DEPARTMENT OF HEALTH AND HUMAN SERVICES

and

CENTERS FOR DISEASE CONTROL AND PREVENTION

convene the

ADVISORY COMMITTEE ON
CHILDHOOD LEAD POISONING PREVENTION

Baltimore, Maryland
March 9-10, 2004

DRAFT RECORD OF THE PROCEEDINGS

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Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The proceedings were held on March 9-10, 2004 at the Admiral Fell Inn in Baltimore, Maryland.

Opening Session

Dr. Carla Campbell, the ACCLPP Chair, called the meeting to order at 8:47 a.m. on March 9, 2004. She welcomed the attendees to the proceedings and opened the floor for introductions. The following individuals were present for the deliberations.

ACCLPP Members
Dr. Carla Campbell, Chair
Dr. William Banner, Jr.
Dr. Helen Binns
Dr. Walter Handy, Jr.
Dr. Ing Kang Ho
Dr. Richard Hoffman
Dr. Jessica Leighton
Dr. Tracey Lynn
Dr. Sergio Piomelli
Dr. Kevin Stephens, Sr.

Designated Federal Official
Dr. Mary Jean Brown,
Executive Secretary

***Ex-Officio*/Liaison Members**
Mr. Byron Bailey (HRSA)
Dr. Michael Bolger (FDA)
Ms. Anne Guthrie (AHH)
Dr. Kristina Hatlelid (CPSC)
Dr. Ezatollah Keyvan-Larijani (CSTE)
Dr. David Jacobs (HUD)
Ms. Patricia McLaine (NCHH)
Ms. Jacqueline Mosby (EPA)
Dr. George Rodgers, Jr. (AAPC)
Dr. Walter Rogan (NIH)
Mr. Robert Roscoe (NIOSH)
Dr. Jan Towers (AANP)

CDC Representatives

Dr. Henry Falk, NCEH/ATSDR Director
Ms. Bonnie Dyck
Ms. Crystal Gresham
Ms. Janet Henry
Mr. Rob Henry
Dr. David Homa
Mr. Penn Jacobs
Mr. Jeff Jarrett
Dr. Thomas Matte
Mr. James Rabb
Dr. Nimia Reyes
Ms. Barbara Rogers

Presenters and Guests

Dr. Victoria Binetti (EPA)
Dr. Craig Boreiko (International Lead Zinc Research Organization, Inc.)
Ms. Barbara Conrad (Maryland DOH)
Ms. Anne Evens (Chicago DOPH)
Dr. Howard Hu (Harvard School of Public Health)
Jane Luxton, Esq. (King & Spalding)
Reuben Koclyk, Esq. (Arnold & Porter)
Mr. Russell Riggs (National Association of Realtors)
Dr. Michael Shannon (Harvard Medical School) [via conference call]
Timothy Sparapani, Esq. (Dickstein, Shapiro, Morin & Oshinsky)

The attendees joined Dr. Campbell in recognizing and applauding the valuable contributions of three members whose terms will expire in May 2004: Drs. Helen Binns, Richard Hoffman and Sergio Piomelli. The outgoing members will receive a plaque and thank-you letter in appreciation of their service on ACCLPP. Dr. Piomelli noted that the ACCLPP charter states members are appointed for four years, but the three outgoing members have only served 18 months. He was insulted and would have refused the appointment if he had prior knowledge that the term would be shorter than four years. Dr. Piomelli plans to write a letter to the HHS Secretary asking for an extension of his appointment and will resign if the request is not granted. Dr. Campbell explained that due to a freeze on appointing new members, a lapse occurred between ACCLPP positions being vacated and new appointments being made. The lapse resulted in some members being appointed for shorter terms. She advised Dr. Piomelli to express his concerns to the HHS Secretary.

Dr. Mary Jean Brown, the Lead Poisoning Prevention Branch (LPPB) Chief and ACCLPP Executive Secretary, asked that the record reflect LPPB's appreciation of the time, attention, dedication and expertise the three outgoing members have contributed. She reminded the members of their responsibility to recuse themselves from discussions that present an actual or perceived conflict of interest.

Update on LPPB Activities

Dr. Brown provided a status report on projects LPPB initiated or completed since the previous ACCLPP meeting. One, a Window Symposium was convened in November

2003 with a multi-disciplinary panel of ~40 experts to discuss the cost, energy and housing benefits, and health effects related to window replacement. The symposium also focused on the need to quantify energy savings for public health departments and to estimate and demonstrate property values. Participants were from the health, energy, construction, rental property and public housing fields and represented the decision analysis, economics, public health, clinical medicine and policy development disciplines. The participants were asked to specifically focus on the following questions during the deliberations.

- What outcomes should be included in a cost-benefit analysis of window replacement in existing single and multi-family dwellings, such as energy savings and lead hazard reduction?
- What are reasonable estimates and ranges of costs that could be used in a decision analysis?
- What essential research should be conducted to capture the relationship between window replacement and each outcome, such as decreased asthma, lower blood lead levels (BLLs), lead poisoning prevention and energy efficiency?
- What are the barriers and incentives to participation for property owners and managers who are interested in participating in a window replacement program?
- What new legislative initiatives or modifications to existing legislation are needed to support this activity?
- What public monies or other funding could be mobilized for window replacement, particularly in distressed or subsidized housing?
- What types of work practices could be recommended?

The symposium participants raised several important points during the discussion. Window replacement can prevent or reduce a child's BLL and also plays a role in asthma. Leaky, poorly maintained or improperly installed windows can cause moisture and may lead to mold-related asthma triggers. Windows serve as high-risk surfaces for childhood lead poisoning because window sills and a young child's mouth are approximately at the same level and window troughs are highly leaded. Substantial evidence has been collected demonstrating that window replacement successfully reduces lead contamination.

For example, an evaluation of the U.S. Department of Housing and Urban Development (HUD) Lead Hazard Control Grant Program was published in 1999 and showed that dust lead levels (DLLs) on window sills and troughs significantly declined after replacement. Follow-up of the same houses until the present showed that the decrease in DLLs was persistent over time. No evidence has been collected demonstrating that DLLs in window sills or troughs substantially increased since window replacement.

However, the impact of window replacement on BLLs and other health conditions is less clear and more difficult to capture, particularly the relationship among moisture, mold and asthma. Mold acts as a trigger for persons with asthma, but the role of exposure to mold in causing asthma in children is uncertain.

The symposium participants reached the following conclusions. Targeted window replacement in low-income homes that makes housing more energy-efficient and affordable is worthy of government support and incentives. Successful strategies include using tax incentives, blending existing federal funding, involving manufacturers and retailers in educational activities, and engaging the insurance industry. Window replacement can satisfy historic preservation concerns if these issues are identified early in the process. To advance this activity, LPPB and the National Center for Healthy Housing will jointly develop a white paper to describe the Window Symposium outcomes and outline responses of the expert panel to the questions. The white paper will serve as a reference document for health department and housing personnel who have an interest in pursuing window replacement.

LPPB will create an easy-to-read and short companion document to the white paper and will also develop a decision tool to assist contractors and others in determining whether window replacement is cost-efficient for a particular home. LPPB will design activities to address barriers that were identified by the participants. In particular, the U.S. weatherization program is well accepted by property owners of low-income units and other types of housing. However, consideration should be given to justifying the benefits of window replacement in an effort to raise the $2,500 cap per unit for weatherization activities. LPPB was pleased to convene a successful forum that allowed multi-disciplinary experts and representatives of disparate communities collectively address housing and health issues.

Two, CDC and HUD will jointly issue a letter to health and housing departments to confirm the authority of these agencies to share addresses where lead-poisoned children currently live or addresses where a series of lead-poisoned children lived in the past. The letter will contain the following language. The Privacy Rule authorizes local entities to release the information because CDC, HUD and the U.S. Environmental Protection Agency (EPA) are authorized by statute to conduct lead poisoning prevention activities. Release of the information is consistent with the missions and capabilities of the agencies and addresses the public health problem of lead poisoning. Programs may disclose to the Office of Healthy Housing and Lead Hazard Control, without parental authorization, the addresses of housing units that have a history of lead-based paint hazards or children with elevated BLLs (EBLLs). HUD will use the data to determine whether these properties are in compliance with the federal Lead Disclosure Rule.

EPA, HUD, the Department of Justice and local health programs have completed 34 enforcement settlements related to the failure of property owners to adhere to the disclosure rule. In these cases, large property owners did not inform tenants of potential lead-based paint hazards. To date, $561,000 in penalties has been collected and commitments were given to test and abate lead-based hazards in >166,000 high-risk rental units. An additional $421,750 has been made available to fund a series of projects, such as the purchase of portable blood lead testing devices, provision of lead hazard abatement training, and implementation of outreach programs.

Three, LPPB's recent research and surveillance activities include the publication of several articles in the *Morbidity and Mortality Weekly Report* (*MMWR*). Ayurveda is a traditional system of medicine primarily practiced in India and South Asian countries; minerals, herbs, animal products or any combination of the three are used. LPPB's *MMWR* article on this issue focused on lead poisoning in adults associated with the use of ayurvedic medications. A case was reported from New Hampshire with a BLL of 81 µg/dL. An analysis of the patient's medications showed lead contents of 12,000 and 17,000 ppm. In addition to New Hampshire, the investigation led to the identification of 12 other ayurveda cases with exceptionally high BLLs in California, Massachusetts, New York and Texas. LPPB was particularly concerned because some of the highly leaded medications were being used to treat infertility in women. An ayurveda health alert will be released in the next two months.

A lead screening study was conducted among prenatal patients in two low-income clinics in Monterey County, California along the U.S./Mexico Border. Of 214 women tested, all with EBLLs were seen in one clinic, 27 had BLLs >10 µg/dL and 8 had BLLs >20 µg/dL. The women represented 13% of the prenatal population screened at the clinic and most were from Oaxaca, Mexico. Dried grasshoppers or "chapulines" with lead levels of 47,000 ppm were among the potential foods identified as sources of the EBLLs.

Four, LPPB is using geographic information systems (GIS) technology for program planning and evaluation of a study in Cleveland. The project will combine tax assessor, blood lead screening and Medicaid data to identify under-served areas of the city. The goal of the study is to present data in a meaningful, useful, simple and quick format to best serve the needs of pediatric healthcare providers. LPPB is preparing a manual to describe common data errors that prevent geocoding as well as techniques to avoid these errors. LPPB will also post GIS 2000 census data on its web site to allow childhood lead poisoning prevention programs (CLPPPs) to quickly collect census data on old housing, poverty, rental property and other issues.

LPPB used GIS to detect an unexpected number of EBLLs around the Charleston, South Carolina Naval Yard. This area did not have a large amount of old housing and

would not have been routinely tested, but lead paint dust was distributed in local neighborhoods from shipyard work and by workers who brought paint home for residential use. LPPB is using GIS in conjunction with the Washington, DC health department to evaluate the impact of recent changes in water chemistry on BLLs of resident children.

Five, LPPB and CDC's other communicable disease programs are adopting the National Electronic Disease Surveillance System (NEDSS). State health departments will use the electronic and laboratory-based reporting system to obtain data on STDs, tuberculosis, bacterial meningitis and other diseases from laboratories and forward the information to CDC. NEDSS will also maintain addresses, patient demographics and disease types. Release 1 of NEDSS is expected to be issued by the end of 2004, but lead will not be included in this version. However, Nebraska and South Carolina are currently deploying NEDSS to transmit data to CDC on vaccine preventable conditions, hepatitis and other diseases. To date, 29 other states have also expressed an interest in implementing NEDSS by the end of 2004. NEDSS will provide LPPB with a wealth of information and capacity to identify risk factors at geographic and population levels.

Six, LPPB is in the process of developing a lead program area module (PAM) that will be the first environmental health condition included in the NEDSS-based system. LPPB completed the prioritization of PAM features by convening meetings to obtain input from state and local partners that use other computerized database systems to manage cases. Joint application development sessions were also held with state and local program staff to discuss development of the lead PAM and usefulness of the system at state and local levels. Over the next 18 months, LPPB expects to migrate data from the Systematic Tracking of Elevated Lead Levels and Remediation system into the lead PAM.

Seven, LPPB is currently focusing on several electronic laboratory reporting issues. Most notably, efforts are being made for health departments to agree on using HL7 and other conventional techniques in submitting data to NEDSS. The overarching goal of these activities is to develop a rapid, common and less labor-intensive electronic laboratory reporting system.

Eight, LPPB is designing health education initiatives due to survey results that show 17 of 37 funded states have no laws to enforce remediation of homes with children who have EBLLs. LPPB is partnering with the Alliance for Healthy Homes (AHH) and the National Conference of State Legislators to compile health education information for state legislators. The materials will contain specific data for each state, including the total number and percentage of pre-1950 housing units; the total number of children <72 months of age and those in poverty; the total number of children tested in 2001 and those with confirmed BLLs $\geq$10 µg/dL; requirements for dust clearance testing; the

proportion of lead paint abatement completed or ordered by the health department; and the existence of a local or state ordinance requiring home inspection and repair of lead hazards in the home of a child with an EBLL. LPPB acknowledges the importance of health education projects because capacity to enforce remediation in states with a significant amount of high-risk housing and large populations of lead-poisoned children will be critical in reaching *Healthy People 2010* goals.

Nine, LPPB is engaging in efforts to improve its vocabulary because "EBLLs," "undue lead absorption," "lead poisoned" and similar terms may not be understood by parents and other care givers of children with EBLLs. LPPB will convene a series of focus groups to improve and obtain reactions to the current lead poisoning terminology. Input from the focus groups will be used as a basis in developing a new lead vocabulary that will be meaningful to LPPB's target audience. One white, one Hispanic and two black focus groups with non-college educated mothers or female care givers of children <6 years of age who have an annual income <$35,000 will be conducted by telephone. Each of the U.S. regions in urban areas will be represented.

Ten, LPPB will release a videotape in May 2004 in an effort to improve blood lead sampling techniques. The videotape will illustrate errors that can cause contamination of capillary blood lead samples and preventive measures.

Eleven, LPPB taught a five-day classroom course and convened a five-day activity in the field to engage individuals in program evaluation. Harvard School of Public Health students collaborated with LPPB project officers to learn more about program evaluation, review the public health process, obtain practical skills and include this experience on resumes. The project officers and students conducted several field activities throughout the country.

In Alabama, case management was evaluated to determine the extent to which protocols are followed and whether case management contributes to decreased BLLs in referred children. In California, education of public health nurses who are not currently involved in lead was assessed to determine if nurses have time to inform families about lead poisoning prevention during home visits and whether changes in practice decreased lead exposure in high-risk families. Other program evaluations included a screening and outreach program by a community-based organization (CBO) in Connecticut; new abatement referral procedures in Detroit; case management in Indiana; an evaluation template for media campaigns in New York City; a housing-oriented primary prevention project in North Carolina; and the "Lead-Safe Baby Program" in Philadelphia. Over the next six to eight months, project officers will begin implementing project evaluations the students wrote in methodology papers. The course was extremely beneficial to project officers, students and lead programs.

Dr. Hoffman inquired about the role of LPPB's GIS projects in improving screening of all Medicaid children. He also asked whether NEDSS will present confidentiality problems since the system will reveal the specific address of a child with lead poisoning, tuberculosis or another condition. Dr. Brown replied that LPPB will use GIS in the Cleveland study to pinpoint specific locations in communities where Medicaid children have or have not been screened. The initiative will be designed to result in active outreach. To the second question, she clarified that NEDSS will not raise confidentiality issues because state health departments are required to report these diseases. Data will be submitted to CDC through NEDSS with no identifiers.

Update on the Strategic Planning Process by State and Local CLPPPs

Mr. Rob Henry, the Program Services Section Team Leader, reported that LPPB funded 42 CLPPPS in 37 states and five cities in FY'03 as a step in reaching the *Healthy People 2010* goal of eliminating childhood lead poisoning. LPPB also convened workgroups with internal staff and federal, state and local partners to discuss strategies to ensure success in this area. In response to this input, LPPB changed several program requirements in the cooperative agreement for state and local programs. Funding is now targeted to areas in the country with populations at highest risk. The five state CLPPPs with the highest number of children at risk for EBLLs were previously asked to address primary prevention, but all CLPPPs are now required to focus on this issue. LPPB and CLPPPs will strengthen collaboration to support protective policies in 17 states that have no laws to protect children with EBLLs.

The most significant change in the cooperative agreement is the requirement for CLPPPs to develop lead poisoning elimination plans. In general, CLPPPs will be expected to strengthen capacity in identifying and reaching vulnerable populations; target resources to high-risk children even in states with universal screening; place heavy emphasis on Medicaid matching; develop strategies to link BLL data to information on children who are at high risk for other conditions; design primary prevention activities; and establish policies to address and protect children.

In particular, LPPB established several guiding principles to assist CLPPPs in creating the plans. "Elimination" should be defined at the state level due to differences in populations and problems by neighborhood, city, jurisdiction and other geographic areas of the state. Participation by leadership in strategic planning activities should be demonstrated and a wide range of stakeholders should be engaged as well, including EPA, HUD, public health departments, Medicaid and environmental regulatory agencies. Data should be compiled to clearly describe the problem. Existing policies or enforcement actions that currently protect children and assist in lead poisoning prevention should be thoroughly reviewed.

Resources for strategic plans should be identified and matched to a work plan with measurable goals and objectives. A strong evaluation component that can be revised and improved over time should be incorporated into strategic plans. In terms of the time-line, CLPPPs are required to submit non-competing continuation applications and draft elimination plans to CDC on March 19, 2004; final elimination plans are due on June 30, 2004. LPPB will use the April 2004 CDC Partners Conference as an opportunity to provide technical assistance to CLPPPs in finalizing the elimination plans. Implementation and evaluation of the plans will continue throughout 2005 and the program announcement will be re-competed in 2006.

Throughout the strategic planning process, LPPB will remain actively involved with CLPPPs; ensure that project officers are regularly informed; and provide technical and scientific assistance through site visits, conference calls, training, conferences, meetings, special projects and evaluation. These activities will identify staff who can assist CLPPPs in resolving problems and will also help CLPPPs to improve surveillance activities and develop work plan goals and objectives. LPPB has released a request for proposals to redesign its national lead training center to be more dynamic, thorough and specialized. The project will provide general and focused training to CLPPP personnel with special skills, including case managers, new program managers and epidemiologists.

Dr. Keyvan-Larijani suggested that LPPB consider a different approach in the strategic elimination plans. For example, resources could be initially allocated to high-risk jurisdictions only to provide an opportunity for these CLPPPs to reach the same BLLs as other areas in the state. All CLPPPs in the state could then collectively take actions toward achieving elimination. Dr. Brown expressed concern with this suggestion because lead poisoning elimination requires considerable infrastructure and support. If resources are only targeted to high-risk areas, infrastructures would most likely need to be reestablished in low-prevalence jurisdictions in the future.

Dr. Hoffman inquired about the ability of the 13 non-funded states to successfully compete in the 2006 program announcement with grantees that have maintained stronger infrastructures and developed elimination plans. Mr. Henry confirmed that LPPB is currently considering strategies to closely collaborate with non-funded states, particularly those that have not been funded in recent history and for which there are no data available to describe childhood lead poisoning problems. LPPB has also discussed the possibility of developing a passive surveillance system for those states that have low prevalence. Dr. Stephens conveyed that a progressive approach may be more practical in which cities, states and counties would first reduce BLLs and then focus on elimination. He also raised the possibility of LPPB creating and distributing a legislator handbook that describes relevant laws and policies for lead poisoning

elimination. To assist in this effort, ACCLPP could identify and suggest laws for each state.

Mr. Henry reported that LPPB is currently collaborating with AHH to collect examples of primary prevention activities from CLPPPs and publish these models in a manual. The section of the manual that will be devoted to policy and enforcement could perhaps be designed as a stand-alone document for legislators. Dr. Campbell added that a wealth of information currently exists for state legislators to access, such as model laws on the National Conference of State Legislators web site.

Dr. Rogan noted that LPPB's activities actually target the "frequency" of EBLLs among screened children rather than "prevalence" of EBLLs. He also pointed out that some of the strategic activities LPPB will evaluate do not have supporting research. He asked if any of the initiatives can be designed to produce information that can be generalized to other settings. Dr. Brown clarified that some of LPPB's activities are research projects, while others are program evaluation projects. For example, some of LPPB's evaluation projects are randomized control trials, while the Chicago High Intensity Targeted Screening (HITS) program was intended to obtain prevalence data on EBLLs using a clustered stratified sample. LPPB and EPA have been discussing the feasibility of conducting a similar project in Mississippi. However, Dr. Brown did not see the purpose of attempting to obtain prevalence rates from Massachusetts and other well-established lead programs.

Dr. Binns suggested other information for LPPB to include in the state legislator report cards, such as whether the lead program is a CDC grantee, the number of years of funding received, and contact information for the state environmental leader. She also advised LPPB to begin outreaching to and partnering with unfunded states by conducting small studies on prevalence rates of EBLLs, housing descriptions and similar issues. Dr. Brown noted on the one hand, LPPB has a strong interest in analyzing a surveillance system in a state that has either achieved elimination or low prevalence. On the other hand, LPPB has received level funding for the past eight years and will not cut program services to conduct these types of special projects.

Dr. Lynn urged LPPB to carefully consider the presentation of information and tone of messages that will be conveyed in the state legislator report cards. Similar to federal agencies, states also have considerable budget constraints and may not view lead issues as a priority compared to other competing activities. Moreover, many states may be reluctant to accept guidance from federal agencies. Dr. Brown confirmed that LPPB will consider these important comments and structure the report cards to illustrate the resource intensity of taking different approaches. Dr. Hoffman announced that health institutes are privately funded organizations for legislators to access health data in one location. The health institutes provide legislators with vital statistics, surveillance data,

Medicaid costs and similar information. He encouraged LPPB to collaborate with these groups in disseminating the state legislator report cards.

High Intensity Screening in Chicago's Strategic Elimination Plan

Ms. Anne Evens, the Chicago Department of Public Health Lead Poisoning Prevention Program Director, described methods to assess BLLs and screening of high-risk children in Chicago. Based on 2001 data, Chicago had 308,415 children ≤6 years of age. Of those, 28% of children 1 year of age and 51% of children 2 years of age had received a BLL test; 12% of those tested had BLLs >10 µg/dL; and 45% of children born in Chicago each year are enrolled in Medicaid. Chicago has 660,000 pre-1950 housing units and 88,000 housing units that are hazardous to children. One in three children tested has an EBLL in some Chicago neighborhoods. However, childhood lead poisoning has been eliminated as a public health problem in 14 of 77 jurisdictions in Chicago.

The Chicago CLPPP is a multifaceted program with 72 staff who focus on surveillance, blood lead screening, medical case management, environmental inspections and enforcement, and the HUD abatement grant. The Chicago CLPPP incorporated four major strategies in its elimination plan. Additional funding is leveraged for abatements related to window replacement in a lead-safe manner, paint stabilization and other lead hazard interventions. Efforts are currently underway to enforce laws at federal, state and local levels to increase the interest of property owners in making properties lead safe and to provide financial incentives. Projects are designed to increase identification of young children with EBLLs and improve screening, particularly in high-risk neighborhoods. An evaluation component is incorporated into the plan to measure progress toward elimination.

The Chicago CLPPP implemented the first HITS in 2001 to determine the prevalence of children <6 years with EBLLs and to evaluate screening efforts. The activity was later expanded to collaborate with the immunization program and CBOs to assess other health indicators, to increase awareness of EBLLs in communities, and to improve screening of children enrolled in Medicaid. HITS has been conducted three times in six communities. These communities account for nearly 33% of BLLs >20 µg/dL in the city according to city surveillance data. The fourth HITS will be launched on April 3, 2004. The effectiveness of screening widely varies by neighborhood in Chicago.
Surveillance data shows a range of children < 6 years screened as low as 26% to a high of 47% in high-risk communities.

The HITS components include development of a protocol, review by an Institutional Review Board, staff training, blood lead testing, measles and rubella titers, informed

consent, health data surveys, cleaning and hepa vacuum training, medical case management, home inspections, abatement, data analysis, evaluation, and recommendations for CLPPP screening initiatives. On the one hand, HITS validated prevalence estimates; gathered baseline data for sentinel surveillance of high-risk neighborhoods; identified 27% of children with BLLs >10 µg/dL who would have been missed by routine screening efforts; resulted in new and improved screening efforts; played a role in enrolling children into primary care and increasing measles and rubella immunization rates to 85%-90%; raised community awareness of EBLLs; strengthened knowledge of other health indicators; and served as an activity that was accepted by community groups and residents. The most significant outcome from HITS activities has been that 61% of children tested in these high-risk neighborhoods had not been previously screened. Of those, 70% were enrolled in Medicaid.

On the other hand, HITS is complex to manage, requires challenging work hours, and raises safety and security concerns. Moreover, the ability to generalize HITS to other settings is questionable. HITS is also costly and will be impractical for a citywide project. On average, $300 was required to screen each child, $320,840 was needed to implement the first three HITS, and $52 per child was allocated for fixed outreach. These costs were found to be much higher than those in pediatric offices or public clinics.

After gathering HITS data, the Chicago CLPPP focused on reasons why 61% of children tested had not been previously screened for blood lead. The analysis showed that children were not presenting for well child visits and physicians were failing to screen during well child visits. The Chicago CLPPP's review of Medicaid billing records showed that 25%-33% of children <6 years of age had not had a well child visit in the previous 12 months. Since adherence to well child visits was found to be better among children 0-12 months of age, the Chicago CLPPP is partnering with the immunization program to increase well child visits among children 13-24 months of age.

The Chicago CLPPP also collaborated with the immunization program to audit >20,000 physician charts of lead screening and immunization rates in >300 clinical settings. Citywide results showed that 67% of providers in high-risk neighborhoods in Chicago are testing children according to the guidelines. However, physicians still cited several barriers to testing, including insufficient staff to draw blood on site, the cost to parents for off-site testing, the lack of free blood lead testing throughout the state, problems associated with drawing blood from young children, and insufficient time to test during well child visits. Surprisingly, providers did not perceive "lead poisoning is no longer a problem" as a barrier to testing.

Overall, HITS was found to be an effective educational tool because most providers have no lead poisoning data on their patients. As a result, the Chicago CLPPP

implemented several activities that have resulted in improved screening rates. Recommendations are made and follow-up assessments are conducted for providers with the lowest screening rates. Healthcare providers are educated through conferences, data mailings and web-based classes with continuing medical education credits. Pediatric and family planning medical residents are invited to participate in the Chicago CLPPP for one day and conduct a site visit with an inspector.

Charts of blood lead testing, immunization rates and well child care visits will continue to be reviewed in providers' offices. Feedback and recommendations for improvement will be given based on these assessments. Educational activities will be specifically targeted to certified nursing assistants and medical technicians as well. The Chicago CLPPP also designed initiatives for parents to increase well child visits, including educational materials distributed through birth certificate inserts, mailings and community meetings; targeted outreach to untested children 13-24 months of age enrolled in Medicaid; free blood lead testing at Women, Infant and Children sites, day care centers and churches; and incentives for testing in certain settings.

Dr. Hoffman remarked that due to seasonality, April 3, 2004 may not be the best date to launch the fourth HITS. Children with EBLLs may not be identified at this time of the year and the overall EBLL rate may be affected. He noted that June-August are the optimal months to obtain EBLLs because windows are more likely to be open and children participate in more outdoor activities during this time of year. Dr. Hoffman also raised the possibility of the Chicago CLPPP using the second dose of measles, mumps, rubella immunization to measure adherence to well child visits since older children receive this dose.

Ms. Evens conveyed that the Chicago CLPPP selected April for the fourth HITS since children will be home for spring break. Based on the earlier HITS, late summer and early fall were not found to be optimal times due to a high refusal rate. Many children are tested during these seasons and most parents are reluctant to have their children undergo another blood draw. However, the Chicago CLPPP will be mindful of seasonality. Dr. Piomelli explained that blood drawn from a finger stick and placed onto filter paper is a successful method to test children and can be used by providers. This technique may address the issue of insufficient staff to draw blood onsite. He emphasized the need for CDC to educate providers in using this procedure. Dr. Piomelli also underscored the importance of the members collectively reviewing and commenting on the HITS results because the study is pertinent, relevant and germane to ACCLPP’s function. Dr. Campbell confirmed that ACCLPP will discuss outstanding issues related to HITS during the “unfinished business” agenda item on the following day.

Lead in Drinking Water

Dr. Victoria Binetta of EPA described recent events related to water quality in the District of Columbia (DC). The Corps of Engineers owns and operates the Washington Aqueduct and uses the treatment plant to draw and treat water from the Potomac River and distribute treated water to ~1 million DC and northern Virginia residents through the Water and Sewer Authority (WASA). EPA regulates drinking water quality under the Safe Drinking Water Act and also manages lead in drinking water under the Lead and Copper Rule. The maximum contaminant level (MCL) is the maximum allowable concentration of a contaminant in treated water. However, MCLs and MCL goals frequently differ because MCLs are determined on the basis of feasibility and cost of treatment, while MCL goals are established by health-based levels. EPA's MCL for lead was 50 ppb in 1975, but the MCL goal has been revised since that time.

Lead in water is generally caused by plumbing systems in buildings, but is rarely a problem in the water source or treated water. As a result, EPA regulates water quality for lead differently than for other contaminants. Most notably, action levels rather than MCLs have been established for lead and treatment technology is used to regulate lead. Water suppliers must adjust water chemistry to make water as non-corrosive as possible and ensure that lead is not leached from lead pipes or other lead fixtures. Despite the differences for lead, water suppliers must still achieve the objectives of other water quality regulations. Utility companies must monitor water from taps that is distributed in individual homes to ensure corrosion is controlled and lead in residential faucets is minimized. For purposes of monitoring, a pool of homes are selected to represent "worst-case" scenarios. If lead-bearing or lead service lines connect a house to a water main within a city, 50% of the sample must be homes with lead service lines. Sample homes are also selected based on vintage, such as construction during a time when lead sodder was more commonly used.

In monitoring homes, water suppliers are expected to achieve a regulatory threshold and must not exceed the action level for lead of 15 ppb. For example, 90% of homes in the sample may have lead levels of $\leq$15 ppb, but no more than 10% can have lead levels of >15 ppb. Utility companies have different monitoring schedules based on the size of the water system; however, monitoring is primarily conducted by homeowners who obtain and bottle water samples for pick-up and analysis by the utility company. WASA offered a $25 incentive for homeowners to provide samples, but many individuals volunteered to participate.

Based on early sampling results, the worst-case homes showed a mean level of 37 ppb and triggered the development of a corrosion control plan. Extensive studies were also conducted to determine optimal corrosion control strategies for DC, such as controlling PH and alkaline levels or adding a corrosion inhibitor. EPA conditionally approved DC's

corrosion control plan, but sampling results from the worst-case homes in June 2002 showed a dramatic increase in lead levels from 8-75 ppb. The cause for the change in water chemistry is still unknown at this point.

DC took several actions to comply with EPA regulatory requirements after the action level of 15 ppb was exceeded. Corrosion control treatment was reviewed and optimized and tap water monitoring was intensified. Brochures, public service announcements and targeted outreach initiatives to pregnant women, children and other high-risk populations were used to educate customers about lead health effects, the occurrence of lead in drinking water and actions to reduce lead exposure. Removal of lines that connect water mains to homes was initiated since the utility company had lead service lines and already optimized corrosion control. To date, <7% of 23,000 lead service lines have been replaced in DC, but utility companies are not required to replace pipes if water samples contain <15 ppb of lead. The monitoring schedule was increased from sampling 50 worst-case homes per year to 100 every six months.

Of every six single-family residences in DC, ~1 is served by a lead service line. WASA began taking one-liter water samples from lead service lines to identify those of highest priority in which lead leached from immediate plumbing fixtures nearest to faucets. WASA saw very high lead levels and an extraordinary amount of leaching based on 2003 sampling results from water in lead service lines. From March-September 2003, WASA tested 4,613 lead service lines and determined that only 27% of samples were below the action level of 15 ppb, while 18% were >100 ppb. The previous educational campaigns and other public outreach activities were not effective because the seriousness of the problem was not known at that time and had not been conveyed. Moreover, press coverage heightened public awareness.

Follow-up actions were taken in response to the more recent information on changes in water chemistry. DC, EPA, WASA and the Washington Aqueduct reached consensus on issuing new guidance. Consumers were generally advised to flush taps for 60 seconds after an inactive period, draw cold water for drinking and cooking, and clean faucet strainers once per month. WASA surveyed historical housing records to identify lead service lines, but admits a 10% level of uncertainty in detecting all lines. Consumers who may have lead service lines were specifically advised to flush taps for ten minutes after significant water use before drawing water for drinking or cooking. Information was mailed to residents in these households to encourage water sampling. Disinfection practices were revised to reduce compounds in the water supply and better control biofilm in distribution pipes. Water meters were replaced in 18,000 homes in 2002-2003.

An advisory was issued on February 26, 2003 recommending that pregnant women, nursing mothers or children <6 years of age in homes with actual or potential lead

service lines not drink unfiltered tap water or use the water to prepare formula or concentrated juices. The DC Department of Health (DOH) is offering free BLL testing for residents in homes with actual or potential lead service lines; conducting follow-up with home visits and case management of target populations; and collaborating with CDC to assess BLLs throughout DC. EPA expects WASA to accelerate the testing schedule and lead service line replacement. WASA will provide filters or an alternate water source for highest-risk populations.

A preliminary report will soon be completed identifying the next series of studies that need to be conducted. EPA Headquarters and regional offices as well as state regulatory agencies were contacted to determine if high lead levels in water had been seen in other parts of the country. To date, similar water quality problems have not been reported outside the DC area, but EPA will still conduct a national compliance review to ensure the action level is not exceeded in other states. For example, all water samples taken in Falls Church, Virginia were found to be <4 ppb, but lead levels in water above the action level were detected in 50% of samples from Arlington, Virginia. Both Falls Church and Arlington are conducting additional sampling in schools and households. EPA will review its regulatory requirements for public education since the outreach and guidance were not successful in DC. As a result, more urgent messages on reducing lead exposure will be communicated to the public.

Dr. Brown confirmed that CDC is closely partnering with the DC and Arlington, Virginia health departments to respond and continue to monitor the lead in drinking water emergency by reviewing existing data and assisting in identifying new data. CDC is also supporting the DC lead advisory that recommended pregnant women and children <6 years of age not drink water from houses with known lead header pipes or service lines unless the water was filtered or bottled. The Brita Water Company supported the lead advisory as well by donating 10,000 water filters for distribution to DC residents.

Dr. Brown also reported that CDC is collaborating with the DC DOH to match water and BLL tests from 1998. Pregnant women, children <6 years of age and all residents in homes with lead levels in water of 300 ppb are being actively targeted for lead testing. However, any individual who requests a BLL test in an emergency room or other setting will receive the test. Dr. Binns was concerned that the lead advisory did not specifically mention “women of child-bearing age” as a population of concern. She encouraged EPA and the DC DOH to partner with the media to effectively communicate health risks from lead to adults.

Update on the Primary Prevention Document

Dr. Campbell reported that the latest version of the document was distributed to ACCLPP in December 2003 and revised based on comments from the members. At the time of the meeting, the document was to be submitted soon to CDC for clearance.

She thanked the members for their comments, diligence and dedication in finalizing the document. By the next ACCLPP meeting, the primary prevention document will have been published as a stand-alone CDC document and distributed to grantees for guidance.

Demonstration of a Web-Based Housing Registry

Ms. Patricia McLaine is the ACCLPP liaison for the National Center for Healthy Housing. She announced that "LeadSafeHomes.info" (LSH) is a web-based housing registry of property information for Baltimore, Boston and Chicago. Several city agencies, EPA regional offices and community groups were instrumental in developing the HUD-funded activity. The project period was extended for one year to create the web site; the initiative is expected to be launched in March 2004. The LSH web site will provide public access to the lead status of homes and lead educational materials. Specific information will be displayed for each city, including a home page, property report, community report and contacts for additional information.

The property report will illustrate age and risk of housing, list recommendations, describe the lead inspection history, outline address and blood lead summaries, and provide links to additional information of interest. The community report will contain a color-coded map to illustrate violation rates and BLLs by census tract, areas with insufficient data, and high-risk block groups within census tracts. For example, no census tracts in Boston had 12% of BLLs >10 µg/dL. The LSH web site will contain an interactive matcher to allow users to scan the entire city for properties that were identified, inspected and de-leaded. Topics of special interests will be categorized by groups, including landlords, parents, healthcare providers, city and state officials, community organizations and tenants. For example, the landlord page will provide information on lead contractors.

Each web page will be tailored for the respective city. For example, distinct symbols will be displayed on the Baltimore property report to illustrate the status in the Maryland lead rental registry program, such as receipt of a full or provisional lead-free certificate, compliance with a full or modified risk reduction standard, or program registry only. City agencies, rental registries, abatement data and GIS mapping files were used as data sources for the LSH web site. Overall, the web site will serve as a powerful tool and allow data to be reviewed differently for neighborhoods, block group areas and specific properties.

Dr. Lynn mentioned that users may interpret the "check mark" symbol to mean all aspects of the home are in compliance and concern is not needed. However, she pointed out that a de-leaded home is not necessarily a permanent solution. Ms.

Barbara Conrad, of the Maryland Department of the Environment, explained that the LSH web site will have a number of potential uses. The housing market may be impacted since landlords and other property owners may be more inclined to meet lead risk reduction standards in units. Prospective homeowners and tenants will have a solid source of information to aid in the decision-making process about a particular property. Homeowners and tenants who can document unsafe units may be able to strengthen court cases against landlords. Advocacy groups for lead safe homes can more effectively assist tenants and homeowners.

Update on National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) Activities

Dr. Henry Falk, the NCEH/ATSDR Director, covered the following items in his status report. First, the consolidation of NCEH and ATSDR was initiated in August 2003 in response to agreement by the HHS Secretary, CDC Director, Office of Management and Budget, Congressional committees and various external groups. Maintaining two environmental agencies in HHS that both report to the CDC Director/ATSDR Administrator was not found to be an efficient process. NCEH was created as a formal CDC center in 1980 after providing environmental health expertise in response to the Three Mile Island accident. ATSDR was established by the Superfund legislation to specifically address lead and other environmental health issues at Superfund sites.

Leadership, management and administrative functions of the two agencies were consolidated rather than fully merged because the Superfund law still requires ATSDR to be maintained as a separate agency. However, the consolidation is expected to promote greater coordination and collaboration between NCEH and ATSDR. To date, administrative offices of the agencies were realigned with a common leadership and similar management positions were streamlined. The consolidation is expected to be completed by the end of 2004. The consolidation will not affect CDC's lead activities due to strong support of and continued commitment to LPPB by the CDC and NCEH/ATSDR Directors. Most notably, Dr. Falk was extensively involved in CDC's early lead studies in the 1970s, participated in the development of the 1991 strategic plan for childhood lead poisoning elimination, and served as the ACCLPP Executive Secretary prior to his appointment as the ATSDR Assistant Administrator.

Second, CDC's Futures Initiative is a broad strategic planning effort that will have a significant impact on the agency-wide structure and resources. Due to the 9/11 terrorist attacks, anthrax episodes and outbreaks of monkeypox and severe acute respiratory syndrome, CDC has received more media attention in the last two years. As a result, the CDC Director launched the Futures Initiative to provide an opportunity for CDC to respond to public health priorities as quickly as possible. The Futures Initiative is

designed to guide CDC's future directions in terms of its organization as a public health agency and issues to address. In particular, CDC will broaden its function from supporting state and local health departments to becoming more engaged with the general U.S. public.

The four Futures Initiative priorities are partnerships, CDC's role in the U.S. health care system, applied research to support extramural activities, and global health. CDC spent a considerable amount of time gathering input on these issues from partners, stakeholders, researchers and representatives of the health care system. NCEH/ATSDR also discussed strategies to strengthen capacity in these areas from an environmental health perspective. CDC will begin implementing the Futures Initiative in January 2005 by focusing on its role in preventing disease and protecting public health from threats. Detailed goals for these two focus areas will be submitted to the CDC Director by the end of March 2004.

Dr. Hoffman inquired about the role of the consolidation in reducing NCEH/ATSDR resources. Dr. Falk clarified that administrative savings were distributed to programs. The consolidation did not place NCEH/ATSDR resources at risk; instead, wars, tax cuts, Department of Homeland Security activities and other competing priorities at the federal level are the cause of budget constraints.

Dr. Banner asked if the consolidation will allow ACCLPP to become more involved with ATSDR activities, particularly lead issues at the Tar Creek Superfund site. Dr. Falk explained that ACCLPP's focus depends on its charter. For example, ACCLPP is charged with addressing broad lead issues at the national level rather than those for specific sites. In lieu of changing the charter, he suggested that updates on lead issues at Superfund or mining sites be provided at future ACCLPP meetings. In terms of Tar Creek, ATSDR is currently reviewing BLL and other environmental data gathered from the site and will submit a report of its findings in July 2004. Dr. Falk offered to provide an update on Tar Creek at the next ACCLPP meeting.

Dr. Ho was extremely pleased that CDC will adopt the National Institutes of Health (NIH) model for research programs. He requested more details on this activity. Dr. Falk replied that the research mechanism will be launched in the next few months. Efforts are currently being made to structure a substantive extramural research program throughout CDC and leverage funds to ensure that the activity grows and flourishes in the future. CDC will place emphasis on distinguishing between basic research and applied research that will be needed to strengthen its programs.

Update on the Adverse Health Effects of BLLs <10 µg/dL Workgroup Report

Dr. Thomas Matte of CDC summarized comments that were submitted for the workgroup to consider while revising the report. Questions raised by these comments included; whether a policy discussion should be included in the background section, whether non-significant results should be considered, whether original data should be analyzed, whether the threshold discussion should be modified, whether non-peer reviewed results should be cited; how the report should address the unexpected outcome of the BLL relationship becoming steeper at lower levels; whether the term "lead Poisoning" should be used; what the format and tone of the conclusions should be; and how conclusions that can be drawn from studies on children's BLLs and health status are impacted by the fact that BLLs can only be measured at certain time points. Dr. Matte noted that minor wording changes that were suggested that did not impact the overall conclusion, as well as suggested additional references were not included in his presentation. Dr. Matte then reviewed changes to the October 2003 draft workgroup report made in response to specific comments. His presentation can be found in attachment A.

To guide the discussion on the workgroup report, Dr. Carla Campbell asked ACCLPP to specifically consider whether the document should be finalized and published at this point or if additional changes need to be made. ACCLPP's deliberations focused on the process of developing the workgroup report and the content of the document. In terms of process, Dr. Banner's understanding was that the workgroup would create a product for ACCLPP to use as a guidance document or scientific commentary; instead, it seemed to him that a stand-alone report will be published without ACCLPP ownership. He added that the workgroup's decisions were made independent of ACCLPP. Dr. Hoffman requested that a statement be incorporated to explain whether or not ACCLPP supports the document. He was not in favor of publishing the report as a workgroup product. Dr. Lynn noted that the workgroup is heavily populated with non-ACCLPP members.

With respect to content, Dr. Leighton found the document to be excellent because the workgroup addressed extremely technical issues, thoroughly analyzed the epidemiologic literature and clarified several complex topics. However she suggested that the document be further edited to shorten particular paragraphs. Dr. Towers was also impressed with the workgroup's thorough review of the available evidence. Dr. Piomelli pointed out that during the previous ACCLPP meeting, the Workgroup Chair stated "current data do not support labeling children with BLLs <10 µg/dl as lead poisoned." However, this important comment is excluded for the current version of the document. The purpose of the report is to emphasize the importance of causality of BLLs <10 µg/dL. The document may be used to make policy decisions and will serve as a critical tool in ACCLPP advising CDC on whether to lower BLL of concern from 10 µg/DL to 5 µg/dL. However, the does not serve as a guidance document because clear and definite conclusions are not made.

Dr. Piomelli further noted that language is not included in the report to emphatically state whether BLLs <10 µg/dL are harmful to children. The conclusions should be clearly stated in bullet points. Dr. Piomelli also stated that the workgroup report was not sufficiently skeptical about the steeper slope of the blood lead IQ relation observed at lower blood lead levels. He wrote a letter to ACCLPP explaining that the Bellinger and Canfied results are due to an artifact due to classification of children as never having BLLs above 10 when in fact their levels may have been above 10 between measurements. He recommended that these findings be rejected. Dr. Piomelli also asserted that the document was not consistent with the version presented by Dr. Weitzman at the October meeting and questioned whether Dr. Weitzman approved of the revised version.

Dr. Matte replied that the workgroup report was modified in response to Dr. Piomelli's comments on misclassification of children as never having blood lead levels above 10, but that the workgroup could not identify a mechanism whereby the increasing slope closer to 0 could be produced by the classification bias Dr. Piomelli described. As a result, the workgroup's change to the current version of the document differs from Dr. Piomelli's opinion. Dr. Matte also noted that Dr. Weitzman had reviewed and approved the revisions to the workgroup document.

Dr. Banner disagreed with the workgroup's approach of citing published data that were not statistically significant to support their conculsions. Inclusion of these data may cause ACCLPP to be perceived as a non-scientific group or the report to be viewed as an unscientific analysis or a political document. The report will be shorter and more useful in these data are removed. Because the current version is voluminous and vague, conclusions about the steeper slope at lower BLLs and other solid points made by the workgroup are minimized. The report references uncertainty in the data, but the document would be strengthened by adding confidence intervals to actually illustrate uncertainty. The document should also clearly state that additional research is needed to determine whether confounding has been fully addressed in observational and non-experimental studies. Dr. Banner questioned whether a potential conflict of interest exists because both the Workgroup Chair (Dr. Weitzman) and the other author of the primary study cited in the report are from the University of Rochester.

Dr. Matte and Dr. Rogan both noted that the use of non-statistically significant findings in reviews of the literature and meta-analyses is consistent with accepted scientific practice. Also, instead of reviewing each individuals study in a vacuum, the workgroup took a scientific approach by interpreting NHANES results, the Canfield study and other relevant data as a collective body of evidence. The workgroup agrees that the report can be enhanced by flagging significant studies or adding "n's" in figures to illustrate

uncertainty in the data. Dr. Matte noted Dr. Weitzman did not have a conflict of interest because of his affiliation with the University of Rochester because he was not directly or indirectly involved with the Canfield study. The workgroup objectively reviewed the Canfield study and the report raised many questions about the interpretation of these data.

Dr. Lynn recognized the workgroup's diligent efforts in collecting, reviewing and compiling a tremendous amount of data and addressing a considerable number of conflicting comments from ACCLPP. She was in favor of the document being finalized with additional editing to condense the text and remove repetitive references to the Bellinger letter and the Canfield study. The document may be perceived as relying too heavily on these data sources. An editor should also clarify the discussion on the steeper slope at lower BLLs. Dr. Lynn also suggested that an executive summary be developed and incorporated into the report.

Dr. Binns mentioned that the report will serve as an important source for researchers in the field. She acknowledged that the workgroup could not make a definite conclusion about the steeper slope at lower BLLs because sufficient data have not been gathered to demonstrate this outcome. Her position was that the data gap is adequately expressed in the document. Dr. Hoffman conveyed that if ACCLPP votes to approve the workgroup report, comments should not be made to drastically change the document.

Dr. Campbell responded to ACCLPP comments on process as follows. The <10 Workgroup used the same process as the Case Management and Primary Prevention Workgroups. ACCLPP and the <10 Workgroup had a considerable amount of interaction during several meetings. The workgroup prepared and presented drafts to ACCLPP for review and comment and revised documents based on feedback from the members. The workgroup report will list the authors, but the document will be published as an ACCLPP product after ACCLPP reaches consensus by a vote. The membership of the <10 Workgroup is similar to other workgroups in which a minimum of two ACCLPP members served along with several non-ACCLPP consultants. Dr. Campbell expressed her appreciation of the diligent efforts by Drs. Matte and Michael Weitzman, the <10 Workgroup Chair, in preparing and revising the report. Similar to Dr. Lynn, she also believed that the document is now in a position to be finalized with editing.

Concerning the criticism by some ACCLPP members that the conclusions are vague or equivocal, Dr. Matte stated that the nature of the workgroup's finding reflects uncertainty in the available evidence. For example, the workgroup was uncertain whether confounding has been fully addressed in observational and non-experimental studies and noted the need for additional research in this area.

Dr. Matte concluded his remarks by advising the ACCLPP to decide whether it agrees with the workgroup's three major conclusions in voting to approve the report. First, the weight of evidence shows an association between BLLs <10 µg/dL and adverse health effects. Second, available data do not allow definitive conclusion about causation, but the weight of evidence for the studies favors and does not refute a causal interpretation. Third, uncertainty in scientific evidence does not point to a threshold BLL <10 µg/dL above which children should be clinically defined as "lead poisoned." Dr. Matte emphasized that the workgroup would likely not endorse the document if it were modified by the ACCLPP to state radically different conclusions on these three issues.

Dr. Binns made a motion for ACCLPP to accept and approve the <10 Workgroup reports as an ACCLPP document; Dr. Handy seconded the motion. Dr. Campbell amended the motion to note that ACCLPP's approval for the workgroup report will be provisional based on the following conditions. The introduction will be reformatted as an executive summary that will list conclusions in bullet points. A "Statement by ACCLPP" will be added explaining that the workgroup wrote the report, but ACCLPP reviewed, provided comments and accepted the document as an ACCLPP product. Both the executive summary and statement will be distributed to ACCLPP for review and comment in June or July 2004. Appropriate tables will be modified to indicate sample size. The report will be submitted to a medical editor for further refinement and the final document will be distributed to ACCLPP. **With no further discussion, ACCLPP unanimously approved the <10 Workgroup report with the provisions stated in the amended motion.**

Update by the Ad Hoc Policy Workgroup

Dr. Helen Binns, the Workgroup Chair, reported that dual efforts are being made for this activity. Drs. Brown and Lynn drafted *Public Health Implications of Adverse Health Effects in Children with BLLs <10 µg/dL* (the policy document), while Dr. Binns drafted *Understanding Children's BLL Results: Information to Aid Decision-Making and Counseling in the Health Care Setting* (the clinical document). Although the two documents are intended to state ACCLPP's opinion, readers are also referred to the case management, primary prevention and <10 Workgroup reports. The policy and clinical documents have different audiences, but ACCLPP should consider whether the reports should be maintained separately or combined. Dr. Binns was in favor of continuing to produce two documents to increase readership and reach diverse audiences. For example, the policy document can be published in a public health journal, while the clinical document can be published in a pediatric journal.

ACCLPP's recommendations on the workgroup's policy and clinical documents are outlined below.

- Design a conceptual framework for both documents that includes strategies for public health agencies, medical providers and follow-up testing.
- Use common and consistent language within and across both documents. For example, refer to "children with BLLs 5-9 µg/dL" as "the group targeted for primary prevention and screening."
- Integrate the two documents as a comprehensive *MMWR* article or stand-alone publication and also publish both documents separately in the literature.
- Avoid combining the documents due to different audiences, topics, purposes and messages.
- Provide specific locations of ACCLPP's case management and primary prevention reports in both documents.
- Present the policy, clinical and <10 Workgroup documents with a common linkage, unified message and internal agreement, particularly to address the disconnect between the policy and <10 Workgroup reports. For example, incorporate language to recommend that primary prevention be targeted to communities with high rates of children with BLLs $\geq$5 µg/dL. Cross-reference the three documents to ensure consistency.
- Consider whether the weight of evidence supports changing the term "managing elevated BLLs" to offer guidance to providers of high-risk populations or if the wording should remain the same as an option for clinicians.

- Develop an abstract or shorten the clinical document because busy clinicians will find the paper too long and difficult to read.
- Maintain the length of the clinical document because all of the issues raised are important for clinicians to know in interpreting BLLs.
- Maintain the user-friendly format of the clinical document because the numbered boxes quickly illustrate important points for busy clinicians.
- Include a statement in the clinical document to explain the lack of experience and evidence in treating children with BLLs 5-9 µg/dL as lead poisoned.
- Add bullet points in the policy document to advise clinicians in certain high-risk jurisdictions to consult with local health departments.
- Revise the tone of the policy and clinical documents to be more positive by highlighting DLL reduction, removal of deteriorated paint and other environmental interventions that are known to reduce BLLs and minimize exposure to lead in housing regardless of the child's BLL.
- Emphasize in the beginning of the documents that communities with a high prevalence of BLLs 5-9 µg/dL are the same areas with BLLs $\geq$10 µg/dL.
- Ensure that screening recommendations, clinical management guidelines and policy implications are distinguished and not interchangeably used.
- Include text to strongly emphasize that Medicaid requires all children to be tested and CDC recommends state and local health departments develop screening guidelines for clinicians. Reference the HITS data and ACCLPP's Medicaid screening paper that was published in the *MMWR*.
- Postpone further efforts to finalize the policy document until LPPB gathers and includes feedback from the lead poisoning vocabulary focus groups.
- Continue efforts to finalize both documents because the focus groups target parents and consumers, while the clinical and policy documents target clinicians and the public health community, respectively.
- Revise the policy document to include a table of bullet points that lists strategies to comply with the recommendations. Extract bullet points from ACCLPP's case management and primary prevention reports in this effort.
- Include a diagram in the clinical document that clinicians can post in the office as a visual aid to assist in interpreting BLL results.
- Highlight the message in the clinical document that capillary blood samples are accepted by health departments and surveillance systems for screening, but appropriate measures must be taken to control contamination. Provide guidance to clinicians by referencing CDC's established protocol for performing capillary blood draws, the videotape on improving blood lead sampling techniques and other available resources.
- Add a brief section in the clinical document to describe research needs in managing children with BLLs <10 µg/dL, such as a study to identify

differences between capillary blood draws and vena-puncture in determining BLL prevalence.

- Ensure that messages in the clinical document are generally consistent with the lead statement on screening the American Academy of Pediatrics (AAP) Committee on Environmental Health is currently updating. However, be mindful that ACCLPP's clinical document is targeted to a broad audience of providers who serve children, while the AAP statement specifically focuses on pediatricians.
- Replace "BLLs 5-9 µg/dL" with "BLLs <10 µg/dL" throughout the clinical document.

Dr. Brown made follow-up remarks to ACCLPP's deliberations. First, CDC has discussed whether a fundamental recommendation should be made stating that screening children to identify those with BLLs 5-10 µg/dL will be beneficial to the individual child. CDC has not made this statement to date and agreement was reached during the previous ACCLPP meeting not to lower the BLL of concern from 10 µg/dL. However, CDC has no problem producing a document explaining that jurisdictions are using local data to monitor lower BLLs and determine if the Intervention will be effective. Second, CDC notes that efforts in 1991 to target primary prevention to communities with high rates of children with BLLs ≥10 µg/dL were unsuccessful.

Third, LPPB expects to complete the final report on the lead vocabulary in June 2004. The focus group data will inform the process of clinicians communicating with parents, but this activity should not delay efforts to finalize the policy or clinical documents. Fourth, the policy document does not describe strategies to comply with the recommendations because this guidance is available in existing well-written reports. Instead, the policy document references ACCLPP's primary prevention and case management documents as well as CDC's 1991 and 1997 statements on screening and follow-up of children with EBLLs.

Fifth, Dr. Brown was extremely concerned with ACCLPP's focus on and use of the term "5-9" due to the danger of identifying a new group of children who need and can benefit from individual intervention. Since no evidence has been collected to date to support this statement, ACCLPP should use the terms "<10" or "≥10." To address the issue of BLLs 5-9 µg/dL, however, LPPB supports ACCLPP making the following research statement. Very young children with BLLs 5-9 µg/dL may actually be the same children whose BLLs are in the process of increasing. Efforts will be made to rigorously evaluate this trend and determine whether health education, DLL reduction and other interventions will interrupt the cycle. Lead is a poison that is not beneficial to the human body and a safe level of lead does not exist.

Sixth, ACCLPP's letter to the Centers for Medicare and Medicaid Services (CMS) on screening waivers was distributed throughout CMS and reviewed, but new staffs are now involved with this process. Dr. Brown and the new CMS staff will meet on March 10, 2004 to discuss developing consistent guidance. However, CMS has already stated in writing its commitment to creating a waiver process and ensuring screening is performed by aggressively targeting states that do not submit waivers.

Dr. Hoffman placed the following motion on the floor. The <10 Workgroup report should be released in conjunction with the policy document as a collective body of evidence. The policy document should serve as ACCLPP's official statement for the <10 Workgroup report. Relevant text from the clinical document should be incorporated into the policy document. The clinical document should remain as a separate paper to reach a specific audience. Dr. Lynn seconded the motion. **With no further discussion, ACCLPP unanimously approved the motion.**

Drs. Binns, Brown and Campbell described the process to continue developing the policy and clinical documents. Drafts will be distributed to ACCLPP for review by e-mail with a request to submit comments electronically rather than through conference calls. None of the revised versions will be labeled or referred to as "final;" instead, dates will be used to distinguish among drafts. A short abstract will be developed and incorporated into the clinical document. ACCLPP will submit comments on the policy document to Dr. Brown by April 15, 2004 and comments on the clinical document to Dr. Binns by May 15, 2004.

Public Comment Period

Ms. Conrad thanked ACCLPP for voting to collectively release the policy document and <10 Workgroup report because the two documents will serve as powerful guidance to states.

With no further discussion or business brought before ACCLPP, Dr. Campbell recessed the meeting at 5:38 p.m. on March 9, 2004.

Unfinished ACCLPP Business

Dr. Campbell reconvened the ACCLPP meeting at 8:39 a.m. on March 10, 2004. In response to Dr. Piomelli's request on the previous day, she returned the discussion to the HITS results. Dr. Binns indicated that perhaps HITS should be replicated in areas other than Chicago because the study emphasizes the need to further examine

screening efforts. Replication of HITS will provide information on whether the screening status in Chicago is comparable to other areas. HITS data can also be used to highlight existing problems with screening and emphasize the need to develop strategies to address this issue. Dr. Hoffman suggested that the HITS data be analyzed to provide more detailed cross-tabulations or subsets, such as the percentage of Medicaid children who were screened. The HITS data should also be analyzed to distinguish between true immunizations and maternal antibody in children 12 months of age.

Dr. Lynn mentioned that the greatest value of HITS will be to use the data as a tool to determine the rationale for screening some children and not testing others. Dr. Rogan noted that the General Accounting Office (GAO) recommendations on Medicaid screening were based on 1998 data. He raised the possibility of ACCLPP, CMS or another group updating the GAO study with 2003-2004 data to determine if the rates would be the same.

Ms. McLaine confirmed that the failure to screen at-risk children and the lack of understanding about the importance of screening continue to be problems for case managers throughout the country. She suggested that areas with successes or dramatic improvements in screening be reviewed to gather best practices and lessons learned. Dr. Banner was not in favor of ACCLPP advocating for enforced screening through CMS. This type of action will severely burden programs and worsen access to care. Many pediatricians throughout the country are unwilling to serve Medicaid patients due to low reimbursement rates. Instead, easier, less expensive and innovative strategies should be developed, particularly in areas with low BLL prevalence.

Dr. Leighton was particularly concerned that 25%-33% of children <6 years of age enrolled in HITS had not had a well child care visit in the previous 12 months. As a result, emergency departments present a missed opportunity for providers to perform screening if the child had not been previously tested. Another disconnect is providers who verbally confirm that a child was screened, but the test is not reflected in the medical chart. Dr. Leighton announced that New York City is attempting to address this disparity by collaborating with providers to make changes in practices and increase screening. Based on the discussion, Dr. Campbell listed items that should be emphasized during CDC's upcoming meeting with CMS: ACCLPP's targeted screening guidelines, ACCLPP's recommendation to increase screening of Medicaid children, and the poor Medicaid reimbursement rate.

Dr. Brown provided follow-up remarks to ACCLPP's deliberations. Replication of HITS in other areas will be problematic because all jurisdictions do not have Chicago's long history and trust between at-risk communities and the health department. For example, CDC's recent attempt to repeat HITS in Los Angeles was a dismal failure due to

extremely poor cooperation and the identification of only two children with EBLLs at a project cost of $50,000. CDC is currently considering the feasibility of recreating HITS in Mississippi, but endorsement from the state health department and persons with strong linkages to the at-risk community will be needed.

Dr. Brown hoped that CDC's meeting with CMS will begin to advance Medicaid screening. As an initial step in this effort, areas with low BLL prevalence should be documented and resources should be diverted to jurisdictions with high BLL prevalence. She expressed her support of future efforts to update the GAO report. In the interim, however, the Chicago CLPPP will continue to add and evaluate activities to improve the HITS protocol, such as partnering with the immunization program, collecting cotinine levels, and matching Medicaid and blood lead screening data to specifically target these children. Overall, Dr. Brown was encouraged by future initiatives because providers generally respond if gaps are thoughtfully and politely presented.

Lead Exposure and Pregnancy

Overview. Mr. Robert Roscoe is the ACCLPP liaison for the CDC National Institute for Occupational Safety and Health (NIOSH). He explained that an EBLL in adults is an occupational issue regulated by the Occupational Safety and Health Administration. Medical removal of lead from adults begins at a BLL of 50 µg/dL; adults can return to work when the BLL falls below 40 µg/dL. However, hypertension, kidney disease, central nervous system disorders and adverse reproductive outcomes have been detected in adults with BLLs <40 µg/dL.

NIOSH's Adult Blood Lead Epidemiology and Surveillance (ABLES) program noticed several flaws in BLL reports submitted from all parts of the country, particularly inadequate, misleading or outdated interpretative data on adult BLL laboratory reports. Submission of this information to clinicians resulted in inaccurate diagnoses, patient mismanagement or the mistaken belief that an EBLL within normal limits is not a concern. Clinicians were also found to have insufficient knowledge and understanding about medical management and toxicity from lead exposure among adults. ABLES acknowledged that the lack of national medical management guidelines for adults is an additional flaw.

In response to these concerns, ABLES developed and published guidance for clinicians in *Clinical Laboratory News*, convened an expert panel in March 2003 and drafted a document. The data were submitted to the Association of Occupational and Environmental Clinics to ensure that non-governmental clinicians play a role in finalizing the document. The most contentious area of the report relates to lead exposure among women who may become pregnant and breast-feed.

Management of Pregnant Women with EBLLs. Dr. Jessica Leighton, an ACCLPP member, described the NY State (NYS) mandates for lead screening and reporting of pregnant women. Since December 1993, the NYS law has required that all prenatal healthcare providers take the following actions. Each pregnant woman must be given anticipatory guidance on lead poisoning during pregnancy. Each pregnant woman must be assessed at the initial prenatal visit for high-dose lead exposure. Each pregnant woman at risk for high-dose lead exposure must be screened or referred for screening. Each pregnant woman with a confirmed BLL ≥10 µg/dL must be given risk reduction counseling. A referral to an occupational health clinic must be made if an occupational exposure is identified. Each pregnant woman must be given anticipatory guidance on the prevention of childhood lead poisoning at the postpartum visit.

The 1993 law also requires laboratories to report all BLL results performed on all NYS residents to the NYS health department within five days. After receiving the results from NYS, the New York City (NYC) health department contacts medical providers of all women who had one BLL test of ≥10 µg/dL to determine pregnancy status. The NYC Adult Lead Program distributes a packet of information on lead poisoning prevention to pregnant women with BLLs 10-19 µg/dL, while the NYC CLPPP provides case management to pregnant women with BLLs ≥20 µg/dL. The NYC CLPPP has taken several actions for pregnant women since 2001, such as identifying the lead poisoning source, providing recommendations to eliminate or reduce lead exposure, and consulting with medical providers to encourage follow-up blood testing of the mothers and infants.

Of 51,071 adults tested for BLLs in NYC in 2003, 71% were female. Of the females, 90% were 18-45 years of age and 43 had BLLs >20 µg/dL. Of females with BLLs >20 µg/dL, 72% were pregnant. The NYC adult lead program acknowledges that its current surveillance system contains many duplicates, but efforts are currently being made to apply the NYC CLPPP algorithms to improve the system. The NYC CLPPP is currently following the 72% of pregnant women with BLLs >20 µg/dL. The NYS law requires pregnant women to be tested and assessed during the initial prenatal visit, but the majority of cases had the first blood lead test in the last trimester. The data showed that the median BLL among pregnant women was 25 µg/dL at the initial visit and 16 µg/dL at the last visit. Among newborns, the mean BLL was 15 µg/dL. The correlation between the last BLL of mothers and infants was 0.81.

The majority of pregnant women with BLLs >20 µg/dL were 18-25 years of age, 75% were Hispanic and 16 were Southeast Asian. Of the Hispanic women, 64% were born in Mexico. Of all immigrants, 70% lived in the United States for less than five years. Although 25% of the women admitted to pica behavior, NYC believes the figure to be an underestimate. Use of Mexican pottery and other clay-based products, home

renovations and peeling or chipping paint were reported as additional risk factors for the EBLLs. These findings emphasize the need to enforce abatement of the home before the child is born.

The NYC adult lead program has been managing lead-poisoned pregnant women for several years and developed *Prevention Guidelines for Prenatal Care Providers*. However, NYC was unable to answer questions by prenatal care providers on managing lead-poisoned pregnant women and referred these calls to a local medical center. NYC's lack of capacity in this area emphasized the need to gather additional information and expertise from other sources on the adverse effects of lead exposure to the fetus and mother. To assist in this effort, NYC convened and charged an expert panel in 2003 with answering the following questions.

- What does the current evidence demonstrate regarding health effects of lead poisoning in pregnant or lactating women and neonates?
- At what BLL should education, follow-up testing or another intervention be initiated?
- What are appropriate interventions for healthcare providers treating lead-poisoned pregnant women, such as educational messages, coordination with the NYC CLPPP, frequent retesting, recommendations for nutritional counseling and calcium supplementation, and postpartum guidelines?
- What are appropriate public health department interventions for pregnant women and other family members, such as environmental assessment of the home or risk reduction?
- Which pregnant women should be screened for lead poisoning?
- What are barriers that prevent healthcare providers from risk assessment, delivery and coordination of care, testing and case management?
- What cultural, ethnic and linguistic issues should the NYC CLPPP and healthcare providers be aware of?
- What information on lead poisoning prevention should medical providers be giving all pregnant women?

Dr. Leighton announced that the expert panel has held two meetings, completed a draft of the literature review and expects to submit a report of its recommendations in Spring 2004.

Clinical Care. Dr. Michael Shannon, of the Harvard Medical School, joined the meeting by conference call. He described efforts by the Boston Pediatric Environmental Health Specialty Unit (PEHSU) that resulted in publication of a paper in *Ambulatory Pediatrics* in 2003. Efforts to prevent childhood lead poisoning have historically targeted secondary prevention, such as screening at-risk children. However, the focus is now shifting to primary prevention to assess and abate hazardous environments. Less

emphasis has been placed on lead exposure occurring in the fetus despite the fact that lead freely crosses the placenta; fetal brain development is potentially the most critical window of vulnerability; women of childbearing age may be increasingly exposed to lead as greater numbers join the workforce; and the growing number of immigrant populations brings objects and customs known to be associated with lead poisoning.

Although stable isotope studies show that all women mobilize lead from skeletal stores during pregnancy resulting in transmission of some lead to the fetus, less research has been conducted on the epidemiology of exposure to very large amounts of lead during pregnancy producing severe lead poisoning. The existing literature cites pica, occupations and home renovation as potential sources of exposure in pregnant women, but the mobilization of lead in a woman who was severely lead poisoned as a child is a research gap. Pica is defined as the repeated ingestion of non-nutritive objects, while polypica is the ingestion of more than one non-nutritive substance. In a recent study, 38% of ~100 pregnant women self-reported pica behavior with ice, freezer frost, laundry starch, cornstarch, clay dirt and baked clay dirt; 11 women in the study self-reported polypica.

The Boston PEHSU study was designed to determine the existence of identifiable patterns and the consequences of severe lead poisoning with BLLs $\geq$45 µg/dL during pregnancy. A case series was developed with two data sets and cases of severe lead poisoning that were treated in consultation with the Boston PEHSU were compiled and reviewed. The study represents numerator data, does not reflect incidence or prevalence, and also focuses on a specific population of women who became severely lead poisoned during pregnancy. Based on a systematic review of MedLine and the literature over the past 25 years, 15 cases of severe lead poisoning in pregnant women were identified. By race/ethnicity, seven women were Hispanic, two were Indian and one was white; race/ethnicity was unstated for five cases. At the time of diagnosis, the mean gestational age was 32 weeks and 13 of the 15 women were in the third trimester.

The pregnant women were identified with a mean initial BLL of 72 µg/dL and presented to obstetricians with malaise, fatigue and anemia. One of the 15 women had a BLL of 104 µg/dL and presented with a seizure; five were chelated. Of the 10 women who admitted to pica, a source was identified for 83%. Of these cases, the pica sources included clay, soil, pottery, other clay-based substances, home renovation, and lead-contaminated bone meal imported from India and used as calcium supplementation. At the time of birth, the mean maternal BLL was 55 µg/dL, the mean hematocrit was 29.5%, the mean neonatal BLL of 74 µg/dL broadly ranged from 26-206 µg/dL, and the correlation between maternal and neonatal BLL was highly significant at 0.72. The mean BLL of newborns was 32% higher than maternal BLLs and ranged from 99% higher to 112% lower. Although skeletal abnormalities are reported in some cases in

the literature, no birth defects were identified in the Boston PEHSU series. Of the 15 newborns, 13 underwent chelation therapy.

The uptake of lead in the fetus is cumulative over time and suggests a net unidirectional flow. BLLs in newborns also appear to be higher in offspring of women with low calcium intake. The confounding nature of hematocrit is due to ~99% of circulating lead being bound to the erythrocyte. As a result, anemia, sickle cell disease and other syndromes of chronic anemia may significantly underestimate the overall lead burden. For example, the anemia of the women in the Boston PEHSU series most likely generated underestimates of their lead burden. Conversely, polycythemia may overestimate the lead burden, particularly among polycythemic newborns with a 50%-60% hematocrit at birth.

The Boston PEHSU series argues for targeted lead screening in pregnant women. Several resources are available to assist in this effort. Minnesota's modified questionnaire has been shown to be useful in identifying lead-exposed women with a fair degree of accuracy. New York and other states have initiated prospective investigations to determine the scope of severe lead poisoning among women of childbearing age and pregnant women. The New York health department and American College of Obstetricians and Gynecologists (ACOG) have created guidelines for obstetricians to follow, such as *Lead Poisoning Prevention Guidelines for Prenatal Care Providers*. The Boston PEHSU data also suggest that a prenatal history of pica and use of a complementary/alternative medication or lead-based vocation or avocation may be useful predictors of lead exposure.

The study concluded as follows. The incidence of severe lead poisoning occurring in women during pregnancy is not fully known. Because *in utero* lead exposure produces a significant risk of adverse neurodevelopmental outcomes in children, close follow-up and early referral are extremely important. Consideration should be given to performing secondary prevention by screening pregnant women and conducting primary prevention by providing anticipatory guidance from obstetricians.

Lead Exposure During Pregnancy Studies. Dr. Howard Hu, of the Harvard School of Public Health, summarized a series of studies that focused on the mobilization of maternal bone lead stores and its threat to the fetus. Although significant data gaps exist in this area, several outcomes are known. Lead substitutes for calcium in the hydroxy appetite of bone and causes bone lead stores to continually increase even as BLLs plateau. Lead stores remain in the body for decades and are not inert; most of lead that is absorbed through pulmonary or gastrointestinal routes is deposited in bone. Lead is continuously removed from the hydroxy appetite crystalline structure by passive diffusion. Bone is a dynamic organ that constantly undergoes deposition and

resorption. Pregnancy and lactation are two physiologic stages in life when absorption is greatly heightened.

Study 1 focused on the contribution of maternal lead to maternal BLLs during pregnancy. The cohort was young women who had been raised in central Europe, exposed to lead with a particular isotopic signature and migrated to Australia with a different isotopic signature. The blood subsumed the isotopic signature of the host country, but the BLLs reverted back to the isotopic signature of the home country when the women became pregnant. The results clearly showed that stored lead in bone was the source of lead entering the blood. The proportion of circulating lead from bone ranged from 30%-70%. Because maternal BLLs may pose a threat to fetal development long after environmental lead exposure has actually occurred, focusing efforts on measuring BLLs in children 6 months to 5 years of age may present a missed opportunity to identify the major impact of lead exposure *in utero*.

Study 2 captured indirect evidence on the potential for lead health effects to transfer from mother to fetus. The cohort was women of similar ages and neighborhoods who survived lead poisoning as children; their children were matched with controls. Children of women who were lead poisoning survivors were found to be three times more likely to be learning disabled. In quantifying the relationship among bone lead levels, BLLs and bone lead outcomes, the amount of lead actually in a woman's bones must be estimated. However, this information cannot be gathered through questionnaires because the sources of lead are too numerous and diverse.

Instead, bone lead levels should be directly measured by K-x-ray fluorescence (KXRF). This technique has been validated in several studies and serves as the basis of a series of investigations to compare bone and blood lead and determine its ability to predict adverse outcomes. KXRF showed that bone lead levels were better than BLLs in predicting hypertension. At this point, KXRF has not been used to measure bone lead levels in persons <11 years of age because children store 70%-80% of lead in bone and undergo much more active bone resorption and bone deposition than adults. Studies using KXRF in children 11-12 years of age produced imprecise measurements.

Study 3 analyzed the impact of maternal bone lead levels on fetal and infant development. KXRF was used to measure maternal bone lead levels in >600 women who gave birth in middle-class Mexico City hospitals. All of the women had high bone lead levels from past exposure to leaded gasoline in Mexico City. Although BLLs decreased due to the phase-out of leaded gasoline in the 1990s, bone lead levels of the women remained fairly high. The study triggered the question of whether bone lead levels are better predictors of toxicity than BLLs.

The results showed that maternal bone lead levels were better predictors than maternal BLLs of lower birth weight, lower head circumference at birth, shorter birth length and the growth trajectory from birth to one month of age. The findings remained the same after controlling for birth weight. The data indicate that lead crosses the placenta and affects fetal thyroid function and fetal osteocytes. The study also determined that maternal bone lead levels were independent predictors of cord BLLs in the performance of children at two years of age on the Bayley scales of mental development. The study findings served as a basis in epidemiologic analyses being conducted worldwide to determine the ability of BLLs to predict IQ in children.

Study 4 examined the impact of maternal bone lead levels on maternal health during birth. The cohort was pregnant women in Los Angeles with maternal bone lead levels measured by KXRF. The results showed that maternal bone lead levels predicted increased risk of pregnancy hypertension. Study 5 used animal data to determine risks to lactating infants due to lead mobilization from the maternal skeleton to maternal breast milk. The evidence indicated a potentially significant problem. Another study on this issue applied isotopic ratios to demonstrate contributions of bone lead levels to breast milk and breast milk to infant BLLs. Bone lead levels in the Mexico City cohort predicted higher BLLs in lactating mothers and lead levels in breast milk were found to heavily influence BLLs of lactating infants. However, the actual lead levels in breast milk were fairly low at <2 µg/dL.

Study 6 focused on whether dietary calcium supplementation can lower maternal bone lead mobilization and fetal lead exposure. This effort provides a persuasive argument to consider public health strategies to lower the amount of lead mobilized from the maternal skeleton during pregnancy and lactation. Most notably, an exogenous source of calcium should be provided to ensure that the mother's physiology does not need to dissolve its own bones to meet the enormous demand for calcium in the growing fetal skeleton. Indirect evidence suggests that the strategy may be successful.

Study 7 was a randomized trial demonstrating that a nighttime calcium supplement will depress a specific biological marker of bone resorption. The data also showed that calcium supplements decreased BLLs in lactating women by 15%-20%. Study 8 is an ongoing randomized trial of nighttime calcium supplementation of 1200 mg during pregnancy. The placebo and supplement groups show similar results of a 15%-20% depression in maternal BLLs throughout all three trimesters.

Study 9 considered kinetics and biomarker issues in the context of maternal plasma lead levels. In all blood samples, >99% of lead is attached to the red blood cell and is not available to cross the placenta or other cell membranes. The body of evidence is building toward demonstrating that the amount of lead in plasma compared to whole BLLs can widely vary by factors of 3-5. Plasma lead levels cannot be simply measured

because the process is difficult, technically challenging and requires extremely rigorous techniques to avoid contamination. However, a procedure has been developed to take direct measurements of plasma lead levels using specialized equipment to avoid hemolysis. The results showed variation in the ratio of plasma lead levels to whole BLLs by a factor of 3 in normal adults. Bone lead levels were found to contribute to this relationship. Based on the pregnancy data, plasma lead levels may have a separate ability to predict adverse outcomes that may be the mechanism for bone lead driving reproductive problems during pregnancy and lactation.

Study 10 is an ongoing effort to measure plasma lead at each trimester and identify effects on the infant. Preliminary data show that maternal plasma lead levels, particularly those in the first trimester, predict poor Bayley scores on mental development at two years of age. Although replication of all ten studies is a research need, several conclusions can be made at this point. Fetal lead exposure from maternal bone lead mobilization is problematic. The exposure is toxic, has an effect that is predicted by new biomarkers of dose and may be most damaging in the first trimester. Current data suggest that the mobilization of lead from bone occurs throughout the entire pregnancy, but the mobilization peaks during lactation. Calcium supplementation during pregnancy most likely decreases bone resorption, maternal BLLs and fetal lead exposure by 15%-25%. Other potential strategies may be available to reduce the mobilization of lead from bone during pregnancy, such as research focusing on diphosphanates.

Additional data are needed to determine the potential scope of the problem and the distribution of bone lead levels in women of reproductive age in the United States. Efforts should be made to identify other approaches in estimating bone lead levels without taking direct measurements of lead in bone. Most notably, only four centers have capacity to directly measure lead in bone, a national protocol has not been developed for this technique, and the technology will not be available to every hospital. However, research is currently being conducted to address this data need. The study is focusing on whether combined measurements of urine lead levels, BLLs, markers of bone resorption and environmental history can explain variance in bone lead levels and be used as an algorithm in predicting bone lead levels.

Better studies are needed to determine whether the bone lead level burden of girls who had high lead exposure persist into adulthood, particularly since the current data on this issue conflict. On the one hand, physiologic-based and pharmacokinetic models show that bone lead will “wash out” during adolescent bone growth. On the other hand, indirect evidence demonstrates that bone lead is retained. For example, a published case reported that a woman with a high bone lead level and childhood pica had no current exposure. An analysis showed a correlation between children who had shed primary teeth and their bone lead levels at 18 and 20 years of age. Consideration

should be given to whether policy recommendations for pregnant women can now be made. At this point, ACOG has not released consensus guidelines for pregnant women on calcium intake. This approach should be explored for all women regardless of whether bone lead levels can be measured or if an extensive environmental history can be taken. Current data show that calcium supplementation during pregnancy has relatively few side effects.

Panel Discussion. Dr. Hoffman proposed that NYC's best practices on its high screening rate be compiled and widely shared because many other jurisdictions have poor screening rates. Dr. Brown clarified that Rhode Island and Massachusetts also have high screening rates of 80% and 70%, respectively, among children two years of age. The successes of both states are due to a mature lead poisoning prevention program, a state law requiring screening, active staff to periodically remind providers about the law, and dissemination of public information to educate consumers.

Dr. Stephens suggested that the NYC data on pregnant women with BLLs >20 µg/dL be analyzed to show birth outcomes, results of the home visits and BLLs of family members. He raised the possibility of recommending calcium supplementation for children with marginal BLLs. Dr. Bolger advised ACCLPP to take caution in making this recommendation. Although calcium supplementation may be effective for children with a sub-optimal calcium dietary status, current studies do not clearly indicate whether this strategy will be effective in reducing lead absorption of children with an optimal dietary calcium intake. He also underscored the need to gather additional information before making other dietary recommendations because current data are unclear about the effectiveness of calcium supplementation for women during pregnancy. Dr. Bolger acknowledged that the mobilization of bone depends on the calcium dietary status of the mother.

Ms. McLaine announced that ACCLPP's case management document recommends assessing calcium status and encouraging adequate amounts of calcium in the diet. Dr. Banner remarked that a recommendation on calcium supplementation will be driven by non-lead issues beyond ACCLPP's purview. For example, an article that was recently published in *Pediatrics* focused on bone density and the increasing incidence of fractures. He also noted additional research needs. The current literature minimizes the significant impact of smoking, alcohol and fluoride on maternal lead levels and bone lead deposition. In particular, fluoride affects long-term bone modeling and bone density and also alters the short-term kinetics of the amount of lead incorporated into bone. Dr. Banner proposed that ACCLPP and the Poison Control Center issue joint guidance in Spanish to publicize and discourage pica.

Dr. Binns conveyed that one of the studies Dr. Hu presented demonstrated an impact on fetal and infant development with the Bayley scales. However, these findings differ

from the Bellinger data that showed prenatal lead measures were not significant when techniques other than the Bayley scales were applied. Dr. Lynn suggested that the public health community take proactive rather than reactive measures in using media contacts to more widely deliver educational messages and increase public knowledge of lead health effects during pregnancy. Dr. Towers added that communication campaigns to publicize this issue should include specific preventive messages to enhance cooperation with the recommendations among pregnant women.

The panel made follow-up remarks to ACCLPP's deliberations. Dr. Leighton described some of NYC's best practices for its high screening rate. Medical providers in NYC are generally not aware of the Medicaid screening requirement, but nearly all physicians are knowledgeable of and comply with the 1993 NYS law for lead screening and reporting. Medicaid managed care providers in NYC must submit information on lead testing indicators. NYC matches information with Medicaid databases to ensure screening is performed. NYC established primary prevention laws 20 years ago and created its lead poisoning prevention program 35 years ago. These actions have resulted in NYC having the lowest lead poisoning rates compared to six other large cities.

Dr. Hu explained that bone environmental exposures and lead in blood remaining from the *in utero* period contribute to adult lead levels. Additional studies will be needed to distinguish between these sources and also to determine whether dietary supplementation will have an impact in this area. With respect to calcium supplementation, two women in the Gulson study required to take calcium supplements had reduced lead mobilization. This finding led to a randomized trial of calcium intake that is currently underway. In terms of additional research needs, solid data are currently available on the impact of smoking on maternal lead levels. Alcohol consumption was not noted as a potential confounder in the studies because very few pregnant women drank.

Dr. Hu has not seen reports in the literature on adverse outcomes related to fluoride, but he is open to considering this issue. With respect to the impact of maternal bone lead levels on fetal and infant development, Dr. Hu reported that this study is still underway to obtain more data and follow children in the cohort as much as possible. McCarthy scales data at five years of age are currently being reviewed in the context of the growth trajectory and potential reversal of this trend.

The panel responded to Dr. Keyvan-Larijani's question on whether ACCLPP should make recommendations on chelation during pregnancy. Dr. Hu pointed out that chelation has not been adequately studied to identify potential toxicity and teratogenicity on the fetus. Due to unknown risks, chelation during pregnancy is not recommended. Dr. Shannon confirmed that chelation of specific individuals continues to be a controversial issue in the internal medicine and adult occupational medicine literature.

For example, chelation of asymptomatic pregnant women with BLLs 20-30 µg/dL is not recommended, but the health of the pregnant women in the Boston PEHSU series was in jeopardy without an acute reduction of their body lead burden. In deciding whether a pregnant woman should be chelated, Dr. Shannon mentioned that some studies recommend using an absolute number of a BLL, some research advises reviewing the entire clinical status of the individual woman, and some evidence suggests using significant symptoms and extremely high BLLs as criteria.

The panel responded to Dr. Binns' question on whether current data are sufficient for ACCLPP to make solid recommendations or policy statements on the relationship between pregnant women and lead. Dr. Hu's position was that providers of women who are contemplating pregnancy should note the nutritional intake of their patients and advise calcium supplementation for those who ingest dietary calcium below the recommended daily value. The current evidence is sufficient to provide this guidance. He hoped ACCLPP would take action because both CDC and NIH have reduced lead research projects. Since more data have been gathered for lead than any other toxin, a widely held belief is that additional research on lead is not needed. However, significant data gaps still exist at both population and mechanistic levels. Dr. Shannon agreed that CDC individually or jointly with ACOG should initiate a process to provide better education on lead poisoning during pregnancy and improve screening of women who are potentially at risk for significant lead exposure. The current evidence supports this effort.

The panel responded to Dr. Keyvan-Larijani's question on whether ACCLPP should recommend that lead programs place more priority on screening girls than boys since bone grows faster and is more likely to absorb lead during childhood rather than teenage years. Dr. Shannon acknowledged that the medical community is more attentive to lead-poisoned females than males. The stronger emphasis results in providers seeing females more frequently and engaging females earlier in discussions about chelation.

Discussion on Forming an ACCLPP Lead and Pregnancy Workgroup. Dr. Campbell pointed out that the draft charge for establishing the workgroup was distributed to ACCLPP. The activity is now being considered in response to previous suggestions by several members for ACCLPP to examine this issue in more detail. The draft charge proposes that ACCLPP will convene a lead and pregnancy workgroup to review the literature and other research findings on assessment and screening of pregnant women for lead exposure; evaluation of sources of lead exposure and lead poisoning; management of EBLLs in pregnant women; cultural and behavioral issues influencing lead poisoning and lead exposure in pregnant women; and recommendations for breast-feeding in the presence of elevated maternal lead levels.

The draft charge further notes that to date, neither ACOG nor any other group has issued national recommendations. New York is the only state with lead risk assessment and screening guidelines for prenatal care providers. The draft charge also proposes specific tasks the workgroup will perform. First, data will be evaluated and appropriate recommendations will be issued regarding lead exposure cautions for women of childbearing age and pregnant women, risk assessment and screening of pregnant women, and breast-feeding. Second, data gaps will be described and recommendations will be made for further research in this field. Third, a summary of the evidence and recommendations will be developed for publication in conjunction with ACCLPP. Health departments and practitioners would be the major audiences of the workgroup's products.

Dr. Campbell asked ACCLPP to discuss whether a lead and pregnancy workgroup should be formed and take a vote to formalize the decision. Her position was that this topic is extremely timely, particularly since CLPPPs, heath departments and CDC grantees throughout the country confront lead and pregnancy issues on a daily basis. ACCLPP's role in this effort would be to convene a workgroup with members and outside experts to examine these issues and make general recommendations to the public on pregnant women and lead exposures. Dr. Campbell opened the floor for ACCLPP to weigh in on this issue.

Dr. Brown confirmed that CDC's state and local partners continually struggle with addressing lead and pregnancy issues. Moreover, CDC's information hotline receives questions on a daily basis related to the implications of lead exposure during pregnancy, specific individuals to test and case management of pregnant women with EBLLs. Medical providers are taking actions in the absence of solid science and guidance. Similar to Dr. Campbell, Dr. Brown was also extremely supportive of ACCLPP forming the workgroup. She hoped the initiative would provide an opportunity to convene the best experts to identify current research conclusions, uncertainties in the available data and unknown areas. Dr. Binns was also in favor of ACCLPP establishing a lead and pregnancy workgroup due to the lack of political will and emphasis on this issue at the legislative level. She underscored that progress will not be made unless an authoritative body makes a definitive statement in this area.

Dr. Banner questioned the rationale for forming a workgroup because ACCLPP is now in a position to make a consensus statement about the need to fill current data gaps in lead and pregnancy related to pica, cultural issues, nutrition and the absence of state laws for lead risk assessment and reporting of pregnant women. He conveyed that the ACCLPP statement could also outline current knowledge, such as avoiding chelation of pregnant women with low BLLs due to unknown risks to the fetus.

Dr. Brown agreed that these issues are the primary focus of lead exposure during pregnancy, but she was uncomfortable with CDC or ACCLPP making a consensus statement or issuing guidance without input from outside experts. The process should be more inclusive because NIOSH, the NYC health department and other groups confront lead and pregnant issues on a daily basis. Dr. Campbell added that a lead and pregnancy workgroup with outside experts is needed to legitimize ACCLPP's efforts and produce a more definitive product. From a logistical standpoint, a workgroup is also necessary to ensure that the literature is reviewed and draft reports are developed on a timely basis.

Assuming that a vote is taken to approve the formation of the lead and pregnancy workgroup, ACCLPP was divided on whether the draft charge should be shortened or expanded. On the one hand, Dr. Handy advised that the draft charge be narrowed to ensure meaningful information and useful products are generated. On the other hand, Dr. Leighton suggested that the draft charge be broadened to include making recommendations on medical management of pregnant women with EBLLs and advising providers to consult with a clinical center to obtain assistance in decision-making. Dr. Banner responded to this dilemma by describing the five key areas of the draft charge: appropriate individuals to screen, frequency of follow-up testing, actions to address environmental exposures, treatment strategies, and follow-up of the child. He added that the workgroup should not be charged with conducting a basic science review of low-level lead exposures in pregnant women

Dr. Binns remarked that to avoid duplicating efforts, activities of the ACCLPP workgroup should be based on those of the NYC expert panel. She also noted that the literature on spontaneous abortions and risks from a BLL of 5 µg/dL during pregnancy should not be ignored. Instead of solely focusing on studies of pregnant women with BLLs $\geq$45 µg/dL, the literature should be reviewed as a whole body of evidence. Ms. McLaine emphasized the need for the workgroup to use ACCLPP's recommendations on case management of children as a primary data source. Dr. Towers cited additional data sources for the workgroup to use, including previous meta-analyses, *Put Prevention Into Action* recommendations sponsored by the Health Resources and Services and Administration, and documents describing the basis of these recommendations. Dr. Handy suggested that the workgroup consider patient education as a priority during its deliberations.

Dr. Stephens moved to form the ACCLPP Lead and Pregnancy Workgroup and accept the draft charge; Dr. Hoffman seconded the motion. Dr. Lynn amended the motion to formally add the following items to the draft charge: medical and environmental management of pregnant women, follow-up of infants and children with mothers who have EBLLs, and recommendations for health education needs in this field. **With no further discussion, ACCLPP unanimously passed the motion as amended.**

Drs. Brown and Campbell described next steps to advance the workgroup's activities. The workgroup will consult with the NYC expert panel since this group has already completed a literature review of lead and pregnancy; assistance from Dr. Leighton will be solicited in this effort. An ACOG representative will be recruited to serve on the workgroup. Drs. Leighton and Stephens have volunteered to serve on the workgroup, but ACCLPP should submit additional names of potential workgroup members to Dr. Campbell. The following information will be distributed to ACCLPP by e-mail for review and comment: names of proposed workgroup members, slides of the lead and pregnancy presentations, and a draft outline or table of contents listing the major headings of issues the workgroup will address. The workgroup is expected to be convened and produce a progress report at the next ACCLPP meeting.

New ACCLPP Business

Dr. Lynn requested that ACCLPP place the following item on a future agenda. Minimal emphasis has been placed on interpreting and responding to EBLLs in adolescents 8-18 years of age; no guidance has been developed on this issue to date. EBLLs of 25-35 µg/dL have been identified among persons in this age range in Alaska who serve on rifle teams and practice shooting in indoor ranges. Alaska will soon summarize its investigations, but continues to struggle with providing sound guidance to clinicians who serve these patients. Dr. Brown confirmed that a presentation on this issue can be made at a future meeting to determine whether ACCLPP should take action. She mentioned that NIOSH and other researchers with expertise in EBLLs among adolescents, police officers and other groups resulting from rifle ranges can serve as presenters.

Dr. Brown announced that ACCLPP's charter has been amended to include a parent of an affected child or a representative of the affected population as a member. CDC will submit three potential candidates to the HHS Secretary for consideration, but selection of the new member is at the discretion of the HHS Secretary. Dr. Keyvan-Larijani recalled that ACCLPP drafted a letter to the HHS Secretary to ask the Department of State to adopt lead testing of refugee children entering the United States. He requested a status report of this activity. Dr. Campbell mentioned that CDC provided an update on this issue at a previous meeting and informed the members of efforts to distribute ACCLPP's letters to various participating agencies. However, she agreed that another status report on lead testing of immigrant, refugee and adopted children entering the United States should be given at a future meeting.

Dr. Ho inquired about ACCLPP's role in issuing guidance on the developmental support for children whose BLLs have declined. Dr. Campbell reported that medical management as well as developmental assessment and interventions were covered in

ACCLPP's published case management document. Ms. McLaine noted that despite the case management recommendations, minimal research has been conducted in the context of useful educational methodologies and educational treatment. She raised the possibility of ACCLPP revisiting this issue over the next year to obtain additional input from outside researchers. Dr. Binns added that the case management document will not be useful or known to school personnel. As a result, relevant text from the document should be extracted and published in the school literature to highlight the key concepts of lead poisoning for school personnel. Based on these comments, Dr. Brown confirmed that LPPB will highlight developmental support for children whose BLLs have declined as an issue to address over the next two years.

Public Comment Period

The Chair opened the floor for public comments; no attendees responded.

Closing Session

The attendees joined Dr. Brown in applauding LPPB staff members, Ms. Crystal Gresham, Ms. Janet Henry and Mr. Penn Jacobs, for their tremendous efforts in making logistical arrangements for a successful meeting. The next ACCLPP meeting will be held on October 19-20, 2004. Background materials distributed to ACCLPP for the meeting are collectively appended to the minutes in Attachment 1.

With no further discussion or business brought before ACCLPP, Dr. Campbell adjourned the meeting at 12:06 p.m. on March 10, 2004.

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

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Date

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