in the Surgeon General's Call to Action. Dr. Brown announced that LPPB would attempt to develop a research agenda to determine health savings or benefits from green building technology.

Second, CDC should actively pursue the reorganization of LPPB as a "Healthy Homes" operational unit because this change would allow outcomes beyond child lead poisoning to be analyzed and measured in the future, such as access by children to poisonous household products. Dr. Snodgrass offered to assist LPPB in locating data the Association of Poison Control Centers collects and publishes each year on home hazards.

History of the St. Louis, Missouri Lead Program

Dr. William Kincaid, Director of the City of St. Louis Department of Health, described activities St. Louis is conducting to shift to primary prevention. Several major issues and milestones related to childhood lead poisoning occurred from 1946 to the present in St. Louis. In the 1940s, two children died from lead poisoning after exposure to lead fumes and leaded ashes from the burning of lead-acid battery cases in hand-fired coal heating stoves.

The public health laboratory offered blood lead analysis test kits. Legislation was enacted to regulate the disposal of lead-acid battery casings after education alone was found to be ineffective. The "Seasonal Incidence of Lead Poisoning in Children in St. Louis" study was published in the *Southern Medical Journal*. The study illustrated a clear seasonal pattern in reported cases and deaths in children from lead poisoning based on present standards.

In the 1970s, a mass screening program was piloted in high-risk areas of St. Louis. Of 89 children tested, ~38% had BLLs $\geq$50 µg/dL. Of 32 children with EBLLs, ~59% required hospitalization. The screening program projected that 30,000 children 1-6 years of age were living in high-risk areas of the city. Unexpended funds from other divisions of the health program were used to establish the Lead Poisoning Control Service and create ten

full-time positions. Lead inspections were assigned to the Community Sanitation and Vector Control Section of Environmental Health Services.

Several community groups involved in lead poisoning prevention advocacy united under the "People's Coalition Against Lead Poisoning" to galvanize political will for this issue. The city of St. Louis began to allocate resources to address the problem. Academic institutions sponsored the "Get the Lead Out Conference" with action-oriented workshops to increase awareness at the local level and mobilize forces. A mobile screening project was piloted for one month in the community to strengthen understanding of the epidemiology of lead poisoning. The pilot project identified a high rate of children with BLLs $\geq$40 µg/dL.

Funding under the Public Service Employment Act allowed 17 laboratory and outreach employees to be hired for systematic door-to-door screening and the Greater St. Louis Lead Advisory Council to be formed. A portion of community development block grant funding for detox and inspection was used for lead abatement.

In the 1980s, the housing court addressed 1,431 cases that were referred for prosecution. The budget for lead poisoning prevention in the city of St. Louis was substantially cut. The city received $45,000 from the state Maternal Child Health grant pass-through. All Community Development Agency block grant funds were discontinued. CDC released its revised statement on the prevention of lead poisoning in young children and also issued guidance to local agencies on the elimination of childhood lead poisoning. Lead testing became a major responsibility in medical care and managed care plans.

In the 1990s and early 2000s, managed care arrived in St. Louis. Two public hospitals were closed and a city/county regional hospital was opened. The regional hospital eventually closed and four city clinics established ConnectCare to provide primary care. The Regional Health Commission was formed with representation by the city, county, state and hospitals to assist in organizing a safety net of providers. A shift was made to treat childhood lead poisoning as a public health rather than a medical problem. Testing of children was expanded to include testing of homes and primary prevention. Medicaid began to cover case management of lead poisoned children. HUD and EPA strengthened laws and funding assistance.

Dr. Kincaid described actions that were taken in the city of St. Louis beginning in 2003 to develop a comprehensive action plan for the eradication of childhood lead poisoning by 2010. The St. Louis Lead Prevention Coalition released the "Lead Canaries: The Tragic Tradition of Childhood Lead Poisoning in St. Louis" report. Emphasis was placed on housing to prevent more children from becoming lead poisoned. The focus shifted from interim controls to abatement to achieve primary prevention in St. Louis with full involvement of the community. Childhood lead poisoning was viewed as a public safety and building issue rather than a public health problem.

The critical need for an effective primary prevention system and public resources to remove hazards from low- and moderate-income housing was acknowledged. The mayor of St. Louis made a commitment to and called for resources to establish a primary prevention system. The "Lead Safe St. Louis Logic Model" was developed to increase public awareness of the lead issue and publicize the availability of resources to address this problem. For example, St. Louis has resources to perform lead inspections and abate properties with lead hazards before a child is poisoned at no cost to the homeowner. A targeted media campaign was launched.

Lead testing and immunization rates increased due to these outreach efforts, but the rates have declined over the past few years. As a result, the city of St. Louis asked managed care plans to assist in identifying children who live in high-risk zip codes. This information would be provided to physicians for inclusion in the child's medical chart. Letters were sent to all local physicians with a request to perform more lead testing.

Partnerships were established to build trust with organizations and agencies at city and community levels, the medical community, abatement contractors, the local day care association, real estate brokers, home rental agencies, and funding agencies at federal and state levels. Overall, the percent of children who tested positive for lead in the city of St. Louis decreased from 28% in 1971 to 8.4% in August 2006. The dramatic decrease in children with EBLLs was largely due to implementation of primary prevention and the abatement of homes throughout the city.

Dr. Kincaid also reported on the housing stock. At the national level, 38% of the U.S. housing stock or 98 million units will need ongoing surveillance. At this time, 435,000 homes in the United States have children with EBLLs and 3.6 million homes are priority hazards. At the local level, 65% of 147,076 housing units in the city of St. Louis were built before 1950 and 29% were built before 1978. The city is targeting primary prevention to ~15,000 units with children <6 years of age. Moreover, funds were recently allocated to perform lead testing on pregnant women in high-risk zip codes and take actions to ensure the home is lead safe before the child is born.

Dr. Kincaid acknowledged that the city of St. Louis would continue to face numerous challenges in its comprehensive action plan to eradicate childhood lead poisoning by 2010. However, he was pleased to note that efforts are underway to address these issues. Partnerships between public health and managed care are being enhanced to build a strong data infrastructure. Most notably, public health is in critical need of the data collected by Medicaid managed care plans.

More aggressive actions are being taken to widely publicize the availability of funds for lead abatement. Efforts are being made to decrease mistrust at the local level of the inspection process. Strategies are being implemented to inspect unlicensed day care centers. Activities are being conducted to educate local Realtors on the critical need for ongoing surveillance of homes in the community with lead poisoned children.

Partnerships for a Lead-Safe Community

Ms. Susan Thomas, of the Missouri Department of Natural Resources (MDNR), described key partnerships that were established to develop lead-safe communities throughout the state. The state of Missouri has lead smelters and has mined lead since the 1700s. MDNR identified several areas in the state with a history of lead mining and lead smelting. Five areas in the state were placed on the National Priorities List (NPL) for lead hazards; three additional areas are scheduled to be placed on the NPL over the next few months; and two areas are being addressed by principal responsible parties (PRPs).

EPA's lead testing and sampling resulted in the detection of contaminated levels of lead, the identification of 10% of children in the state with EBLLs, and confirmation of 645 acres with lead deposits. Federal, state and local agencies collaborated in joint efforts to address these problems. Most notably, a statewide inventory was performed to identify environmental hazards. Oversight was provided during the development of MDNR's work and remediation plans. Community roundtables were held for local agencies to obtain input from and provide up-to-date information to community members about residential sampling and other activities.

Public health assessments were conducted at all NPL sites in the state. Outreach and educational activities included lead testing in health departments, community events and child care facilities. Surveillance data were collected and disseminated to prioritize cleanup of lead hazardous homes, playgrounds and other areas. Educational materials were developed and distributed to communities and the local health department. Funding was provided for remediation efforts, particularly soil and water sampling. Legal actions were taken to ensure that PRPs would be fully engaged and provide funding for the cleanup of contaminated sites. A lead cleaning kit and materials were distributed to families in the community to assist in maintaining clean homes and reducing lead hazards.

Ms. Thomas was pleased to announce that the partnerships and outreach efforts resulted in the remediation of >500 residential properties, schools and child care facilities. In 2005, only 2% of children tested for lead in a high-risk community had EBLLs. However, MDNR acknowledges the need for additional activities to be conducted. More private wells should be sampled and more areas in the county should be remediated. Education and blood lead testing should be continued in the community.

Funding by the Agency for Toxic Substances and Disease Registry (ATSDR) was cut and should be renewed in order for the county health department to continue to conduct lead poisoning prevention projects in the community. Lead hazards should be eliminated throughout the state, particularly at NPL and Superfund sites. MDNR will continue to collect environmental samples from these areas and conduct other activities in collaboration with its partners. Ms. Thomas pointed out that MDNR provided EPA with its recommendations to eliminate childhood lead poisoning and achieve other long-term outcomes.

Ms. Kite advised MDNR to obtain a technical assistance grant from ATSDR or EPA. She pointed out that these funds could assist Missouri in developing lead-safe communities throughout the state. In response to Dr. Stephens' question, Dr. Brown confirmed that she would ask ATSDR about previous or ongoing activities to test lead levels in livestock at Superfund sites.

Update by the Lead and Pregnancy Workgroup (LPWG)

Dr. Jessica Leighton, the LPWG Chair, provided a status report on LPWG's activities after the March 2006 ACCLPP meeting. The timeline to draft, revise and finalize the lead in pregnancy report was changed. The first draft will be circulated to ACCLPP for review and comment in January 2007 rather than in December 2006. ACCLPP's comments will be incorporated by May 2007. The second draft will be distributed to ACCLPP in August 2007. Additional input will be obtained from ACCLPP during the fall 2007 meeting. The third draft with ACCLPP's final comments will be submitted to CDC for the clearance process in October 2007.

Dr. Leighton reminded ACCLPP of the chapters that would be written for the lead in pregnancy report:

- Introduction, background and significance of lead.
- Biological and environmental measures of lead.
- Health effects of lead in pregnancy.
- Sources of lead exposure and control of sources in pregnant women.
- Epidemiology, risk factors and screening of women of child-bearing age.
- Recommendations on the assessment of and interventions for lead-exposed pregnant women, including source identification, source elimination, behavioral interventions, chelation and follow-up.
- Nutrition and breast-feeding recommendations for lead and pregnancy.
- Research, policy and education needs.

Dr. Leighton announced that LPWG's next steps would be to continue to develop the first draft of the lead in pregnancy report. To advance this effort, she asked ACCLPP to provide input on several complex questions LPWG is still attempting to answer. She also outlined a number of recommendations LPWG proposed that could potentially address these issues.

Issue 1. Do the benefits of breast-feeding outweigh exposures to lead? At what maternal BLL or increased infant BLL should breast-feeding be discontinued? LPWG used current data in an effort to answer these questions. LPWG's rough estimates showed that a maternal BLL of 40 µg/dL could increase an infant BLL by ~5 µg/dL.

LPWG proposed the following recommendations for breast-feeding. Breast-feeding should be continued at BLLs 10-40 µg/dL, but should be discontinued if the infant BLL rises and no additional sources of exposure are detected. A "wait and see approach" should be recommended in which the mother and infant would continue to be tested. Efforts should be made to ensure that no other sources would affect the mother or infant. Pregnant women should be advised to take calcium supplements and prenatal vitamins as recommended.

Issue 2. Should supplementation exceed levels already recommended during pregnancy? LPWG acknowledged that the evidence supports calcium supplementation. LPWG agreed that current data are inadequate to support guidance on supplementation with iron, vitamin C and other nutrients over the recommended levels.

LPWG proposed the following recommendations for supplementation. Supplementation with 1,200 mg of calcium/day should be recommended during pregnancy if the BLL is $\geq$10 µg/dL. The majority of calcium should be from dietary sources rather than supplements. WIC or health insurance should cover calcium supplementation. Current nutritional recommendations for supplementation with other nutrients during pregnancy should be reinforced, such as vitamins C and D and iron.

Issue 3. What definition should be used for "pica?" LPWG reviewed and extensively discussed the definition in the *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition. Pica is defined as "persistent eating of non-nutritive substances for at least one month. Eating of non-nutritive substances would be inappropriate to the developmental level. Eating behavior would not be part of a culturally sanctioned practice." LPWG also discussed the possibility of developing and distributing a questionnaire to assist physicians in determining whether their patients have pica.

LPWG proposed the following recommendation for pica. Providers should obtain a BLL on pregnant women who admit pica behavior or those who are suspected of engaging in pica behavior.

Issue 4. At what BLL should providers consider chelation of pregnant women and neonates? At what point during pregnancy would the risk of lead exposure outweigh the risk of chelation therapy? Are symptoms a prerequisite to consider chelation of pregnant women?

LPWG proposed the following recommendations for chelation of pregnant women. Chelation therapy should not be considered for women with BLLs $\geq$45 µg/dL until the second half of pregnancy due to the teratogenicity of chelating agents during the first half of pregnancy. Chelation therapy should be performed in consultation with an experienced specialist in chelation.

Issue 5. What actions should healthcare providers and public health agencies take to prevent lead exposure in pregnant women in the United States?

LPWG proposed the following recommendations for prevention. All healthcare providers should provide routine anticipatory guidance to educate pregnant patients on risk factors associated with exposure to lead. Public health agencies should develop and distribute educational materials and guidance to healthcare providers on lead exposure during pregnancy, risk factors, screening and management.

Issue 6. What should be the BLL of concern for pregnant women?

LPWG proposed the following recommendations for the BLL of concern. The BLL of concern should be 10 µg/dL for consistency with the childhood BLL of concern, but specific language should be included for pregnant women. At a BLL of 5 µg/dL, public health agencies should not take actions. Providers should counsel patients on sources of lead, conduct a nutritional assessment, and perform follow-up testing. At a BLL of 10 µg/dL, clinical providers should ask health departments and health agencies to distribute educational materials to physicians and their patients.

At a BLL of 15 µg/dL, providers should counsel patients on reducing lead sources. Public health agencies should initiate actions to identify and reduce exposure to lead sources. At a BLL of 40 µg/dL, nursing mothers should be advised to discontinue breast-feeding. At a BLL of 45 µg/dL, providers should consider hospitalizing and chelating their patients. Public health agencies should refer providers to experts in the management of lead-exposed pregnant women.

Dr. Leighton announced that LPWG would convene its next meeting in November 2006. LPWG would continue to discuss the unresolved issues, but more emphasis would be placed on research, policy and education needs for lead in pregnancy. She reiterated her request for ACCLPP to provide guidance to LPWG on answering questions in the six areas.

ACCLPP made a number of suggestions to assist LPWG in addressing the unresolved issues. Several members also made general recommendations for LPWG to consider in developing and disseminating the lead in pregnancy report.

General

- The initial draft of the report should be distributed to childhood LPPPs (CLPPPs) and other reviewers outside of ACCLPP to obtain input from a wide and diverse audience.
- A short summary statement about the lead and pregnancy report should be written and published in *Pediatrics* and the American College of Obstetricians and Gynecologists peer-reviewed scientific journal. This approach would notify providers about the existence and location of the document.

- The report should describe global implications that could occur when other parts of the world adopt U.S. guidance. These recommendations could have different impacts on infants with other serious risk factors outside of the United States. For example, a child in Kosovo could die from starvation or a diarrheal disease if the mother with an EBLL is advised to discontinue breast-feeding, but has no clean water supply or access to formula.
- The report should strongly emphasize that the lead and pregnancy recommendations serve as guiding principles only. Clinical discretion should be used on a case-by-case basis.

Breast-feeding

- Maternal BLLs for breast-feeding should be calculated with the age of the mother at the time of delivery and an excretion factor because infants excrete lead.
- The report should provide options on feeding infants if breast-feeding is not recommended for women with EBLLs.
- The report should take a strong position that breast-feeding is the absolute cornerstone of maternal child health.
- The "wait and see" approach should be deleted from the report because misinterpretation of this recommendation might discourage breast-feeding.
- The following recommendation should be included in the report: "Consider discontinuing breast-feeding if a serial rising of the BLL or a significant difference in the BLL is observed."

Supplementation

- The report should advise women to have a certain intake of lead-free calcium.
- The guidance on calcium supplementation should be expanded to advise pregnant women to take an adequate amount of vitamin D.
- The report should emphasize the need to ensure current and continued adequacy of the iron status of the infant.
- Caution should be taken in applying the Mexico data on supplementation with 1,200 mg of calcium/day during pregnancy to the United States. Studies have demonstrated negative effects in U.S. women with a daily calcium intake at this level.

Pica

- The report should encourage an investigation of current exposures for pregnant women with a known EBLL. The investigation should include questions to determine whether the pregnant woman is eating non-nutritive substances.

Chelation

- Caution should be taken in recommending chelation of pregnant women with BLLs $\geq$45 µg/dL. Plasma is the driver of brain lead, but no data have been

collected to date on lead levels from plasma that travel to the brain. Blood and urinary lead levels are not sufficient markers for plasma lead. Moreover, chelating agents are not specific to lead and would also remove zinc, iron, calcium and other needed metals from the pregnant woman.

BLL of Concern

- The report should take into account other ongoing efforts that are addressing the BLL of concern. For example, EPA's recently revised air quality criteria document for lead discusses data that support a blood lead threshold <10 µg/dL.

Prevention

- The report should strongly emphasize that prevention begins before pregnancy. A recommendation should be made to assess prior exposure in addition to current risks of exposure.

Dr. Brown made several remarks in response to suggestions by some of the ACCLPP members. First, LPPB would provide the draft lead in pregnancy report to several partners for review and comment, including CLPPPs, the American Academy of Pediatrics (AAP), and the Health Resources and Services Administration Bureau of Maternal and Child Health.

Second, the lead in pregnancy report would be released as a CDC publication of recommendations for lead exposure during pregnancy and lactation. The document would be modeled after the blue book on *Managing Elevated Blood Lead Levels in Children*, but would not serve as an ACCLPP statement. Third, language in the lead in pregnancy report on the BLL of concern would be consistent with CDC's August 2006 statement that noted a "safe" blood lead threshold has not been identified for fetal or childhood exposure.

Update by the Model Codes Workgroup (MCWG)

Ms. Jane Malone, the MCWG Chair and ACCLPP liaison to AFHH, provided a status report on MCWG's initial discussions and activities after the workgroup was formally established following the March 2006 ACCLPP meeting. MCWG held two conference calls in September 2006 with its membership of ACCLPP members, liaisons, *ex-officio* representatives and external colleagues.

MCWG extensively discussed its purpose and charge. Model codes should be improved to advance and expand primary prevention. To fulfill this charge, MCWG would review the entire landscape of primary prevention activities conducted by CDC, EPA, HUD, and other agencies at federal and state levels.

MCWG acknowledged that federal efforts to reduce exposures to lead should be expanded, but the existing infrastructure to keep housing lead safe should be maintained. MCWG agreed that current mandates, incentives and recommendations at the national level are not effectively translated to policy at the local level. For example, disclosure regulations that were passed in 1996 requiring property owners to provide renters and prospective buyers with information on hazards of the property have not been enforced to date.

MCWG reviewed the current environment of model codes. Model building construction codes affect the construction or substantial renovation of properties. Property maintenance codes govern physical conditions of the property and could play a role in the occupancy of rental properties. Each state and local jurisdiction has the authority and discretion to develop individual policies. The adoption of model codes could result in several advantages in terms of policy, research, screening and basic protection.

The International Code Council (ICC) is an organization that was founded in 1994 to develop, publish and update model codes. ICC encourages states and localities to adopt consensus models that lead to consistent enforcement and higher quality construction. However, model codes are not developed with "lead-safe" language.

MCWG identified three areas that would need a significant amount of attention to incorporate lead poisoning prevention language into model codes. First, the International Property Maintenance Code (IPMC) requires intact paint and prohibits peeling paint in buildings. However, the IPMC considers peeling paint as a cosmetic problem and only discusses lead safety in the commentary. Second, the International Existing Building Code (IEBC) is completely silent on lead hazards and does not require lead-safe practices or prohibit dangerous practices. Third, strong advocacy efforts would be needed to include EPA's pending renovation and remodeling rule into existing building codes.

MCWG ensured that its recommendations were consistent with ACCLPP's position. For example, ACCLPP is on record with its support of local laws and regulations requiring lead-safe housing treatment; repair and maintenance of properties; treatment of dust lead hazards and deteriorated paint; and post-clearance dust testing. ACCLPP also made two additional recommendations. Agencies should be authorized to ensure properties are lead safe. Compliance with housing regulations should be assured through citations and other enforcement actions.

Overall, MCWG agreed that international code enforcement bodies do not provide communities with optimum tools to address basic lead hazards. As a result, MCWG proposed additional language that should be included in the IPMC and IEBC on lead-safe work practices (LSWPs), maintenance of exterior and interior surfaces, clearance testing, changes in occupancy, additions to existing buildings, and alterations and repairs.

Ms. Malone pointed out that excerpts from the IPMC and IEBC as well as MCWG's proposed language on lead poisoning prevention were distributed to ACCLPP in the

meeting packets. The proposed guidance was consistent with EPA and HUD language. ICC held a hearing in September 2006 to review public comments on its model codes, but none of ACCLPP's previous comments on lead poisoning prevention were included. ICC would hold a final hearing in May 2007 to reach definitive conclusions on adopting public comments for its model codes.

MCWG intends to develop and submit an ACCLPP position statement for consideration in ICC's final hearing, but the statement is not expected to be adopted in the upcoming code cycle. Most notably, ICC expressed opposition to requiring property owners to take additional actions to reduce lead hazards.

In the interim of ICC's next code cycle over the next three years, MCWG would explore the possibility of implementing several aggressive strategies. For example, ACCLPP's position statement on lead poisoning prevention could be widely disseminated to advocates throughout the country. This approach could be used to encourage ICC members and local code officials to implement model codes at the local level. The ICC President could be contacted for a discussion about including lead poisoning prevention language in model codes. Non-ACCLPP members could attend and provide testimony during the next ICC hearing. Ms. Malone announced that ACCLPP still had time to submit comments on the IPMC and IEBC for consideration during the final ICC hearing in May 2007.

Several ACCLPP members made comments for MCWG to consider in its ongoing efforts to include lead poisoning prevention language in the IPMC and IEBC.

- The proposed changes in Section 304.2.1 of the IPMC should be separated to clearly distinguish between methods that should and should not be used in LSWPs.
- The proposed changes in the IEBC should describe specific methods that are used to determine whether properties are lead free. ASTM International and other consensus standards should be quoted in this effort.
- The proposed changes on "lead safety" in the IEBC should be changed to "lead-based paint safety."
- Strong efforts should be made to identify a "model code champion" who has experience and a long-standing reputation in the codes process. Mr. Hays committed to providing MCWG with the names of potential champions.

Dr. Brown confirmed that she would contact EPA to determine whether XRF readings in the field without a quality assurance program could serve as a legal basis in a court of law to establish the presence or absence of lead paint in properties.

Dr. Brown also described MCWG's next steps. Ms. Malone would present the draft ACCLPP position statement for review and comment on the following day. If ACCLPP voted to approve the position statement, the document could be submitted to ICC for

consideration in the May 2007 model code hearing, distributed to advocacy groups, posted on the LPPB web site with other ACCLPP materials, and disseminated to individual citizens.

Update on the ACCLPP Clinical Paper

Dr. Helen Binns, the ACCLPP liaison to AAP, served as the primary author of ACCLPP's paper on *Understanding Blood Lead Levels and Primary Prevention*. She announced that the clinical paper was accepted by *Pediatrics* for publication and was also submitted to the *Morbidity and Mortality Weekly Report* (*MMWR*) for joint publication. However, the *MMWR* editors expressed serious reservations about publishing the paper. Drs. Binns and Brown were informed that the document was inconsistent with the *MMWR* format and inadequately addressed the subject matter.

To address these concerns, Dr. Binns resubmitted the paper to the *MMWR* with a revised introduction and the addition of a new "methods" section. *MMWR* accepted the revised paper and placed the document on its publication calendar. Dr. Binns was informed that *MMWR* would complete the editing and review process in mid-January 2007. The paper would be resubmitted to *Pediatrics* at that time for publication in April 2007.

Dr. Brown emphasized that *MMWR* would not make substantive changes during the editing and review process. The revisions would be consistent with the *MMWR* format, but would not change the spirit of the document that ACCLPP approved.

Update on the Lead Policy Statement (LPS)

Dr. Benjamin Gitterman, the ACCLPP liaison to the American Public Health Association (APHA), provided an update on the APHA LPS that was approved in December 2005. The LPS took a position that the standard for a BLL of concern in children should be lowered from 10 µg/dL. ACCLPP extensively discussed the LPS during the March 2006 meeting and agreed to formally communicate its concerns by drafting and sending a letter to the APHA Executive Director.

Several members provided input on the tone and content of the letter. On the one hand, the letter should commend APHA's solid intentions in publishing the LPS. On the other hand, the letter should express ACCLPP's concerns in three major areas. The LPS was published with numerous technical errors. The LPS was published with inaccurate and inflammatory remarks about ACCLPP's composition and membership. APHA failed to communicate with ACCLPP prior to publishing the LPS.

Although some ACCLPP members were in favor of a positive, diplomatic and constructive tone for the letter, other members emphasized the need to formally convey ACCLPP's

concerns. The members noted that APHA is a huge professional association with ~30,000 members. Moreover, APHA's policy statements are placed in the public domain and have tremendous implications for the broader public health community.

After the previous meeting, Dr. Carla Campbell, the former ACCLPP Chair, drafted a letter to APHA highlighting ACCLPP's comments. However, Drs. Gitterman and Rhoads discussed other approaches that might result in better and more effective outcomes than sending a letter to the APHA Executive Director. As a result, Dr. Rhoads asked Dr. Gitterman to explore these options and did not sign and send the letter.

Dr. Gitterman responded to this request by engaging in discussions with APHA senior leadership. One of the functions of the APHA Action Board and the Policy Council of the Environmental Health Section is to archive or remove outdated policy statements from the public record or recommend changes to policy statements based on errors or updated information.

Dr. Gitterman proposed three options for ACCLPP to consider based on his conversations with APHA leadership. First, a presentation could be made during the November 2006 APHA meeting on ACCLPP's proposed changes to the LPS or the rationale to entirely remove inaccurate portions of the LPS from the public record. Second, a revised letter could be sent to the APHA Executive Director based on outcomes from the presentation during the APHA meeting. Third, the original draft letter could be signed by Dr. Rhoads and sent to the APHA Executive Director.

Dr. Gitterman explained that the three options were not mutually exclusive and could be combined. He asked the members to provide additional input on other approaches to effectively communicate ACCLPP's concerns to APHA on the LPS.

ACCLPP was divided on its next steps in communicating with APHA. On the one hand, some members believed that ACCLPP's formal advisory committee process was ignored. For example, ACCLPP reached agreement during its March 2006 meeting to send a letter to the APHA Executive Director. Dr. Rhoads had serious reservations in taking this approach after the meeting and did not sign and send the letter to APHA as agreed to by ACCLPP. No e-mail messages or other communications were circulated to notify ACCLPP members about this development.

On the other hand, several members agreed with Drs. Gitterman and Rhoads that approaches other than sending a letter to the APHA Executive Director would be more effective in achieving ACCLPP's goals.

- ACCLPP's letter should be submitted for publication in the APHA journal. In addition to providing corrections on technical errors in the LPS, the letter should also contain factual information on the diversity of ACCLPP's current

composition and membership. This approach would give ACCLPP's comments more credibility and result in a more global impact.

- Dr. Gitterman should have a face-to-face discussion with APHA as proposed. The conversation should be followed up with a formal letter from ACCLPP.
- ACCLPP members should be given a deadline of November 1, 2006 to submit proposed changes on the LPS to Dr. Rhoads. This timeline would allow Dr. Gitterman to make a presentation during the November 2006 APHA meeting.
- The resolution of a disagreement with APHA should not be viewed as important ACCLPP business. For example, Dr. Rhoads should sign and send the original draft letter to the APHA Executive Director to resolve this issue in an expeditious manner.

A motion was properly placed on the floor and seconded by Drs. Angeloni and Stephens, respectively, for Dr. Gitterman to take the following actions. ACCLPP's proposed changes on the LPS would be presented to APHA. Discussions would be held with Dr. Rhoads to ensure that the language accurately reflected ACCLPP's position. An update on the discussion with APHA would be provided to ACCLPP.

The motion was tabled and would be revisited during the "New Business" agenda item on the following day. Copies of the LPS and ACCLPP's draft letter to the APHA Executive Director would be distributed to ACCLPP to facilitate the discussion.

Data on School Performance and Concurrent BLLs

Dr. Walter Rogan, the ACCLPP *ex-officio* representative for the National Institutes of Health, presented data from studies that analyzed the relationship between school performance and concurrent BLLs. The Boston prospective study was conducted with a cohort of children 10 years of age who were tested with the standard Wechsler Intelligence Scale for Children. The data showed that children with low BLLs at 24 months of age had IQs of ~120, while those with BLLs >15 µg/dL at the same age had IQs of 112.

The Boston study resulted in the development of the following paradigm. BLLs peak at 2 years of age and determine IQ at school age. Concurrent BLLs would be less important than peak BLLs. This theory had implications for screening programs, blood lead testing of children at 2 years of age and clinical trials.

The Cincinnati study was conducted with a cohort of children with higher BLLs and lower mean IQs than the Boston cohort. The data showed a stronger association between IQ and BLLs at 6 years of age than BLLs at 2 years of age. Results from the Cincinnati study were more commonly observed in large prospective data sets and clinical trial data than findings from the Boston study.

The Treatment of Lead-Exposed Children (TLC) clinical trial was conducted with a cohort of 780 children who were divided into groups with BLLs above and below 25 µg/dL at 2 and 7 years of age. The data showed that children 2 and 7 years of age with BLLs higher than the median lost 3.6 IQ points. Children with high BLLs at an early age and low BLLs at a later age had IQs that were the same as the referent group. Children with high BLLs at both early and later ages had IQs that were the same as those with high BLLs at a later age. TLC data demonstrated the importance of BLLs at 7 years of age.

A published study showed that the number of IQ points lost per 10 µg/dL of blood lead. BLLs in later years were found to be associated with IQ and a strong relationship was seen with smeared BLLs. A study was conducted with NHANES data on blood lead concentration and reading scores.

An international pooled analysis of seven prospective studies was conducted to determine the relationship between low-level environmental lead exposure and children's intellectual function. The cohort of ~1,000 children was prospectively followed from infancy through 5-10 years of age. Variables in the analysis included peak BLLs, early childhood BLLs from 6 months to 2 years of age, mean lifetime average and concurrent BLLs. Maternal IQ was found to be a strong predictor of child IQ and stable over time. All of the variables contributed to child development to some degree, but the length of time spent with an EBLL appeared to be the strongest measure.

Dr. Rogan pointed out that several conclusions could be reached based on the studies. Lead-associated intellectual deficits occur at concurrent BLLs <10 µg/dL. Previous studies indicated that peak BLLs at 2 years of age governed IQs at 5 years of age and later, but more recent data do not support this paradigm.

No evidence has been produced to support (1) a threshold for lead-associated intellectual deficits; (2) a specific age or a critical BLL to define "lead toxicity;" or (3) efforts to identify a new threshold for BLLs. The data showed that a younger age and length of time with a higher BLL played more important roles in lead-associated intellectual deficits. Sufficient evidence has been produced to mount an aggressive campaign to eliminate childhood lead exposure and shift efforts toward long-term primary prevention.

Several ACCLPP members made suggestions on efforts that could be made to strengthen the focus on primary prevention.

- Clear messages should be widely communicated to explain the rationale for primary prevention. For example, many more children would be identified and more community resources would need to be allocated if the BLL of concern was lowered from 10 µg/dL.
- Existing educational materials should be thoroughly reviewed to promote a broader perspective that lead hazards are important for all persons. For

example, EPA's draft document on LSWPs solely focused on adverse health effects from lead to children <6 years of age and pregnant women. A study was recently conducted with NHANES data that listed causes of death in adults with BLLs <10 µg/dL.

- CDC should develop and distribute guidance materials to schools.
- ACCLPP should outreach to the Office of Special Education Programs because this agency recently finalized the Individuals with Disabilities Education Act regulations.
- CDC should call for additional research on the relationship between school performance and concurrent BLLs due to existing gaps in knowledge on how exposures to school age children occur.
- CDC should change its messages and materials to emphasize that educational efforts for health prevention should be targeted to all children.
- Caution should be taken in expanding primary prevention language to include children of all ages because many federal, state and local regulations are specific to children <6 years of age.

Dr. Brown offered to develop a short guidance document based on key points from ACCLPP's discussion. The document would be distributed to ACCLPP for review and then disseminated to state and local lead programs. Dr. Brown highlighted several messages that would be included in the guidance document. The focus on children <6 years of age should be maintained because this population has the greatest exposure to lead. NHANES and other data show that children at this age are more likely to have a high lead exposure.

Previous studies indicated that adverse health effects related to lead exposure would not occur at older ages, but more recent data do not support this paradigm. As a result, schools should be safe. Lead in drinking water initiatives and other school-based activities should be supported. This information should be distributed to EPA and other agencies. LPPPs should strengthen case management to provide children with known EBLLs with Head Start or similar high-quality and intellectually preschool environments.

Public Comment Period

Ms. Jeanne Arraghe is the Coordinator of the City of St. Louis Lead Safe Program. She informed ACCLPP that St. Louis has faced several challenges in shifting efforts toward primary prevention, but progress is being made. St. Louis provides LSWP training and EPA and HUD clearance following remediation. Individual property owners are remediating units as well.

St. Louis is introducing a new program in which abatement projects will be awarded to contractors on a rotating basis to expedite the process. Four citizen advocates were added to the lead safe program to assist families in undergoing the remediation process. The

average number of days for remediation was decreased from 250. Detox crews and inspection teams immediately begin the remediation process 24 hours after BLLs >30 µg/dL are identified in a home.

St. Louis has a progressive code enforcement program. A $2 fee is charged on building permits for every $1,000 in construction/rehabilitation work. The fees are placed in a lead remediation fund for a total of ~$1 million per year. St. Louis uses the lead remediation fund as matching dollars to receive HUD grants. St. Louis does not allocate funds to train personnel in enforcing codes, but federal funds were awarded to the city in 2003 to train its 96 building inspectors as lead risk assessors. However, only 33% of building inspectors received the training and the remaining 66% attended a two-day general awareness training course to reduce the amount of time spent from work.

St. Louis traditionally performed remediation in response to EBLLs only, but ~53% of referrals to the city now involve cases where individuals voluntarily request lead inspections. St. Louis has requirements for housing conservation districts that mandate a visual inspection prior to issuing an occupancy permit. At this time, ~70% of the city participates in housing conservation districts.

Building owners who do not remediate chipping, peeling or flaking paint are referred for a lead inspection and fined for any lead hazards identified. Building owners are not released from this responsibility until the property is completely remediated. St. Louis has authority to enforce compliance with lead safety in schools and periodically performs risk assessments in schools. St. Louis will continue to monitor schools and communicate the importance of this effort.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 5:05 p.m. on October 17, 2006.

Demolition as a Source of Exposure for Children with EBLLs

Dr. Brown reconvened the ACCLPP meeting at 9:35 a.m. on October 18, 2006 and yielded the floor to the first presenter. Dr. Felicia Rabito, of Tulane University School of Public Health and Tropical Medicine, presented a study that was conducted to analyze the potential relationship between demolition and EBLLs in children.

Local governments demolish aging or substandard housing to revitalize communities. Previous studies showed that urban housing demolition is a potential source of environmental lead exposure. Settlement of lead dust serves as an ambient pathway for lead and a potential source of exposure.

At the national level, ~1.8 million older housing units are estimated to be demolished over the next ten years throughout the United States. At the local level, the city of St. Louis issued permits in 2001-2002 for the demolition of >2,000 buildings. The demolitions might serve as a significant exposure source because ~94% of housing in St. Louis was built before 1978. The Missouri Department of Health and Senior Services conducted exploratory research and observed a spatial correlation between EBLLs and demolition or abatement.

Tulane used findings from the Missouri exploratory research project to determine whether children exposed to demolitions would be more likely to have higher BLLs than non-exposed children. The study was conducted in 2002 in the city of St. Louis. The screening rate of children in St. Louis was ~40% at that time.

The study was designed as a retrospective cohort study. An environmental public health tracking approach was taken in which existing data sources were used to conduct health outcome research. A multi-variate regression analysis of BLLs and demolitions was developed and controlled for other known risk factors for EBLLs. The unit of analysis was at the individual level, but census block data were also used.

BLLs were used as outcome variables and demolitions were used to confirm exposure. A number of covariates were considered, such as age of child, gender, race and age of housing. The sampling frame was designed with Missouri CLPPP blood lead surveillance data collected in 2002 and St. Louis demolition permits issued in 2002. Additional data sources included tax assessor records and U.S. Census Bureau data.

Inclusion criteria were children 6 months to 6 years of age who were screened for lead in 2002 and lived on a census block where at least one demolition occurred. Only one blood lead test per child was allowed, but cases where children were exposed to multiple demolitions were recorded. Data had to be available on the age of housing when the child's lead test was conducted.

The "exposed" group was children who had a lead test within 45 days of the demolition, while the "unexposed" group was children who did not have a lead test at any time after the demolition. For purposes of the study, "demolition" was defined as the actual completion date. The period of time between issuing the permit and completing the demolition was 73 days on average. Demolitions of various types of housing were included in the study.

After integrating the Missouri CLPPP blood lead surveillance and St. Louis demolition permit data sets, 1,196 children were found to be eligible for the study representing 710 demolitions and 396 census blocks. Of the study population, 314 children were exposed and 882 were unexposed. The cohort was evenly distributed in terms of gender and had more African American children than any other racial group. The regression analysis excluded missing data on race. The cohort was slightly younger and had slightly higher BLLs compared to the Missouri CLPPP blood lead surveillance data set.

Several actions were taken to overcome limitations of the study. Census block data were used as a surrogate for unavailable data on direct measures of home lead exposure. Previous studies demonstrated that census block data are reasonable geographic variables in terms of relevancy of exposure to ambient or deposited lead. Children in the study were matched by neighborhood to address unavailable or limited data on condition of housing and neighborhood characteristics. Two additional limitations of the study were no collection of primary data and unavailable data on dispersion of lead particles after demolition.

Dr. Rabito summarized the results of the study. Exposure to one demolition was weakly associated with an increase in BLLs in an unadjusted model, but was not associated with an increase in BLLs in an adjusted model for age of child, gender, race and age of housing. Exposure to multiple demolitions was associated with an increase in BLLs in an unadjusted model and also in an adjusted model for age of child, gender, race and age of housing. The age of child, race and age of housing were significant predictors of an EBLL.

Multiple demolitions combined with other sources of exposures might increase BLLs in high-risk children. Race was unexpectedly a strong predictor in the study and indicated the occurrence of residual confounding. The data were mapped by race to analyze the spatial distribution. Age of housing and inner-city residence as surrogates to characterize risk were not found to be robust measures across racial groups. Dr. Rabito was pleased to announce that the city of St. Louis reviewed the study results and emphasized the need to improve future efforts in containing lead dust during multiple demolitions.

ACCLPP commended Dr. Rabito and her co-collaborators for conducting a solid study that resulted in new quantitative data on the potential relationship between demolitions and EBLLs in children.

Panel Presentation on Laboratory Measurement Issues

Dr. Rhoads explained that the panel presentation was placed on the agenda for ACCLPP to consider the feasibility of recommending more rigorous criteria for laboratories to measure BLLs. The current standard is ± 4 µg/dL. A series of presentations would be made to guide ACCLPP's discussion.

Overview. Dr. Patrick Parsons, Director of the Blood Lead Proficiency Testing Program at the New York State Department of Health, provided an overview of blood lead testing methods. Prior to 1970, the BLL of concern was 60 µg/dL, crude methods were used to measure BLLs, and detection limits were imprecise. The early methods required a significant amount of venous blood to perform analyses and served as an impediment to widespread screening.

A new technique was developed in 1971 that revolutionized blood lead methods. A smaller amount of blood was needed to perform analyses and capillary blood screening became feasible. The availability of analytic technologies resulted in the initiation of mass screening programs throughout the 1970s.

The BLL of concern was lowered to 25 µg/dL in 1985. Analytical laboratories were pressured to improve performance in detecting and measuring BLLs with more precise and accurate methods. Proficiency testing programs (PTPs) were established specifically for blood lead to promote improvement in laboratory performance and agreement among laboratories. Certified reference materials for BLLs became available to improve technology. The introduction of atomic mass spectrometry advanced the field of detecting low BLLs.

Several issues play a critical role in current methods to measure BLLs. Sensitive techniques that are presently used increase the difficulty of managing contamination. Point-of-care screening technology to measure BLLs has complicated blood lead methods. The number of laboratories that are certified to measure BLLs dramatically increased. For exarnple, New York State now has >74 certified laboratories compared to <10 in the 1970s. A study was conducted to monitor laboratory performance and showed variation in both laboratory performance and implementation of blood lead techniques in the United States.

All clinical laboratories in the United States are required to have federal CLIA certification to measure BLLs. All PTP providers must be CLIA-approved if the program is used for CLIA certification. Blood lead is one of the few analytes regulated by CLIA. Proficiency testing is defined and fixed in CLIA as the greater of $\pm$4 µg/dL or $\pm$10% of the target value. A determination has not been made to date on whether this parameter in CLIA is reasonable based on current technology. Federal certification is also required for occupational testing, but Occupational Safety and Health Administration (OSHA) regulations are less rigorous and outdated. OSHA requires laboratories and PTPs to score $\pm$6 µg/dL or $\pm$15% of the target value.

The New York State PTP requires all state laboratories that test clinical specimens originating from the state to have a state laboratory permit, successfully participate in the state PTP, and obtain a satisfactory onsite inspection every two years. New York State laboratories must follow the state's published standards for blood lead and trace elements. Of ~105 laboratories that participate in the New York State PTP, 10-12 are independent reference laboratories. U.S. laboratories can use the New York State PTP or three other CLIA-approved PTPs in Wisconsin, Pennsylvania and the College of American Pathologists.

Laboratories can also use PTPs outside of the United States, but these programs are not CLIA-approved. However, non-U.S. PTPs provide a basis of comparison for acceptable performance criteria between the United States and other countries. PTPs outside of the United States participate in a harmonization network and have proposed a feasible and

reasonable standard of ±3 µg/dL for European laboratories. A study that served as the basis for this standard was published in 2002.

For U.S. laboratories, CLIA requires three test events with five specimens each year. The fixed target value of ±4 µg/dL must be used with an upper value <40. For satisfactory performance, laboratories must score at least four of the five specimens correctly in each test event. Each test event is monitored over time. Laboratories must maintain satisfactory performance in at least two of three consecutive test events.

Laboratories that do not maintain satisfactory performance would be subject to sanctions or remediation. For example, the New York State PTP sends a letter instructing a laboratory with unsatisfactory performance to cease patient testing. The New York State PTP then collaborates with the laboratory to identify specific issues, resolve problems and improve performance.

A study was published in 1999 on methods to determine proficiency testing criteria. The study was based on a systematic hierarchal approach that considered both clinical and state-of-the-art analytical parameters. Performance goals established by regulatory bodies were also considered as factors in determining criteria. The study concluded that ±3 µg/dL should be established as proficiency testing criteria. Alternatively, the National Committee for Clinical Laboratory Standards recommended ±2 µg/dL or ±20% of the target value as proficiency testing criteria for a BLL of 10 µg/dL.

Before efforts are made to measure analytes with new methods, several terms should be clearly defined. "Accuracy" is closeness to the true value, a measurement of a bias and a systematic error. "Precision" is a random error or the spread of results in repeating the same test on the same sample. "Reproducibility" is agreement among laboratories that use the same methods.

Dr. Parsons raised several points for ACCLPP to consider during its discussion. The current consensus is that better laboratory performance is needed and each laboratory could improve its individual performance if the requirements were reasonable and the improvements were supported. A study that was published in 1992 on the performance of New York State laboratories supports the current consensus.

Test event data used in the study showed that 80%-90% of laboratories had satisfactory performance with proficiency testing criteria of ±6 µg/dL throughout the 1980s. The number of laboratories with satisfactory performance decreased with proficiency testing criteria of ±4 µg/dL in the early 1990s, but 95% of laboratories regained satisfactory performance over time. An analysis of New York State laboratories also supports the current consensus. The results showed that only 2 of 19 laboratories were unable to achieve satisfactory performance with proficiency testing criteria ranging from ±1 to ±4 µg/dL.

Dr. Parsons pointed out that potentially negative consequences and other issues should be considered in the decision-making process. For example, an immediate change in the standard from ±4 to ±2 µg/dL at this time might result in laboratories being unable to maintain certification or deciding to discontinue blood lead testing. Older lead care systems might be unable to meet new standards. Laboratorians would need to educate users in the limitations of various technologies to promote informed decision-making.

Dr. Parsons noted that a phased approach might be more preferable and feasible. For example, criteria of ±3 µg/dL could be recommended at this time because this standard is desirable, feasible and consistent with current European standards. The impact of the change could be evaluated in one or two years. If additional laboratory improvements were made, a standard of ±2 µg/dL could be considered at that time.

Federal Perspective. Dr. Robert Jones, of the CDC Division of Laboratory Sciences, provided a federal perspective on changing the current proficiency testing criteria. The limit of detection (LOD) is driven by statistics, while the limit of quantitization (LOQ) is driven by policy. The CDC laboratory considers the LOQ and LOD as equal, but other laboratories have different values for these parameters.

Differences in LODs among laboratories have several implications. A laboratory with an LOD of 2 µg/dL would be unable to distinguish between a BLL of 2 and 4 µg/dL with more than 95% confidence. Laboratories with an LOD of 1 µg/dL could only have a "best guess" of 0-2 µg/dL.

A proficiency test challenge with a low-level sample of 1 µg/dL would require a laboratory to have no bias and perform the test with absolute accuracy. Lowering the BLL of concern to <10 µg/dL would still result in a significant error rate. Blood lead acceptable limits are extremely critical from a surveillance perspective, but are less important from a clinical perspective. Errors in blood lead measures would result in flawed surveillance data.

CDC laboratory data and blood lead proficiency testing results from the Wisconsin PTP were collected from 2001-2006 to examine the observed value minus the target value. The CDC laboratory had very few failures at ±3 µg/dL with the LeadCare II handheld instrument and multiple failures at ±2 µg/dL. Graphite furnace atomic absorption spectrometry (GFAAS) resulted in minimal failures at ±3 µg/dL and multiple failures at ±2 µg/dL. Inductively coupled plasma (ICP) mass spectrometry resulted in no failures at ±3 µg/dL and minimal failures at ±2 µg/dL.

The CDC laboratory recently introduced a new lead and multi-metal performance (LAMP) testing program. Laboratories that used the LAMP technology had better performance at lower blood lead concentrations. Minimal failures were seen at ±3 µg/dL, while multiple failures were observed at ±2 µg/dL. Laboratories that used the LAMP technologies would have had a significant amount of failures at higher blood lead concentrations. Overall,

laboratories would have minimal failures if proficiency testing criteria were changed to ±3 µg/dL and significant failures at ±2 µg/dL with the range of currently available techniques.

Dr. Jones explained that analytical accuracy and precision are only two factors to consider in the decision-making process to change the current proficiency testing criteria. The entire PTP process should be examined. For example, laboratory performance and blood lead test results vary based on the expertise of the individual laboratorian.

Costs should also be considered. Most notably, the homogeneity of samples would need solid control and consistency. The target value of each proficiency testing sample would need to be improved with much more precision to reduce errors. Containers for samples would need to be acid washed to remove random lead. Samples would need to be transported frozen. The CDC laboratory conducted a bench quality control project with ICP mass spectrometry data from 2003-2006. Accurate, precise, clean and extreme measurements were used in the project, but this approach would be cost prohibitive for routine clinical diagnosis, screening and medical management.

Program Perspective. Dr. Noel Stanton, of the Wisconsin State Laboratory of Hygiene, provided a program perspective on changing the current proficiency testing criteria. Laboratories in the Wisconsin PTP include ~540 active participants, ~40 international laboratories, and ~20 laboratories that do not report on a regular basis. CLIA regulations require PTPs to formally evaluate proficiency specimens and pass or fail laboratories.

PTPs meet this requirement with ≥80% of selected referee laboratories reaching consensus on the target value of proficiency specimens or a peer group of laboratory participants reaching consensus on analytical methods. However, the PTP's results are considered acceptable if consensus is not reached on establishing the target value and the sample is not formally evaluated.

The Wisconsin PTP offers proficiency testing to its participants at no cost and provides services to laboratories that conduct pediatric childhood lead poisoning testing in states. The Wisconsin PTP is unique based on its implementation of monthly non-regulatory testing events. This approach was taken because frequent external quality control checks encourage laboratories to detect and correct analytical problems. The monthly testing events are in addition to the testing of three events with five specimens each year required by CLIA.

Target values for all analytical methods in the Wisconsin PTP are determined by 14 referee laboratories that consider all currently available techniques. However, samples taken with the LeadCare II device are graded separately with the mean score of all participants. The Wisconsin PTP was unable to identify a group of referee laboratories to grade LeadCare II results. These specimens are frozen prior to distribution to participants. Laboratories that use the LeadCare II device account for 60% of the Wisconsin PTP, but performance is poorer and the variability is greater than those using other methods.

An analysis was performed with data from 155 laboratories to identify potential impacts in the Wisconsin PTP if more stringent proficiency testing criteria were established. All current blood lead methods with the exception of the LeadCare II device were included in the analysis. Proficiency testing criteria ranging from ±1 to ±4 µg/dL were used. A dramatic decline in the performance of referee laboratories was not seen with the first sample until the standard was changed to ±1 µg/dL.

A separate analysis with the LeadCare II device and the current standard of ±4 µg/dL showed that laboratory performance declined fairly rapidly as blood lead concentrations increased. Three of five samples were formally evaluated with acceptability criteria of ±3 µg/dL, but only one of five samples were formally evaluated with acceptability criteria of ±2 µg/dL. Acceptable results for each sample were in the mid-70% range with acceptability criteria of ±1 µg/dL.

Overall, the analyses showed that performance in blood lead measurements with respect to proficiency testing acceptability criteria declined as concentrations increased regardless of the method used. The decrease was steeper for the LeadCare II device compared to other methods that were evaluated. Significant impacts with referee methods were only seen with acceptability criteria of ±1 µg/dL.

Another analysis was performed to determine laboratory performance on an event basis. The laboratories were divided into referee, LeadCare and combined groups. In the referee group, ~92% of laboratories had acceptable event scores with the current standard and 88% had acceptable event scores with a standard of ±3 µg/dL. Only 20 laboratories failed a specific event with a standard of ±1 µg/dL. However, a much steeper decrease would have been seen if the five specimens had a lower range than 10-55 µg/dL.

In the LeadCare group, ~84% of laboratories had acceptable event scores with the current standard. However, laboratory performance increased with lower acceptability criteria because fewer samples were evaluated. Improvement was also seen in the combined group of referee and LeadCare laboratories.

Dr. Stanton summarized key findings of the analyses. Performance would improve in laboratories that use the LeadCare II device as acceptability criteria are narrowed because consensus would not be needed to report samples to the Wisconsin PTP. Laboratories that use other methods could accept new criteria of ±1 or ±2 µg/dL without a significant increase in cost or additional burden.

Dr. Stanton agreed with Dr. Parsons' proposed phased approach of establishing a new standard of ±3 µg/dL at this time, evaluating laboratory performance, and further reducing the standard to ±2 µg/dL based on laboratory performance at that time. Acceptability criteria of ±1 µg/dL would significantly increase laboratory failures regardless of the method used. This impact would be more dramatic at lower blood lead concentrations.

Lead Care II Instrument. Dr. Jones provided an update on the new LeadCare portable blood lead analyzer. CDC released a request for contracts in 2001 to convert the moderately complex LeadCare instrument to a CLIA-waived device. In September 2006, the Food and Drug Administration (FDA) officially announced that the LeadCare II device met CLIA-waived acceptability criteria.

LeadCare II is easier to use, decreases the number of errors, and can produce results every 3.5 minutes. The key features of the device are as follows. The start button was eliminated and the electronics were enhanced. A calibration key is used to upload data. The panel was improved to provide more information. A capillary collection device is included and sensor-activated testing is available. The device is amenable to fingerstick sampling and requires 50 microliters of whole blood.

The advanced electro-design eliminates random contamination and stabilizes the temperature of blood. The testing system contains a new plastic device to transfer the blood reagent from the mixture to the actual electrode. A video on fingerstick blood collection is distributed with device. The cost of the device is $2,200, but the cost per test would vary based on the number of kits purchased at one time and the inclusion of quality control supplies.

The waived criteria for LeadCare II are as follows. The device must be automated and produce a minimal risk of erroneous results from the average user. Only fresh blood that was collected within 24 hours can be used. The blood must be maintained at ambient temperature. However, blood can be added to the reagent and the mixture can be maintained at ambient temperature for 48 hours. The mixture can also be refrigerated and analyzed within seven days. The LOD range for LeadCare II was established at 3.3-6.5 µg/dL. CDC measured an LOD of 1.4 µg/dL, while FDA measured an LOD of 3.3 µg/dL.

Dr. Jones summarized general findings from tests with LeadCare II because CDC could not publicly share manufacturer data at this time. LeadCare II was found to be compatible with GFAAS. CDC performed tests with Wisconsin PTP data to compare the original device and LeadCare II. Preliminary results showed fairly well comparability between the two instruments. Proficiency testing samples from actual laboratories did not show unusual outcomes or wide concentration ranges.

Dr. Jones noted several limitations in the preliminary data. LeadCare II has not been evaluated in actual practice to date. The number of data elements is insufficient to reach definitive conclusions at this time. An evaluation in primary care facilities with ~430 data elements to compare LeadCare II and GFAAS showed better results than CDC's preliminary data. CDC's data should not be used to make inferences on the bias of human blood samples with LeadCare II. Appropriate target values for the instrument have not yet been established.

Drs. Jones, Parsons and Stanton provided additional details on laboratory measurement issues in response to ACCLPP's specific questions and comments.

- LeadCare II is designed to be used as a rapid point-of-care screening tool with fresh blood. The device is extremely useful in capturing children who would not otherwise receive a blood lead test. However, LeadCare II has poor performance at higher BLLs and should not be used to make clinical judgments in proceeding with chelation therapy.
- Medicaid reimbursement to laboratories for blood lead testing widely varies among states, such as $16.72 in Wisconsin versus $22.50 in California. The cost to perform tests also differs among laboratories based on the specific technology used and the volume of samples.
- Wisconsin PTP data showed that laboratories are capable of obtaining sufficiently reliable results with filter paper sampling if valid samples are provided. However, training on appropriate collection techniques must be provided to ensure that laboratories are given valid samples.
- The New York State PTP is exploring the possibility of incorporating specific language in its standards to advise laboratories that LeadCare II should be used as a screening rather than a diagnostic tool.
- FDA and the LeadCare II manufacturer should explain the rationale of using the OSHA standard of $\pm$6 µg/dL rather than the CLIA standard of $\pm$4 µg/dL to assess accuracy because the device is CLIA-waived.
- LeadCare II might be useful in WIC clinics. These data could then be transmitted to surveillance programs.

Dr. Rhoads announced that time constraints and the loss of ACCLPP's quorum would not allow the voting members to make formal recommendations on a new proficiency testing standard. He proposed the following approach to advance this effort prior to the next meeting. A small workgroup could be formed to discuss the implications of more rigorous proficiency testing criteria and explore the possibility of ACCLPP making a formal recommendation on a new standard. Due to the current lack of data, the workgroup would not be charged with addressing the LeadCare II device.

The new workgroup could present its initial observations to ACCLPP during the next meeting. The voting members could make a decision at that time on whether ACCLPP should make a formal recommendation to the HHS Secretary on establishing more stringent proficiency testing criteria.

No ACCLPP members voiced opposition to Dr. Rhoads' proposed approach. As a result, Drs. Charlton, Rhoads and Snodgrass volunteered to serve on the new workgroup. Dr. Charlton would also engage experts from the Environmental Health Laboratory Branch of the California Department of Health Services in the workgroup's discussions. Dr. Brown announced that ACCLPP liaison and *ex-officio* members were also welcome to serve on the new workgroup.

Several comments were made for the new workgroup to consider in its discussions. Dr. Angeloni emphasized that the purpose and use of the LeadCare II device should be clearly explained to laboratories in specific geographic areas. On the one hand, the state of Rhode Island would not consider using this technology due to its extremely high screening rate and effective reporting system. On the other hand, the LeadCare II device might be more useful in states with low screening rates and difficulties in reaching certain communities.

Dr. Bolin noted that more emphasis should be placed on filter paper sampling as a screening approach. Although filter paper sampling is not as accurate as venous blood samples, this method has increased the number of children screened from ~2,000/year to ~15,000-18,000/year over the past five years. Filter paper sampling results have been well within tolerable acceptable limits when compared to and confirmed by venous blood samples.

Dr. Brown pointed out that LPPB is also concerned about losing data with the LeadCare II instrument. As a result, LPPB is collaborating with the manufacturer to develop a transparent data collection tool that clinicians would use. The manufacturer intends to make available the names of LeadCare II distributors and individual purchasers when possible. A spreadsheet is provided with the device free of charge.

Dr. Brown also stated LPPB's position on LeadCare II for the record. The device is not robust enough to diagnose children or make determinations on lead inspections or chelation of individual children. Even if venous blood samples were included in LeadCare II, a more scientifically robust analytic method would be needed before crucial decisions could be made about individual children.

New ACCLPP Business

For the first business item, Dr. Rhoads pointed out that three documents were distributed to ACCLPP for review: (1) the APHA LPS; (2) ACCLPP's original draft letter to APHA; (3) and a new draft letter to the editor of the APHA journal. Dr. Rhoads highlighted key points in the new letter. APHA published the LPS and ACCLPP is interested in responding to certain points in the document. ACCLPP's rationale for not lowering the BLL of concern from 10 µg/dL at this time is explained. Dr. Rhoads noted that both the original letter to the APHA Executive Director and the new letter to the editor of the APHA journal could be sent.

Several ACCLPP members made comments on the three documents. First, ACCLPP's actions and focus on several of the recommendations in the LPS should be more strongly emphasized in the new draft letter to the editor of the APHA journal. Second, ACCLPP should either submit a letter to the editor of the APHA journal or an official ACCLPP

Closing Session

Dr. Rhoads thanked the LPPB staff for making logistical arrangements to support the meeting. The next ACCLPP meeting would be held on March 14-15, 2007 in Atlanta, Georgia.

With no further discussion or business brought before ACCLPP, Dr. Rhoads adjourned the meeting at 1:07 p.m. on October 18, 2006.

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

1/17/07
Date

George G. Rhoads, M.D., M.P.H.
ACCLPP Chair