DEPARTMENT OF HEALTH AND HUMAN SERVICES

and

CENTERS FOR DISEASE CONTROL AND PREVENTION

convene the

ADVISORY COMMITTEE ON CHILDHOOD LEAD POISONING PREVENTION

Atlanta, Georgia
October 19-20, 2004

RECORD OF THE PROCEEDINGS

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ADVISORY COMMITTEE ON
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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 October 19-20, 2004 at the Doubletree Hotel-Buckhead in Atlanta, Georgia.

Opening Session

Dr. Carla Campbell, the ACCLPP Chair, called the meeting to order at 8:44 a.m. on October 19, 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. Walter Handy, Jr.
Dr. Ing Kang Ho
Ms. Valarie Johnson
Dr. Jessica Leighton
Ms. Sally Odle
Dr. George Rhoads
Dr. Catherine Slota-Varma
Dr. Wayne Snodgrass
Dr. Kevin Stephens, Sr.
Dr. Kimberly Thompson
[via conference call]

Designated Federal Official
Dr. Mary Jean Brown,
Executive Secretary

***Ex-Officio*/Liaison Members**
Dr. Benjamin Gitterman (APHA)
Ms. Anne Guthrie (AHH)
Dr. Kristina Hatlelid (CPSC)
Dr. Ezatollah Keyvan-Larijani (CSTE)
Ms. Patricia McLaine (NCHH)
Ms. Jacqueline Mosby (EPA)
Dr. Routt Reigart II (AAP)
Dr. Walter Rogan (NIH)
Dr. Phyllis Stubbs-Wynn (HRSA)

CDC Representatives
Ms. Bernadette Burden
Ms. Crystal Gresham
Ms. Janet Henry
Mr. Rob Henry
Ms. Pamela Holland
Dr. David Homa
Mr. Penn Jacobs
Mr. Jeff Jarrett
Ms. Monica Leonard
Mr. David Mullen
Dr. Nimia Reyes
Ms. Renee Ross
Ms. Nikki Walker
Ms. Lee-Yang Wong

Presenters and Members of the Public
Mr. Stic Harris (Georgia Division of Public Health)
Reuben Koclyk, Esq. (Arnold & Porter)
Jane Luxton, Esq. (King & Spalding)
Dr. Tracey Lynn (U.S. Department of Agriculture)
Mr. Robert Putnam (CITE)

Dr. Campbell made two announcements before opening the floor for the first presentation. The *Final Report of the Evaluation of the U.S. Department of Housing and Urban Development (HUD) Lead-Based Paint Hazard Control Grant Program* was distributed in the meeting binders and is also available on the HUD web site. Members are welcome to provide Dr. Campbell with names of potential candidates to fill the current vacancy on ACCLPP.

Dr. Mary Jean Brown, the Lead Poisoning Prevention Branch (LPPB) Chief and ACCLPP Executive Secretary, conveyed that members with a real or perceived conflict of interest on any agenda item are responsible for recusing themselves from voting or participating in the deliberations. She was extremely pleased to announce that LPPB submitted its first annual report to Congress on childhood lead poisoning prevention activities for FY'01-FY'02. The document was distributed to ACCLPP for review.

Update on LPPB Activities

Dr. Brown provided a status report on LPPB's current and future projects. At the agency level, CDC is the nation's prevention agency with a mission to promote health and quality of life by preventing and controlling disease, disability and injury. At the center level, the National Center for Environmental Health (NCEH) promotes health and quality of life by preventing and controlling disease, injury and disability related to interactions between individuals and their environments outside the workplace. At the branch level, LPPB is attempting to eliminate childhood lead poisoning as a public health problem by 2010.

LPPB is housed in NCEH's Division of Environmental Hazards and Health Effects. NCEH recently consolidated with the Agency for Toxic Substances and Disease

Registry (ATSDR) and was renamed to NCEH/ATSDR. LPPB uses its Administrative, Program Services, and Epidemiology and Surveillance Teams to conduct the following activities. State and local health departments and tribal health authorities are assisted in building capacity to prevent childhood lead poisoning in the respective jurisdiction. Solid support is given in the following areas: state and national childhood lead poisoning surveillance programs; public and private lead poisoning prevention education initiatives; program evaluation and other childhood lead poisoning prevention program (CLPPP) quality assurance activities; primary prevention initiatives; and laboratory capacity, technology and quality control.

Partnerships are established to control lead hazards in high-risk communities. Blood and environmental lead analysis technologies and laboratory performance are supported at both national and international levels. Policy statements and guidance documents are developed. Financial support, technical assistance and consultation are provided to state and local CLPPPS. Childhood lead poisoning surveillance is implemented and data are reported from a national perspective. Public and private partnerships are built to improve prevention capacity. Childhood lead poisoning prevention education is supported and conducted. Applied research activities are performed, but on a limited basis due to LBBP's budget constraints. However, the U.S. Environmental Protection Agency (EPA) will soon announce a grant for new and innovative strategies to identify and prevent lead poisoning in subgroups of the population that may have been overlooked in the past.

LPPB requires grantees to take several actions in documenting a significant lead poisoning problem and demonstrating capacity to address the issue in a holistic manner. Solid efforts must be made to develop a childhood lead poisoning elimination plan for the particular jurisdiction. Children at highest risk must be targeted for screening and emphasis must be placed on primary prevention. For example, a state that does not perform screening and has no knowledge of whether children in the area are exposed to lead would not meet LPPB's funding criteria. Surveillance capacity must be evidenced and a system must be available to provide case management to children identified with elevated blood lead levels (EBLLs). Strategic partnerships must be developed with key agencies and organizations.

Protective policies should be established to prevent retaliatory eviction of lead-poisoned children and ensure lead paint abatement workers are trained and certified. Expertise in program evaluation must be demonstrated. LPPB currently funds 42 CLPPPs in 36 states and six cities and is now collaborating with the state of Mississippi to increase its ability to successfully compete during the next funding cycle. LPPB will award ~$31 million annually during the three-year project period that began in FY'03; the new funding cycle will begin in FY'06. LPPB's funding has been fairly stable over the past seven years.

LPPB is extensively focusing on childhood lead poisoning prevention plans and is pleased to announce that many jurisdictions throughout the country are making solid commitments to this effort. Health, housing and environmental agencies, community organizations and universities with potential responsibility for preventing lead poisoning are involved in developing elimination plans. The plans are categorized into five elements with long-term goals, objectives and activities as well as clearly defined roles and responsibilities of agencies.

The long-term goals of the five plan elements are as follows. 1) For screening and surveillance, efforts should be made to ensure that all children at risk are screened for lead poisoning and statewide surveillance data are used in the most effective manner. 2) For primary prevention, families, communities and professionals should be provided with the necessary knowledge and tools to protect children from lead poisoning. 3) For lead source identification and reduction, a surveillance database should be developed, lead source identification activities should be coordinated, and lead hazard remediation efforts should be targeted to minimize childhood exposure to all lead hazards.

4) For policy and legislative development, regulations and policies should be established at state and local levels to support the creation and maintenance of lead-safe housing for families with young children. 5) For resources, additional public and private dollars should be leveraged for primary prevention activities, lead source identification and remediation efforts. LPPB is taking several actions to improve data collection, transfer and quality. Collaborative efforts are being undertaken with internal CDC partners to develop a web-based tracking system for states. A lead surveillance report was published in 2003, but the document will be updated with new data within the next six months. Evaluation activities have increased as well.

LPPB is focusing on mechanisms to link different data sets to fill gaps. Census data provide information on age of housing, rental properties, race/ethnicity and other risks for children with EBLLs. Tax assessor data are being used at the address level to obtain the name of the property owner, price of sold properties, and number of units in a particular property. Tax assessors in some cities also maintain data on the quality of properties. Chicago, New York, Rhode Island, Wisconsin and other states are linking BLL testing data and Medicaid encounter data. LPPB should not pay for screening children who are eligible for or enrolled in Medicaid because Medicaid dollars should be allocated to this effort, while LPPB funding should be used to target non-Medicaid children who are being missed.

LPPB is using geographic information systems (GIS) to provide state and local CLPPPs with guidance in assessing and directing childhood lead poisoning prevention activities. Mapping applications produced by this program have been extremely effective as an

educational tool for healthcare providers, decision-makers, legislators and remediation contractors. The program also uses screening, tax assessor and census data to direct elimination efforts. Controlling or eliminating lead hazards in addresses that result in multiple poisonings could potentially save $45,000 in lifetime earnings for children who move into these properties over the next ten years. LPPB expects to publish a report from the GIS initiative in January 2005.

LPPB is engaged in several activities with its partners. The Alliance for Healthy Homes (Alliance) published an easy-to-read guide in June 2004 to assist program managers, state and local health departments and HUD field offices in overcoming barriers to data sharing. The document focuses on requirements established by the Health Insurance Portability and Accountability Act of 1996 for lead-related data and delivers a basic message that privacy considerations should not prevent children from accessing lead-safe housing. The Alliance developed and published the report because many state and city health departments were unwilling to provide housing agencies with addresses due to medical confidentiality and other privacy concerns.

HUD is allocating $611 million to 265 state and local agencies that are qualified to receive the funding for lead hazard abatement. A review of data in three cities underscores the need for these grants. In Cleveland, Ohio; Jacksonville, Florida; and New Orleans, Louisiana, 71-1,000 HUD subsidized properties accounted for 199-3,000 children with EBLLs over periods of three to 15 years. The number of children with BLLs $\geq$10 µg/dL ranged from 1,683-30,715 in the three cities over the time periods; 33%-39% of these children lived in addresses where more than one child was identified. The number of addresses where more than one child was identified ranged from 18%-35%.

CDC, EPA and HUD are partnering in "Operation Clean House" to address these problems by enforcing sections of Title X. Sections 1012 and 1013 are lead-safe housing rules for properties with a HUD subsidy and require abatement of public and Indian housing, multi-family Section 8 properties and the voucher program if a child is identified with an EBLL. CDC will review and improve surveillance data in collaboration with the state or local health department and submit the refined data to HUD to identify subsidized properties and enforce the lead-safe housing rules.

Section 1018 requires property owners to disclose information about lead poisoning and lead paint in privately-owned properties. EPA and HUD will jointly review privately-owned housing to determine whether owners have fulfilled disclosure requirements. Non-compliant property owners will have an opportunity to voluntarily settle in lieu of paying a fine. The disclosure enforcement initiative has been extremely effective in de-leading 160,000 units throughout the country and generating a considerable amount of funding. The three agencies will launch the collaborative effort over the next year in 10

to 12 cities that have a significant lead problem, geographic diversity and capacity to address these issues. The sites include Baltimore, Birmingham, Chicago, Cleveland, Detroit, Hartford, Houston, Jacksonville, Los Angeles, Philadelphia, St. Louis and Syracuse. CDC will evaluate the efficacy and efficiency of the project. All three agencies will continue to strongly emphasize the need to make solid linkages between health and housing agencies at the local level.

LPPB acknowledges the need to consider sources other than lead-based paint due to the public health impact of these sources collectively. Several actions can be taken to facilitate this effort. Communities at risk for other lead sources should be identified. Lead poisoning prevention activities should be incorporated into health and community services targeted to families at high risk of exposure from cultural or traditional practices, medicines or cosmetics that may contain lead. Current and new non-essential uses of lead should be controlled or eliminated, particularly in toys, food implements and cosmetics.

ACCLPP members urged LPPB to explore the possibility of screening uninsured children. Initial steps can be taken in this initiative if CLPPPs partner with emergency rooms and the Women, Infants and Children (WIC) Program to increase screening. These settings frequently serve as medical homes for uninsured children. CLPPPs could also survey healthcare providers to identify barriers to testing and then use this information to educate physicians. However, ACCLPP noted challenges in implementing this initiative. Most notably, states are mandated to screen Medicaid children, but often change eligibility requirements to re-categorize this population as "uninsured." ACCLPP members encouraged LPPB to incorporate lead abatement rather than lead hazard reduction into primary prevention activities for properties that result in multiple poisonings of children.

Non-Residential Lead Exposure Sources

Dr. David Homa of LPPB described other sources of lead exposure that were recently reported to LPPB. The most common exposure sources in the United States are leaded paint in homes, soil and dust contaminated by leaded paint, past leaded gasoline and industrial emissions. Other sources of lead exposure are from water, air, food, firearms and cosmetics; herbal and folk remedies; smelting, battery recycling, bridge work, radiator repair and other occupations; stained glass, fishing weights, furniture refinishing, ceramics and other hobbies; and pottery, cookware and dinnerware.

Other exposure sources are diverse, based on cultural beliefs and traditions, difficult to regulate, and important for certain sub-populations. Traditional ethnic foods and remedies are particularly challenging to regulate. LPPB receives reports of other

sources of lead exposure from several internal venues. Articles on lead exposure are forwarded to LPPB for review and comment prior to submission for publication in CDC's *Morbidity and Mortality Weekly Report* (*MMWR*). Reports are provided to LPPB with a request to conduct further investigation through an Epi-Aid. Centers, institutes and offices throughout CDC provide LPPB with information on other lead sources as well. External data sources include LPPB grantees, other federal agencies, non-governmental organizations, academic investigators, advocacy groups and the general public.

Examples of lead poisoning from other sources are summarized as follows. Ayurveda is a traditional form of medicine that is practiced in India and other South Asian countries. Ayurvedic medications are created with both standardized and non-standardized formulations and may contain herbs, minerals, metals or animal products. Some Ayurvedic medications contain lead from the manufacturing process, but lead may also be intentionally added due to a perceived therapeutic benefit. Pushpadhanwa is an Ayurvedic medication recommended for fertility problems that contains mercury and 7%-8% lead.

Dartmouth Medical Center physicians proposed a case report to the *MMWR* in May 2003. The subject was a female 37 years of age with rheumatoid arthritis, diffuse abdominal pain, nausea and vomiting six days in duration, microcytic anemia, an identified BLL of 81 µg/dL, and a greatly elevated zinc protoporphyrin (ZPP) level of 286 µg/dL. The case history showed that the subject took five different Ayurvedic medications containing 60-17,000 ppm of lead. The *MMWR* submitted the case report to LPPB for evaluation and comment. LPPB concluded that a new report could reinforce messages of earlier articles published in the *MMWR* from 1984-2002 on lead poisoning from traditional remedies.

The California Department of Health reported two similar cases to the *MMWR* involving Ayurvedic fertility medications. No other home or occupational lead sources were identified in either of the cases. A female 31 years of age presented in 2003 with nausea, vomiting, lower abdominal pain, severe microcytic anemia, an initial BLL of 112 µg/dL, and a greatly elevated ZPP level >400 µg/dL. The case history showed that the subject took nine different Ayurvedic medications containing 21-73,900 ppm of lead. She presented ~2 weeks after a miscarriage and had discontinued use of the medications one month prior to the miscarriage due to an abnormal ultrasound. A male 34 years of age presented in 2003 with back pain, abdominal pain and a BLL of 80 µg/dL. The case history showed that most of the ten different Ayurvedic preparations taken by the subject were not labeled and contained 36-78,000 ppm of lead.

The *MMWR* suggested that the California and New Hampshire cases be combined, but LPPB became aware of five similar cases in New York City, three in Massachusetts and

one in Texas between 2000-2003. Many of these cases were discussed on CDC's Adult Blood Lead Epidemiology and Surveillance (ABLES) listserve. The cases involved both males and females 19-62 years of age with BLLs ranging from 27-100 µg/dL. The subjects took Guglu, Sundari Kalp and Jambrulin for arthritis, diabetes and menstrual cramps. Upon testing, the medications were found to contain 14,000-96,000 ppm of lead. LPPB decided to incorporate these cases into the report of the California and New Hampshire cases.

LPPB coordinated with state and city partners to compile, combine and edit the case reports. An Epidemiologic Information Exchange (Epi-X) posting was published in September 2003 with the exception of the Texas case, but a full report of all cases was published in the *MMWR* in July 2004. The *MMWR* article was accompanied by an editorial that emphasized the need for culturally sensitive education and outreach to communities. In May 2003, LPPB was contacted by a university investigator in California who had established a pilot prenatal screening program for lead in a county health department. An evaluation of the first six months of the program indicated that ~13% of women screened at one clinic had BLLs $\geq$10 µg/dL. All of the patients were from one region in Mexico and may have developed EBLLs by consuming dried grasshoppers. An analysis showed that this source can contain up to 450 ppm of lead. The California clinic offered educational and nutritional interventions to women identified with BLLs $\geq$10 µg/dL and expressed an interest in publishing an *MMWR* report.

LPPB was challenged in developing the *MMWR* article because CDC had not established a policy statement regarding the potential benefits of prenatal lead screening or the efficacy of interventions for women identified with EBLLs. As a result, an editorial was drafted to emphasize primary prevention and identification of lead sources in household. Statements to endorse a prenatal lead screening program or its interventions were not included. *MMWR* decided not to publish the report due to the lack of CDC policy in this area. Moreover, publication could imply that CDC endorsed prenatal lead screening programs and interventions. LPPB learned that the *MMWR* is not inclined to publish articles on topics for which CDC has not developed policy guidance. This experience illustrates the importance of ACCLPP's activities and recommendations to LPPB programs.

Other lead sources reported to LPPB are outlined as follows. Litargirio is used by Dominicans as a deodorant and treatment for fungal infections and burns. This product can contain lead and was reported by Rhode Island and New York City, published in an Epi-X posting and investigated through an Epi-Aid. LPPB and the Rhode Island Department of Health are currently developing a full *MMWR* report of litargirio. In 2003, a child four years of age ingested a toy necklace in Oregon that contained 39% lead, was manufactured in India and distributed throughout the United States. This event led to the recall of 1.4 million necklaces and was the largest voluntary recall in the history of

the Consumer Products Safety Commission (CPSC). The case was published in both the *MMWR* and *Pediatrics* in 2004.

In 2002-2003, a child 18 months of age in New York City was identified with a BLL of 23 µg/dL from ceramic dinnerware. A comprehensive investigation of the home showed that the dinnerware was manufactured in France and leached 29.6 µg/dL. This level exceeded the Food and Drug Administration (FDA) standard of <3 µg/dL. The case was published in the *MMWR* in July 2004. All of these cases demonstrate diverse challenges in identifying and obtaining reports of other lead exposure sources in populations. LPPB is aware of the critical need to develop a more coordinated and systematic approach to track other lead sources and outcomes.

Mr. David Mullen of LPPB discussed efforts that are being made to eliminate and control non-residential lead sources. Leaded house paint as well as dust and soil contaminated with paint are the most common sources of lead exposure for young children in the United States. However, ~33% of childhood lead poisonings are associated with exposure to sources other than residential lead paint in some parts of the country. Other lead sources can contain very high lead concentrations and include pottery from countries without strong lead control; lead cosmetics and topical medicines produced in foreign countries; consumer products with negligently or intentionally high concentrations of lead; and occupational sources and hobbies.

From 1988-2003, child lead poisonings from consumer products containing lead were reported with BLLs ranging from 5-238 µg/dL. Products ingested in these cases included a lead curtain weight, ceramic lead glaze, a lead pocket watch, lead sinkers, lead shot from a broken toy, lead pellet from a pellet gun, and a lead medallion pendant from a necklace. In 2003-2004, litargirio was found to have as much as 40% of lead and a name brand sidewalk chalk was found to contain lead as well. From 1987-2004, child lead poisonings from foods containing lead were reported with BLLs ranging from 15-70 µg/dL. Foods consumed in these cases included a homemade beverage from a ceramic jug; water or apple juice from containers with lead soldered seams and brass fittings; infant formula from a samovar lead soldered urn; Tamarindo jam; a bright orange powder containing lead; and candies containing lead sold in Hispanic communities.

CDC is aware of the critical need to create a tracking system that will identify locations of alternate sources of lead exposure and determine the degree of harm caused by these sources. For example, CPSC issues voluntary recalls of consumer products that contain lead, but does not enforce regulations banning the manufacture of these products. FDA supports research to determine risks to children who consume foods that contain lead, but does not prohibit the sale of these products. Overall, federal policies do not control or eliminate present and future harm to children because lead-

based consumer products and foods are still available during CPSC's voluntary recalls and FDA's studies.

In an effort to address this problem, CDC will convene a federal interagency task force meeting in December 2004. The agencies will review non-essential sources of lead poisoning, discuss current federal policies, and create a consistent and uniform public policy to properly document non-essential lead sources. The new initiative also calls for clearly defined roles of agencies involved in lead control and the design of a surveillance system that provides solid information on the frequency, location, method of contamination and risk of harm to children from non-essential lead sources. Consideration is being given to involving the Federal Bureau of Investigation in the interagency task force to specifically address retained bullets, but all federal agencies are expected to comply with the new public policy in an effort to eliminate or control children's exposure to non-traditional sources. After the initial meeting in December 2004, LPPB may invite the Mexican Consulate to join the task force to provide guidance on local practices in Mexico.

ACCLPP agreed that minimal attention has been given to non-residential lead exposure sources at state and local levels. The products and diverse cultural populations that use other sources are not formally or regularly monitored, but non-traditional sources collectively may now be the leading cause of severe lead poisoning in the United States. ACCLPP and other advisory groups can play an important role in assisting state and local programs to develop effective strategies, identify lead hazards and address these problems. Solid linkages should also be made with specific communities that use non-essential lead sources, but cultural anthropologists or other persons with expertise in cultural sensitivity must be extensively involved in community-based efforts. For example, investigators may view the consumption of dried grasshoppers as pica behavior, but the Mexican population considers this product to be an expensive delicacy.

In addition to using ACCLPP and other advisory groups, CDC should also explore the possibility of collaborating with the lay press of specific cultural populations to disseminate and widely publicize information on lead hazards from other sources. For example, information on Ayurvedic medications that contain lead could be given to the Indian physician's association and also published in two national Indian newspapers. These groups are more likely than CDC or the *MMWR* to deliver culturally sensitive messages to communities, but LPPB should still serve as the authoritative source of information on lead. LBBP could create a web site with a list and illustrations of other lead sources as well as descriptions of cultural groups that use specific products. LPPB could also facilitate the development of a national registry for the public to report lead poisonings from non-essential sources and review other cases. However, LPPB should be mindful of the fact that a significant percentage of the population is not literate. Low-

tech strategies should also be applied to disseminate information on non-essential sources of lead.

ACCLPP pointed out that information on lead poisoning from non-essential sources has been traditionally obtained through isolated reports from cultural and ethnic populations. As a result, ACCLPP was extremely supportive of LPPB's plans to convene the interagency task force and described several areas where the new group can play a critical role. Awareness of cultural and ethnic practices among specific groups should be raised. Rules regarding the importation of food and nutritional supplements into the United States should be enforced. Children of illegal immigrants with no access to healthcare should be tested for lead poisoning. Data should be obtained on the background contamination of dietary supplements and vitamins. ACCLPP noted that the task force will be challenged in developing the surveillance system because non-traditional sources of lead are deeply incorporated into and strongly practiced by cultural groups.

Dr. Brown addressed ACCLPP's comment about the surveillance system by announcing that the interagency task force will evaluate whether the North American Free Trade Agreement or Toxic Substances Control Act can be used to regulate these imports. These agencies will take legislative actions to create and enforce federal policies on controlling or eliminating other sources of lead in the United States, but success of this effort will largely depend on political will of the particular country.

Status Report by the Lead and Pregnancy Workgroup (LPWG)

Dr. Jessica Leighton, the LPWG Chair, provided an update on LPWG's activities since the previous ACCLPP meeting. The members formally represent ACCLPP; CDC; the American Academy of Family Practitioners; American College of Obstetrics and Gynecology; American Academy of Pediatrics; Council of State and Territorial Epidemiologists; and other experts in the pregnancy and childhood lead poisoning prevention fields. LPWG convened a meeting and conference call in July and September 2004, respectively, to more clearly define its charge. LPWG will summarize the evidence to issue clinical and public health recommendations in the following areas: prevention of lead exposure for women of child-bearing ages and pregnant and lactating women; risk assessment and screening of pregnant women; medical, public health and environmental management; breast feeding; follow-up of infants and children of mothers with EBLLs; and further research and health education needs in the field.

LPWG formed three subgroups to review the literature and develop recommendations to ensure the members were not overburdened with tasks. Subgroup 1 will take the following actions to focus on prevalence, risk and screening. The literature will be

reviewed on the distribution of BLLs and other measures of lead body burden in women of childbearing age, pregnant women at various gestational ages, lactating women and newborns. Data on risk factors and sources of EBLLs in pregnant and lactating women will also be evaluated. The literature on relationships between maternal BLLs, bone lead levels and newborn BLLs as well as pregnancy and postpartum BLLs will also be assessed. Subgroup 1 will make recommendations on when to screen pregnant women for lead poisoning, triggers that may predict which women to screen, and culturally sensitive interventions to reduce exposure to potential sources of lead.

Subgroup 2 will take the following actions to focus on maternal, pregnancy and child outcomes. The literature will be reviewed to assess the impact of EBLLs on spontaneous abortion, stillbirth and other fertility issues; pregnancy-induced hypertension and other maternal health issues; pre-term delivery, gestational age, birth weight, birth length, head circumference and other pregnancy outcomes; neurodevelopmental outcomes due to prenatal exposure; and behavioral outcomes due to prenatal exposure to lead at various BLLs. Subgroup 2 will make recommendations on guidance medical providers should give to women of child-bearing age about delaying pregnancy and advice to pregnant women about potential outcomes when BLLs are elevated.

Subgroup 3 will take the following actions to focus on management, treatment and other interventions. The literature will be reviewed to evaluate the amount of breast milk transmitted from mother to infant; benefits and hazards of breast-feeding when BLLs are elevated; effectiveness of nutritional supplementation during pregnancy and lactation; and indications, contraindications and adverse effects of chelation on pregnant women, the fetus and neonate. Subgroup 3 will make recommendations on the follow-up testing schedule at various BLLs for pregnant and lactating women and the neonate; the BLL at which women should not breast-feed; appropriate nutrition counseling or nutritional supplements; use of chelating agents; and various BLLs at which public health agencies should intervene.

LPWG intends to recommend further prospective studies if the literature reviews reveal that current data are not sufficient to clearly define the problem. LPWG estimates that its tasks will be completed on the following dates: literature reviews in March 2005; draft summary of the literature reviews in September 2005; subgroup recommendations in December 2005; draft report on the recommendations in June 2006; and final report of the literature reviews and recommendations in December 2006. Dr. Leighton announced that ACCLPP members are welcome to join LPWG.

Dr. Nimia Reyes of LPPB reported that LPWG extensively reviewed two previous activities to consider options in fulfilling its charge. Literature review methods used by the Mt. Sinai Workgroup (MSWG) and ACCLPP's Adverse Health Effects of BLLs <10

µg/dL Workgroup (<10 WG) are outlined as follows. The <10 WG was charged with determining whether available evidence supports negative associations between health indicators and children's BLLs <10 µg/dL and if observed associations are likely to represent a causal effect of lead and health. The <10 WG did not develop policy recommendations or address policy issues.

MSWG was charged with assessing the impact of lead exposure during pregnancy on maternal, fetal and infant health outcomes; addressing issues related to the identification and management of lead-exposed pregnant women; and making clinical and public health recommendations for New York City. The <10 WG fulfilled its charge by establishing criteria for studies; identifying issues of relevance to make causal inferences from observed associations; reviewing articles by members and other authors; and obtaining expert assistance from Batelle Memorial Institute. MSWG fulfilled its charge by identifying clinical questions; searching the literature based on these issues; and reviewing articles by members and other authors. Based on these efforts, LPWG could fulfill its charge by building on and updating the MSWG report, reviewing more recent data, identifying gaps and making recommendations.

The <10 WG used its members, ATSDR's 1999 lead toxicological profile, Medline and Toxfile as data sources; MSWG used its members, Medline, Cochrane Reviews, Wilson Omnifile Full Text Mega and Reprotox. Based on these efforts, LPWG's data sources could include its members, Medline, ToxNet, ReproRisk, ABLES, National Health And Nutrition Examination Surveys (NHANES), projects currently funded by the National Institutes of Health (NIH), and other sources as needed, particularly for socio-cultural issues.

The <10 WG established specific criteria to select research to review, including studies published in English; studies using graphite furnace atomic absorption spectrometry or anodic stripping voltammetry to measure BLLs; studies showing an association between children's BLLs and IQ or general cognitive index; or studies showing an association between children's BLLs <10 µg/dL and health outcome. Selection criteria used by MSWG included data published or translated into English; human studies; recent articles from 1980-present; studies with actual lead measurements to detect exposure; cohorts of pregnant women or fetuses; and studies of relevance to the charge. MSWG's exceptions to these criteria were to review animal studies if no human data were available and evaluate research in populations other than pregnant women or fetuses if the research was relevant. Based on these efforts, LPWG's selection criteria to review data could include human studies published in English with actual lead measurements; cohorts of women of childbearing age, pregnant and lactating women, fetuses, infants and children; and studies of relevance to the charge.

The <10 WG searched the literature by reviewing ATSDR's 1999 lead toxicological profile; using Dialog to conduct a computerized search of databases; identifying citations in articles; evaluating articles identified by members; assessing the relevance of titles and abstracts; obtaining and reviewing relevant articles; and abstracting relevant studies. MSWG reviewed the literature by searching databases with selected terms; identifying citations in articles; evaluating articles identified by members; assessing the quality of articles; eliminating articles by title; reviewing abstracts for relevance; obtaining and reviewing relevant articles; and abstracting relevant studies. Based on these efforts, LPWG could review the literature by searching databases with selected terms; identifying citations in articles; evaluating articles identified by members; reviewing titles and abstracts for relevance; obtaining and distributing relevant articles to subgroups; and assessing articles subgroups have reviewed and abstracted.

The <10 WG used several factors to abstract studies, including study location, sample size, ages at which BLLs and outcomes were measured, blood lead distribution, and other variables relevant to the charge. Factors applied by MSWG included the study's purpose, objective, methods, results, conclusions, quality measure, population, outcomes and reviewer's comments. Based on these efforts, LPWG could abstract studies based on the study's purpose, objective, methods, location, population, sample size, BLLs measured, outcomes assessed, results, conclusions and reviewer's comments. Dr. Reyes conveyed that LPWG welcomes input from ACCLPP on the options proposed to fulfill its charge.

ACCLPP members expressed conflicting views about LPWG's membership. On the one hand, Dr. Banner previously objected to LPWG's composition, but his concerns were not presented to ACCLPP for a discussion and formal vote. LPWG members were selected during conference calls in which the full ACCLPP did not participate. For example, Dr. Wayne Snodgrass is a new ACCLPP member with an extensive background in drug transfer, toxicology and other neonatal issues, but is not an LPWG member. Dr. Banner expressed the concern that persons who serve as both LPWG members and authors of pivotal research that will be used to formulate recommendations should be excused from the decision-making process.

Dr. Banner felt that LPWG will be unable to perform an effective, critical and unbiased literature review if the authors are present during these discussions. For example, LPWG may be uncomfortable in noting that a particular study does not address non-traditional lead exposures and other more recent issues if the author is present. He also stated that involvement of the authors in the literature review may ultimately weaken ACCLPP's credibility, particularly since workgroup members are not required to disclose financial or other conflicts of interest. Moreover, he believes ACCLPP members are listed as "authors" of workgroup products, but this designation may be inaccurate since the members do not actively participate in workgroup activities, are not

involved in the actual development of documents, and do not have editorial authority over the content.

On the other hand, Dr. Campbell emphasized that LPWG was formed under ACCLPP's standard process of establishing workgroups. ACCLPP does not traditionally vote on the composition of workgroups; instead, members are invited to volunteer or submit names of other potential candidates. LPWG members were selected by reviewing the literature and identifying authors who had developed solid papers on lead and pregnancy issues. ACCLPP applies a transparent and inclusive process of allowing members, liaisons and *ex officios* to regularly review, discuss and provide input on workgroup recommendations. ACCLPP members must approve final workgroup documents through a formal vote before CDC takes action. Although the lead and pregnancy activities are underway, LPWG still welcomes additional participation from new ACCLPP members and outside experts.

Similar to all other workgroup documents, ACCLPP will attempt to reach consensus on LPWG's final report. The document will still be submitted to CDC for publication if a majority vote is obtained, but a statement can be included in a preface to note that some members opposed the document and explain the rationale for the disapproval. ACCLPP reports that are submitted for publication must undergo CDC clearance, but substantive changes are not typically made during this process.

If major revisions are proposed during this process, the ACCLPP Chair, Executive Secretary and voting members, if necessary, will review and discuss the recommended changes and propose solutions. ACCLPP can choose to publish its guidance as an *MMWR* article, a free-standing CDC document or a paper in a non-CDC journal. Dr. Campbell pointed out that several actions can be taken to resolve Dr. Banner's objection to LPWG's composition. For example, the ACCLPP Executive Secretary could advise all LPWG members to be aware of potential conflicts of interest. Minutes of LPWG meetings and conference calls highlighting key discussion topics could be produced and distributed to ACCLPP.

Several ACCLPP members strongly disagreed with Dr. Banner's suggestion to exclude authors of sentinel studies from LPWG's activities. They felt 1) expertise in the lead and pregnancy field is quite limited and authors of key articles should be involved in all LPWG discussions to provide critical insights about study methods, limitations and applicability to other research; 2) this input will be particularly crucial since LPWG members represent expertise in pregnancy, lactation, EBLLs and other relevant issues; 3) LPWG will follow the standard and transparent process of regularly presenting updates to ACCLPP for review and guidance on literature review results, references and iterations of draft documents; and 4) the diverse membership and ACCLPP's

ongoing input will not allow a single individual to influence LPWG's recommendations or other outcomes.

ACCLPP members suggested other activities for LPWG to consider while refining its charge. Lead may be mobilized from the bone during pregnancy in females who were exposed during childhood. This effect may result in low birth weight and other adverse pregnancy outcomes. As a result, women of childbearing age with previous lead exposure should be specifically identified as an LPWG target population and incorporated into the literature review. LPWG is proposing to limit its literature review to human studies, but animal data should be evaluated as well. These studies can provide answers on issues related to teratogenicity as well as prenatal and postnatal exposures to lead. Recommendations by the subgroups should include advice to females to increase calcium intake during their teenage years due to the accumulation of bone calcium during this time period.

Dr. Brown made follow-up remarks to ACCLPP's deliberations. Two LPPB staff will participate in LPWG conference calls and meetings, take notes and produce summaries of the salient points of these discussions. However, full minutes of LPWG proceedings will not be generated due to LPPB's insufficient resources to perform this task. All documents developed by workgroups and formally approved by ACCLPP ultimately become CDC recommendations. LPPB will be unable to justify LPWG's recommendations if the guidance is formulated without the advice and input of experts in the lead and pregnancy field. To address Dr. Banner's concern, however, Dr. Brown offered to explore the possibility of asking authors to recuse themselves from LPWG discussions while their papers are being critiqued or if a particular topic presents a financial or other type of conflict of interest.

The discussion was concluded with a motion by Dr. Slota-Varma for ACCLPP to endorse LPWG's current composition and accept additional members who wish to join; Dr. Handy seconded the motion. **The motion carried with nine votes in favor and two opposed.**

Update on the Primary Prevention Document

Ms. Nikki Walker of LPPB provided a status report of the document. The paper presents ACCLPP's recommendations on a housing-based approach to primary prevention of childhood lead poisoning. Guidance is provided on accomplishing primary prevention and lowering childhood lead exposure in communities around the nation through the elimination of deteriorated paint and contaminated dust and soil. A rationale and outline of a comprehensive program for developing and implementing a

primary prevention strategy are described. References and resources that may be useful in accomplishing this goal are listed.

LPPB printed 150 copies of the primary prevention document in preparation of the ACCLPP meeting, but will print an additional 4,850 copies for dissemination to a variety of audiences. In general, the document targets health departments and housing agencies at state and local levels, community-based organizations, advocacy groups, legislators and the private sector. In particular, the document will be distributed to the following groups: funded and non-funded CLPPPs, HUD, EPA, the Alliance for Healthy Homes, National Center for Healthy Housing (NCHH), National Conference of State Legislators, and ACCLPP members, liaisons and *ex officios*. LPPB will encourage these agencies and organizations to further distribute the document to respective grantees, target populations, constituents and other stakeholders. Electronic copies will be available on the CDC web site at www.cdc.gov/nceh/lead and the Alliance's Healthyhomesnet and Leadnet web sites. ACCLPP was asked to provide LPPB with names of additional groups that should receive the primary prevention document.

The HHS web site policy states that reports or recommendations to the HHS Secretary must be transmitted to the Office of the Secretary for a 30-day review prior to posting on CDC's web site. However, LPPB has received authorization to post the primary prevention document on CDC's web site within the next week. In addition to widely disseminating the document, LPPB will also utilize primary prevention information to support all efforts of CLPPP elimination plans. LPPB is aware of the critical need for CLPPPs to have the most up-to-date information regarding primary prevention of childhood lead poisoning. Key lessons described in the document will be incorporated into national lead training sessions that will be held within the next year.

ACCLPP applauded the tremendous efforts of Ms. Patricia McLaine and Ms. Amy Murphy who chaired the Primary Prevention Workgroup and were instrumental in developing the document that will serve as an extremely important resource for state and local CLPPPs. ACCLPP suggested that the National Realtors Association be added to the distribution list for the primary prevention document.

Ms. Walker was pleased to announce that CDC has issued new guidelines in CD-ROM, DVD and VHS formats on using capillary or fingerstick techniques to appropriately collect and handle blood lead samples. LPPB has disseminated the guidelines to state and local health departments and professional organizations, but welcomes names of additional recipients from ACCLPP. The CD-ROM was also provided to ACCLPP.

Update on the Public Health Implications of Adverse Health Effects of BLLs >10 µg/dL in Children Statement

Dr. Brown and Dr. Tracey Lynn, of the U.S. Department of Agriculture, provided a status report on the document. Dr. Lynn is a former ACCLPP member and serves as a principal co-author of the paper with Dr. Brown. ACCLPP formed an ad hoc group to develop a statement that would serve as a forward to the <10 WG report. The document is targeted to the public health community and describes public health implications of research findings regarding adverse health effects at low BLLs.

The group's guiding principle in developing the paper was that primary prevention must serve as the foundation of lead poisoning prevention efforts because no amount of lead in a child's blood is safe. The intent of the public health statement is to shift the focus from identifying an individual lead-poisoned child to implementing a broader primary prevention effort that reduces, controls or eliminates lead exposure across children regardless of the BLL. The group plans to submit the preface, public health statement and <10 WG report for the CDC clearance process at the same time.

Some ACCLPP members questioned whether the BLL of concern should be lowered from 10 µg/dL. On the one hand, the level should be reduced to trigger interventions, resources and other public health actions at the community level. Clear and positive language has not been generated to date to explain to communities the rationale for not lowering the BLL of concern to 5 µg/dL. They raised concerns that the public health community would most likely not continue this debate if the at-risk population of children was white, affluent and suburban rather than poor, minority and urban.

On the other hand, the document concludes that the BLL of concern should not be lowered from 10 µg/dL at this time. Primary prevention of housing-based and other sources of lead exposure is strongly promoted due to the inability to scientifically defend a lower BLL. For example, recent evidence shows a potential bias in the increasing slope of lead against IQ among children with BLLs ≤10, but these data have not been thoroughly evaluated to date. From a clinical perspective, many providers believe that too much emphasis is placed on lowering the BLL of concern from 10 µg/dL because the "threshold" was established based on politics rather than health. The change will cause limited resources for immunization and other children's health issues to be diverted to identify children with low BLLs.

Several members submitted written editorial comments and other changes to Drs. Brown and Lynn, but verbal suggestions were also made to refine the document.

- Add text to clearly describe appropriate public health actions to take to address low BLLs at the community level.

- Separate the issues of shifting to a primary prevention model and lowering the BLL of concern from 10 µg/dL because these topics are distinctly different and should not be combined.
- Note that most state and local health departments are struggling to conduct secondary and tertiary prevention activities and do not have additional resources to shift to primary prevention efforts. Specifically address the fact that many public health departments will be unable to implement primary prevention recommendations due to budget constraints in the absence of identified resources for primary prevention.
- Clearly state the purpose of the document in the introduction and conclusions. Divide "conclusions and recommendations" into two separate sections. Incorporate a strong statement into the new conclusions section to link important points. Define the target audience and identify key messages to deliver to strengthen and clarify these sections.
- Acknowledge the importance of soil as a potential source of lead exposure for children, particularly since public health departments typically do not sample soil and overlook this source during dust wipe sampling.
- Place more emphasis on the critically important role of parents in primary prevention activities, such as strategies to clean homes, provide children with proper nutrition and address behavioral issues.
- Note that the document will generate minimal interest due to competing priorities of public health agencies. Engage the media in widely publicizing the tremendous benefits of primary prevention. Deliver messages that effectively demonstrate adverse health effects to children from lead paint and soil.
- Replace the confusing term of "BLL of concern" with more clear language. Use specific and different terms to define public health actions, science and toxicology, and clinical recommendations. Include positive language, such as "BLLs >10 µg/dL serve as a solid indicator for communities at highest risk."
- Avoid rushing to publication; instead, use the document as an opportunity to clarify the current lead vocabulary.
- Clearly state that primary prevention is being promoted since pharmacologic treatment and environmental interventions are largely ineffective and the science does not support recommending a certain BLL of concern at this time.
- Make stronger recommendations for public health agencies to provide education and materials to community members and at-risk populations.
- Clarify the guidance on page 9 to assist public health agencies in identifying or defining "areas where the risk of exposure is disproportionately high."

- Include an acknowledgment section to formally recognize Drs. Brown and Lynn as the principal co-authors.

Several members agreed that the public health statement should be refined based on the suggestions, but ACCLPP should formally support the document at this time. The paper offers clear and solid guidance to the public health community in appropriately allocating resources and complying with the primary prevention model.

Dr. Brown made several remarks in response to ACCLPP's discussion. She and EPA have engaged in dialogue about lowering the BLL of concern from 10 µg/dL. EPA created a mathematical model to estimate the percentage of children in a particular setting with a certain lead exposure who may develop BLLs ≥10 µg/dL. The model uses lead absorption rates, particulate size and other parameters of lead exposure to make estimates. However, Dr. Brown is extremely concerned about establishing a new BLL of concern that is <10 µg/dL because this population may be subject to the vulnerable child syndrome. Moreover, the enormous amount of resources that will be needed to identify individual children at the lower BLL will be to the detriment of primary prevention activities.

CDC acknowledges that public health departments are facing severe budget constraints, but HUD's allocation of $611 million to 265 state and local agencies can be used as a solid resource in implementing primary prevention recommendations. Overall, the document is designed to reduce the number of lead-poisoned children if federal agencies, public health departments and state and local governments comply with the primary prevention recommendations.

Dr. Brown thanked the members for providing suggestions to strengthen the public health statement and encouraged ACCLPP to submit additional input. However, she provided comments to specifically clarify the recommendation to place more emphasis on the role of parents. The overarching purpose of primary prevention is to institutionalize lead safety rather than teach parents proper cleaning methods. Children with solid nutrition who live in properly maintained homes are still at risk for EBLLs if the property has lead-based paint and soil.

Dr. Campbell concluded the discussion by proposing the following process. The authors will revise the public health statement based on ACCLPP's written and verbal suggestions. The modified document will be distributed to ACCLPP via e-mail within the next month with a ballot for the voting members to formally approve, disapprove or approve with changes. The issue of lowering the BLL of concern from 10 µg/dL will not be revisited since ACCLPP agreed by a formal vote at a previous meeting not to recommend a new BLL of concern.

Update on the Targeted Screening of Medicaid Children Policy

Dr. Campbell reported that CDC and the Centers for Medicare and Medicaid Services (CMS) are jointly in the process of developing a policy in response to ACCLPP's recommendations in September 2002 to create a lead screening exception for Medicaid-eligible children. The full report of the recommendations; ACCLPP's September 2002 letter to the HHS Secretary to introduce the document; the response from the HHS Secretary; and background materials were distributed to ACCLPP for review. ACCLPP undertook this effort after reviewing 1999-2000 data that demonstrated some states were not complying with the universal lead screening policy for Medicaid children. A federal mandate is currently in existence for all states to screen all Medicaid children at 12 and 24 months of age and 3-6 years of age if the child had not been previously tested.

In developing the lead screening exception, ACCLPP evaluated resource constraints, screening rates and other data, criteria or conditions states could potentially use to support targeted rather than universal screening of Medicaid children. ACCLPP used these data to include three examples in the report of evidence-based approaches states could use to implement targeted screening. A list of lead screening resources was also provided. ACCLPP recommended that only states with an approved lead screening exception be permitted to conduct targeted screening.

Specific criteria for approval were not outlined; instead, the state would be required to submit a solid evidence-based case to support the screening proposal. However, ACCLPP described evaluation methods for the screening process and also referred states to CDC's 1997 document that contains clear screening criteria, a prevalence level cutoff of 12 µg/dL and a housing level cutoff of ~27% of pre-1950 housing for non-Medicaid children. CDC has made strong efforts over the past two years to strengthen collaboration with CMS in implementing the policy. CMS is developing a work plan for ACCLPP's recommendations, but progress in actually implementing the policy is unknown at this time. CMS was invited to the current ACCLPP meeting to present a status report, but no representatives were able to attend.

Dr. Campbell is now asking ACCLPP for suggestions to obtain feedback on the process that will be used to implement the policy. For example, ACCLPP could send a letter to the HHS Secretary to request information on the current status of the policy and the plan HHS and CMS will use to implement the recommendations. Direction from the HHS level will be needed to prioritize this issue within CMS. Dr. Brown added that no states have applied for the lead screening exception because CMS has not formally established the policy. Although the agencies extensively discussed the policy over the past two years and tentatively agreed on a process, CMS is now conducting a literature review.

ACCLPP members made several suggestions in response to Dr. Campbell's request. Data should be gathered and compiled into a report to thoroughly review current screening practices of Medicaid children, particularly in high-risk areas. Current data should be used to replicate the 1999 General Accounting Office study, but an announcement was made that initial steps have been taken in these efforts. The Alliance and National Health Law Program (NHLP) jointly submitted a Freedom of Information Act request to obtain lead screening data that CMS collects from states. CMS recently responded by providing information for the past three years. The Alliance and NHLP have analyzed the data and expect to issue a summary report in the near future, but the findings show that compliance among states in lead screening of Medicaid children has not improved.

Other suggestions made by ACCLPP to advance this initiative are as follows. ACCLPP should provide states with specific criteria to use in submitting lead screening exception proposals instead of only referring to CDC's 1997 document for non-Medicaid children. CDC could perhaps regenerate interest by proposing to jointly launch and fund a demonstration project in a sample of states with CMS. The initiative could be designed to document the process of implementing the policy; produce cost-effectiveness data on eliminating universal screening in some states; and serve as a basis for broader application in the future.

ACCLPP and CDC should be cautious in advancing the policy because CMS may take the position that states only need to screen if a problem has been demonstrated. Lead screening of Medicaid children may further decrease if states perceive that no problems exist in the particular jurisdiction. ACCLPP should recommend that states actually determine whether a problem exists and not rely on judgment. One member suggested that ACCLPP should not write a letter to the HHS Secretary at this time; instead, the Alliance/NHLP summary report should be used as the basis to revisit the lead screening exception. For example, ACCLPP could submit the document to the HHS Secretary to demonstrate that screening of Medicaid children has not improved. With this approach, ACCLPP will have a stronger foundation to inquire about actions HHS and CMS will take to implement the policy.

Dr. Brown reported that a question on Medicaid status was incorporated into NHANES, but an analysis cannot be performed because the population of children with BLLs $\geq$10 µg/dL is extremely small. As a result, CDC is exploring the possibility of conducting a stratified analysis of children with BLLs $\geq$5 µg/dL to determine whether Medicaid children are being tested and if this population is still at disproportionate risk.

The discussion was concluded with a motion by Dr. Rhoads for ACCLPP to draft a letter to the HHS Secretary; include an offer for CDC to jointly fund and launch a

demonstration project with CMS; distribute the letter to members for review, comment and approval via e-mail; and attach the Alliance/NHLP summary report on screening of Medicaid children to the final letter. The motion was seconded by Dr. Handy and **unanimously approved**. Dr. Banner, Dr. Campbell and Ms. Guthrie will serve on an ad hoc group to draft, circulate and revise the letter as necessary.

Update on the Clinical Paper

Dr. Campbell conveyed that the public health implications statement and clinical paper both serve as companion documents to the <10 WG report. The statement is targeted to the public health community, while the clinical paper is directed to clinicians. The clinical paper provides information to aid in decision-making and counseling in healthcare settings. Similar to the public health statement, ACCLPP used the same process of establishing an ad hoc policy group to develop the clinical paper. All iterations of the document have been distributed to ACCLPP for review and comment. ACCLPP previously agreed to submit the paper to *Pediatrics* for publication. Dr. Campbell confirmed with the editor-in-chief that *Pediatrics* accepts papers from committees outside of the American Academy of Pediatrics, but all ACCLPP members would need to sign a conflict of interest form prior to publication. Dr. Campbell inquired whether ACCLPP could reach consensus on the document and publication venue at this time.

ACCLPP members expressed conflicting views about the document and publication venue. On the one hand, a peer-reviewed journal and not ACCLPP will have editorial control over the clinical paper. The document is too lengthy, cumbersome and confusing for busy clinicians and does not appear to be useful for practicing pediatricians. On the other hand, a double-spaced document of 27 pages of text and references is consistent with other *Pediatrics* articles. The document is extremely well written and user-friendly for practicing clinicians and offers helpful information to pediatricians about the determinants of development, laboratory errors for BLLs and other issues regarding BLLs <10 µg/dL. The clinical paper can be refined with minor changes, but should be approved by ACCLPP at this time.

ACCLPP made several suggestions to strengthen the clinical paper.

- Select key messages from the boxed points and place these items in a new and short summary section after the abstract.
- Clarify the boxed points because the text does not advise clinicians on counseling parents of children with EBLLs and taking other actions during daily practice. Repeat these messages in a box in the abstract.

- Reformat the clinical paper in accordance with the uniform style and requirements of *Pediatrics* or other journal that will publish the document.
- Publish all three <10 reports in a CDC venue because clinicians are more likely to read one comprehensive package and use the series of documents as a health education tool.
- Explore the possibility of publishing the boxed points or a summary of the clinical paper in *AAP News*.
- Remove "BLLs Below 10 µg/dL" from the title because the document also applies to BLLs >10 µg/dL.
- Reformat the document as an annotated case study to ensure that key points are compiled into one location.
- Submit the clinical paper to family practice journals, *Contemporary Pediatrics* and other journals if the document is rejected by *Pediatrics*.
- Note that the document will be accessible to parents through media announcements and web site postings. Ensure that the clinical paper also addresses the needs of this audience.
- Advise clinicians to determine whether the child is in a high-risk situation and then make judgments about retesting or re-screening with some periodicity until a pattern is established.
- Include language to inform clinicians that a diagnostic test is always appropriate if a child's exposure to lead is suspected.
- Extract key messages from the "blood lead screening" section on page 13 and place the text earlier in the document.

Dr. Brown provided additional details about the publication and dissemination process. Journals typically do not make substantive changes to papers submitted for publication, but CDC will retain the right to retract the article prior to publication if agreement cannot be reached on revisions proposed by the journal. The <10 WG report and public health implications statement will be published together in a stand-alone document and will serve as a revision to CDC's statement on preventing lead poisoning in young children. The clinical paper will be published in a peer-reviewed journal because ACCLPP previously pointed out that this venue will be more effective than a CDC forum in reaching pediatric providers. The clinical paper is targeted to any individual who provides care to a child or the family of a child.

ACCLPP acknowledged the outstanding efforts of Dr. Helen Binns who chaired the Ad Hoc Policy Group and served as the principal author of the clinical paper. A request was made to formally recognize Dr. Binns in the acknowledgment section of the document. Dr. Campbell concluded the discussion by tabling the vote on the clinical paper until the following day.

Overview of the Georgia State Lead Elimination Plan

Mr. Stic Harris, of the Georgia State Division of Public Health, described activities being conducted by the Georgia CLPPP (GCLPPP). Version 1 of GCLPPP was developed in the mid-1990s, received CDC funding and had an active lead advisory committee (LAC). GCLPPP did not reapply for CDC funding in 1997 and was forced to disband because the state was unwilling to support the program. Version 2 was established in 1999 when GCLPPP reapplied and was awarded CDC funding. GCLPPP has been operating under Version 2.1 since 2001.

Under GCLPPP's current version, statewide screening guidelines were developed, approved and disseminated in 2004. Efforts were then made to involve three key partners in the state to address health, housing and enforcement issues, incorporate the screening guidelines, and focus on childhood lead elimination. The three partner agencies are Georgia's Division of Public Health, Department of Natural Resources (DNR) and Department of Community Assistance. GCLPPP decided to issue a request for proposals (RFP) to write a statewide lead elimination plan that would be specific for children in Georgia. No bids were submitted in response to the first RFP in March 2004, but three proposals were submitted for the second RFP in May 2004 because GCLPPP allocated more funding to the project. Healthy Housing Solutions was awarded the contract and began performing tasks in June 2004.

GCLPPP is creating the elimination plan with several components. For the needs assessment, the contractor conducted interviews with the state health department, its partners, seven regional lead coordinators who perform case management throughout the state, and 25 persons who serve as LAC members. For LAC, the contractor recommended that several new members be added, including CDC, the Georgia Apartment Association, Georgia Realtors Association, Legal Aid for both the city of Atlanta and state of Georgia, a state legislator, private abatement workers, risk assessors, and the DNR Historic Preservation Division.

LAC still needs representation from several key groups in the state, including private insurance providers, landlord groups and associations, parents, banks and mortgage lenders, and the diagnostic and treatment components of the Early Periodic Screening, Diagnostic and Treatment program. GCLPPP convened a summit in September 2004 in preparation of writing the plan and developing a logic model for implementation and evaluation. The summit was well attended by LAC members and was also open to representatives of Georgia's 19 health districts and the general public. GCLPPP presented data and then divided the participants into six subcommittees to focus on primary prevention; screening and surveillance; case management; housing and lead reduction; statutes, codes and enforcement; and education and outreach.

Each subcommittee is organized with a chair and representatives from GCLPPP and the contractor. All six subcommittees held individual follow-up meetings after the summit to develop goals, objectives and activities for the respective focus area. LAC reconvened in October 2004 to review notes taken during the six subcommittee meetings, create a mission statement, develop a statement of purpose, clearly define "elimination" for purposes of the state plan, and formally adopt goals and objectives proposed by the subcommittees. LAC agreed that Georgia could reach the *Healthy People 2010* goal of eliminating childhood lead poisoning by decreasing BLLs 0.5% every two years. With the current BLL prevalence of 3% in the state, LAC will need to achieve a level of 2.5% in 2006, 2% in 2008 and 1.5% in 2010.

At this point, the state lead elimination plan is being written and will be circulated to LAC. A meeting will be held in November 2004 for LAC to review and comment on the draft plan. The contractor will revise the plan based on LAC's comments and submit the final document to GCLPPP in November 2004. The plan will be submitted to CDC by December 1, 2004. GCLPPP will then shift its focus to the logic model for implementing and evaluating the plan and will also address limitations in the process.

For example, some LAC members have personal agendas. Private insurers and landlord associations are extremely important in implementing screening guidelines and addressing housing and financial issues, but these groups have not expressed an interest in participating in LAC. However, GCLPPP has established a solid foundation to continue to make progress and has also created a sound communication process with its partners and the public. Partners of the state health department as well as LAC members have made strong commitments to extensively participate in both short- and long-term activities to eliminate childhood lead poisoning in the state of Georgia.

ACCLPP urged GCLPPP to continue efforts to include landlord groups in the development and implementation of the lead elimination plan. GCLPPP may achieve more success in this area by offering to fund lead hazard control activities. This approach would decrease the burden on property owners.

Ms. Pam Holland, the GCLPPP project officer, underscored the importance of offering incentives to federal, state and local agencies. For example, a CLPPP could offer to certify daycare centers or educate staff in exchange for conducting lead testing of children. These partnerships will be critical for CLPPPs to successfully develop and implement lead elimination plans. Dr. Brown announced that the overview of the GCLPPP lead elimination plan represents a new feature of ACCLPP meetings. In the future, some meetings will be held in areas outside of Atlanta for ACCLPP to learn about lead activities being conducted by state and local health departments. The next meeting will be held in New Orleans, Louisiana with a presentation by Dr. Stephens on lead activities in this jurisdiction.

Update on the Case Management Document

Dr. Brown reported that CDC published ACCLPP's recommendations on managing EBLLs in young children in March 2002 and has since evaluated the document. Over the past two years, the report has become a critical resource for healthcare and other service providers who intervene in the lives of individual children with EBLLs. The document is widely available through CDC's web site, lead information hotline, LPPB, and state and local CLPPPs. The recommendations were developed with three goals. Further lead exposure would be prevented and BLLs in children identified with EBLLs would be reduced. Information and guidance would be provided to CLPPP case managers. Case managers would become familiar with the activities and responsibilities of primary healthcare providers, inspectors, nutritionists and other personnel who deliver services to children with EBLLs and their families.

The evaluation was designed with the following goals. Areas where state and local programs most and least closely met the recommendations would be identified. Barriers to implementing the guidance would be determined. Actions taken by state and local programs would be assessed. Model programs that had been developed and implemented would be evaluated. The evaluation was conducted by NCHH from May-October 2003. During nine training sessions, 428 program staff from 36 states were trained. Of the trainees, 395 completed evaluations and 54% were nurses. Of the respondents, 46% responded to a follow-up survey one year after training. However, this rate does not represent the actual number of respondents because many trainees provided a group response.

Several areas were assessed during the pre-training phase from publication of the document in May 2002 until the first training session in May 2003. Of 407 trainees who most closely met the recommendations, 14% conducted timely environmental assessments; 12% routinely wrote case management plans; 11% made two home visits; 8.6% followed blood lead screening guidelines; and 7.1% provided education to care givers and communities. Of 379 trainees who least closely met the recommendations, 12% had no written case management or individualized care plans; 9.8% admitted to poor communication and coordination with primary care providers; 9% had not conducted developmental assessments; 7.9% had inadequate resources for lead hazard control; and 5.8% lacked Medicaid reimbursement for case management and environmental inspections.

Of the barriers to implementation described by 285 trainees, 16% cited lack of resources; 12% cited lack of adequate staffing; 9.8% cited lack of political will or support for the program; 8.8% cited poor communication and coordination by primary care providers; and 6.7% cited lack of local regulatory enforcement or local ordinances. The

training sessions were held for one to two days and were extremely well received. Several areas were assessed during the one-year follow-up after training.

Of 165+ trainees who reported making a change based on the training sessions and published recommendations, 78% changed the organization, coordination or delivery of case management services; 54% changed environmental assessment and intervention; 45% changed medical assessment and intervention; 39% changed nutritional assessment and intervention; 39% changed developmental assessment and intervention; and 37% changed educational assessment and intervention. Of factors that facilitated these changes, 48% reported program leadership; 35% reported consensus within the program of the need for and direction of change; and 34% reported action with the program's authority.

Of factors that impeded changes, 37% reported lack of staff; 35% reported lack of budget; 13% reported a change outside of the program's authority; and 12% reported lack of political support. In an effort to fill these gaps, CDC will provide additional funding; more training to state and local partners; and sample care plans, educational materials, developmental and nutritional status testing tools, and other ready-to-use resources. CDC recently awarded an RFP to NCHH to develop a lead training center. The curriculum is currently being developed through a collaborative effort and will be based on ACCLPP's published recommendations to manage EBLLs among young children.

The training sessions will contain a basic lead component targeted to all participants and different tracks directed to case managers, program managers, epidemiologists and environmental health specialists. The training session for program managers will be piloted in January 2005 in either Atlanta or Washington, DC. CDC expects to conduct two to three training sessions per year with a maximum of 75 trainees. CDC will urge HUD and EPA to also involve program managers in the training sessions and will encourage other federal partners to hold additional sessions.

ACCLPP commended LPPB on designing an organized and standardized process to disseminate and provide training on the case management recommendations. Data from the one-year follow-up survey demonstrate that the training sessions made a positive impact. ACCLPP made several suggestions to strengthen future training sessions. Other ACCLPP and CDC guidelines should be incorporated into the courses. Federal partners should be encouraged to support "team trainees" to facilitate collaboration. For example, CDC, EPA and HUD could send staff to training sessions as one team for the public health, housing and environmental components of case management. Consideration should be given to developing a specific track for EPA regulators. Data from the Louisville Training Center courses should be reviewed and lessons learned should be applied whenever possible. The 75 participants per training

session should be divided into smaller groups for more effective training and targeted discussions.

Public Comment Period

Ms. Holland pointed out that ACCLPP's discussion of lowering the BLL of concern from 10 µg/dL was the most important agenda item, but the members expressed conflicting opinions about this critical issue. As an LPPB project officer, she strongly emphasized the need for state and local CLPPPs to have consistent guidance and messages.

With no further discussion or business brought before ACCLPP, Dr. Campbell recessed the meeting at 5:16 p.m. on October 19, 2004.

Overview of the Treatment of Lead-Exposed Children (TLC) Trial

Dr. Campbell reconvened the ACCLPP meeting at 8:40 a.m. on October 20, 2004 and yielded the floor to the first presenter. Dr. Walter Rogan is ACCLPP's *ex officio* member for NIH/National Institute of Environmental Health Sciences (NIEHS). He provided an overview of the TLC Trial. The study is a formal clinical trial to evaluate the use of succimer as an oral chelating drug in preventing or reducing lead-associated cognitive, behavioral and neuropsychological deficits in toddlers. Nationally representative prevalence data of 16.4 million U.S. homes were reviewed to determine the number of homes and percentage of children ≤6 years of age with a lead hazard based on age of home. The number of homes built in the time periods of pre-1940, 1940-1959, 1960-1977 and 1978-1998 ranged from <58,000-~2 million. Of these homes, the percentage of lead hazards was estimated to range from <1%-81%. Of homes in which children ≤6 years of age resided, 25% had lead hazards in 2000.

In 1976, the mean BLL was 15 µg/dL among U.S. children 1-6 years of age, the prevalence of BLLs >10 µg/dL was 88%, and 13.5 million children had BLLs >10 µg/dL. Significant progress has been made since that time as evidenced by nationally representative prevalence data. In 1999-2000, the mean BLL was 2.2 µg/dL, the prevalence of BLLs >10 µg/dL was 2%, and <500,000 million children had BLLs >10 µg/dL. In 1991, the broad scientific consensus was that cognitive impairment followed lead exposure at low levels and blood lead at two years of age was associated with deficits beginning at four years of age and continuing thereafter. Data showed that BLLs at birth were not associated with defects and IQ in children five years of age. BLLs at two years of age begin to be associated with full-scale IQ at five years of age. The postnatal mean was strongly influenced by the peak BLL and associated with IQ at

five years of age. The overall size of the effect was ~3 IQ points per 10 µg/dL of blood lead, particularly in BLLs 10-20 µg/dL.

CDC redefined "lead poisoning" in 1991 as BLLs ≥10 µg/dL and also recommended universal screening. Because the published guidance created thousands of new cases, several agencies were concerned that children would be given succimer inappropriately. The drug is orally administered and only licensed for children with BLLs >45 µg/dL, but can be given in an outpatient setting in a controlled lead-safe environment. Succimer is a white crystalline powder that is extremely difficult to administer to children due to the large size and unpleasant odor and taste of the capsule.

NIEHS and a drug manufacturer sponsored TLC to demonstrate that oral administration of succimer would lower BLLs. TLC is a multi-center, randomized, placebo-controlled and double-blind clinical trial of succimer among 780 children for the prevention of lead-induced cognitive and neuropsychological impairment, growth retardation and behavior disorders in toddlers. All children in TLC received vitamin and mineral supplementation and home cleanup for lead dust suppression.

TLC sites included Baltimore, Cincinnati, Newark and Philadelphia because these cities represented large volumes of pediatric lead poisoning cases. The cohort was 12-33 months of age at randomization with referral BLLs of 20-44 µg/dL and no disqualifying medical conditions. During the pre-treatment phase, field investigators drew two BLLs that were confirmed by CDC to be between 20-44 µg/dL; obtained consent; distributed vitamins and minerals; and conducted an evaluation to determine whether the house could be cleaned according to the TLC protocol. Of the succimer group in 1994, 55% were male, 5% had Spanish speaking parents, 76% were black, 72% had parents without partners, 41% had parents with less than a high school education, and 96% were on public assistance.

The randomized subjects were 24 months of age with a mean BLL of 26 µg/dL, mean birth weight of 3.1 kg, a Bayley Mental Developmental Index of 84 and parental IQ of 81. The baseline characteristics were comparable to the placebo group. The succimer group had a BLL that was 0.5 µg/dL higher than the placebo group at baseline, but this difference was statistically indistinguishable. BLLs of the succimer group decreased to a mean of 13 µg/dL after one week of receiving the drug compared to the mean BLL of ~23 µg/dL of the placebo group. However, BLLs of the succimer group increased at week 20 as lead mobilized from bone. Of children who received the first round of succimer, 80% did not have BLLs <15 µg/dL on day 43 of TLC.

At 36 months of follow-up, the TLC cohort was five years of age and was tested for full-scale IQ, behavioral index as well as attention/executive and sensorimotor functions. These functions measure the child's hand-to-eye coordination and ability to pay

attention to a task, suppress the urge to answer prior to knowledge of a question, and answer immediately after hearing a question. No differences were seen between the succimer and placebo groups for any of the tests. The psychometric tests were not administered until 36 months of age because instruments to measure brain function are unreliable and unstable in children ≤3 years of age. The children were followed until school entry and sophisticated tests were performed to identify deficits in cognitive, attention/executive and sensorimotor functions.

The data showed an extremely small statistical difference in attention/executive function of children seven years of age in the succimer group. The findings also suggested that the attention of the succimer group was a little better than the placebo group. However, TLC did not produce evidence to demonstrate that succimer is beneficial to children. Treatment was not found to lead to better scores on cognitive, neuropsychological or behavioral tests at 36 months of follow-up when the children were five years of age or additional follow-up at seven and 7.5 years of age.

TLC did not generate data on the use of succimer, but 41% of families reported difficulties in administering the drug. The succimer group was associated with unexplained, excess trauma based on hospitalization, history and physical examination data. Events reported in the succimer group included a near drowning, asthma attacks and head injury from an iron. Succimer is an expensive drug that is taken for six months and resulted in symptoms in children who were previously asymptomatic. The findings do not support conducting another trial to determine if succimer would be effective in children with BLLs <45 µg/dL. The investigators reasonably inferred that the prevention of lead exposure at the outset is the most effective approach to preventing lead-associated defects.

ACCLPP suggested that the TLC investigators use animal models to identify expression or repression of genes in response to lead, determine pathways and locate small molecules to enhance repair. TLC data should be used to emphasize the importance of improving the environment, particularly housing-based problems that cause lead poisoning. Dr. Brown has learned from one state that Medicaid will not reimburse for succimer if the child's BLL is 44 µg/dL or lower.

Update on ACCLPP Recommendations for Adopted and Immigrant Children

Ms. Walker's status report covered the following areas. ACCLPP developed guidance for internationally adopted, refugee and immigrant children because these populations typically have EBLLs. ACCLPP urged the HHS Secretary to address this public health problem in a September 2002 letter. Although lead paint is the major source of childhood lead poisoning in the United States, major sources worldwide include leaded

gasoline, lead-glazed ceramics, mining and smelting, battery repair and recycling, cottage industries, flour mills, medications, cosmetics and consumer products.

Risk factors for lead toxicity in the developing world include multiple sources that differ from those in the United States; industrial sites located in or near residential areas; more intense exposure to outdoor environments due to hot climates; child labor; inadequate capacity for data collection, surveillance and environmental monitoring; and inadequate tracking of lead use and consumption.

All internationally adopted children are state-regulated, but the Hague Convention on inter-country adoption is not expected to be ratified in the United States until 2006. The Hague Convention will establish minimum procedures, assign a country point of contact, and require agencies that oversee international adoptions to receive approval and certification. From 1989-2003, immigrant visas issued to orphans entering the United States increased from ~8,000 to ~21,000. From 2000-2003, China, Russia, Guatemala and Korea accounted for the majority of international adoptions.

In August 2004, 35 adopted Chinese infant girls arrived in the United States, nine were adopted by families in Massachusetts and two were identified with BLL >25 µg/dL. CDC is closely collaborating with federal partners, CLPPPs and organizations to target and disseminate guidance to parents of adoptive children, healthcare providers and adoption agencies. CDC is also creating an information kit about internationally adopted children and lead poisoning to support National Adoption Month in November.

The number of refugees who entered the United States increased from ~25,000 in 2003 to ~53,000 in 2004. The cap on the number of refugees who are allowed in the country is currently 70,000 and Africa accounts for the largest number of refugees. In 2004, African refugee children resettled in the Manchester, New Hampshire area and had normal BLLs based on initial screening. However, increased BLLs based on follow-up testing indicated exposure in the United States. Of the 34 affected children, 15 had BLLs $\geq$20 µg/dL, one had a BLL of 72 µg/dL, and four were hospitalized and received chelation therapy.

Recommendations for refugees are currently being developed by LPPB with several components. Initial screening should be performed upon U.S. entry; follow-up screening should be performed 30-60 days after placement in a permanent residence; and all children, six months to 16 years of age, should be screened. An environmental investigation should be conducted of the residence before the child is placed or immediately after the child assumes occupancy. The investigation should include a visual inspection and complete dust wipe analysis.

Nutritional, social and behavioral risk assessments should be conducted as components of case management. Referrals should be made to service provider organizations, such as Medicaid, WIC, Head Start, family and children services, and lead hazard remediation partners. Health education and outreach should include the development of culturally appropriate materials for target populations as well as training and education modules for healthcare providers, refugee and resettlement case workers, and partner agencies at federal, state and local levels.

CDC, the New Hampshire CLPPP, U.S. Department of State (DOS), Office of Global Health Affairs and Office of Refugee Resettlement are collaborating to adapt the New Hampshire refugee screening guidelines as a national protocol. A state-based initiative to further investigate the refugee cases in New Hampshire is underway. Most legal immigrants originate from Mexico and India and primarily settle into California after arrival in the United States. CDC is partnering with CLPPPs, the DOS Office of Consular Affairs, and U.S. Citizenship and Immigration Services to develop screening recommendations for legal immigrants.

ACCLPP raised several points for CDC to consider in further development of screening recommendations for internationally adopted children, refugees and legal immigrants. Healthcare providers throughout the country are involved in international adoption clinics to medically evaluate children for international adoptions. CDC should contact these clinics as potential partners in this initiative. CDC's recommendation to include dust wipes in environmental investigations of refugee children may serve as a barrier to reaching private property owners. Some countries may be willing to provide CDC with batch samples that can be tested for lead prior to children entering the United States. This strategy is relatively inexpensive since investigators are not required to obtain samples in the field.

Dr. Brown added that CDC has made the most progress with the refugee screening guidelines and expects to finalize recommendations for this population in November 2004. DOS and other partners have been extremely responsive to this initiative due to the death of a refugee child from lead poisoning in New Hampshire in 2000. Recommendations for internationally adopted children and legal immigrants should be finalized over the next several months, but the three populations are distinctly different, have diverse needs and require unique approaches. LPPB is committed to ensuring that ACCLPP's guidance is institutionalized.

Update on the Lead Vocabulary Project

Ms. Walker's status report covered the following areas. The primary objectives of the project are to identify factors or attributes of lead poisoning prevention terminology that

are confusing or misunderstood by the public; develop messages and guidelines to increase the public's accurate knowledge about prevention terminology; and assist healthcare providers in improving communications with patients. The project was initially designed with three face-to-face focus groups of 30 black, white and Hispanic participants, but the methodology was not approved by the Office of Management and Budget (OMB). As a result, two 60-minute telephone focus groups were conducted with nine participants because OMB approval is not required if ≤9 human subjects for an entire project are involved.

The participants included four English speaking persons from Atlanta in group 1 and five Spanish speaking persons from Los Angeles in group 2. Eligibility criteria included mothers of at least one child <6 years of age, a high school graduate or less, and an annual family income <$35,000. The participants did not express an immediate concern about lead poisoning, had minimal or no knowledge of lead symptoms and treatment, and recalled media reports of lead poisoning. CDC did not assume that certain terms would be understood and asked the participants to describe their knowledge of the terms toxic, elevated blood lead level, lead poisoning, lead exposure, chronic exposure, cumulative, level of concern and asymptomatic. The participants misunderstood five of the eight terms or believed their friends would misinterpret the terms.

Several scenarios were proposed to obtain feedback on the best terms to use to clearly describe actions that should be taken in response to certain BLLs. For low BLLs 2-10 µg/dL, the child's exposure to lead should be eliminated; families should learn more about lead poisoning; and physicians and health departments should provide education. The participants were asked if these actions should be defined as a family action, early action, early prevention or other level. Responses widely varied within and between groups. For mid-BLLs 10-20 µg/dL, the residence should be investigated for lead and repaired; landlords should repair problems; and home repairs should be completed to prevent the child's exposure to lead. The participants were asked if these actions should be defined as a public health action, environmental, lead safety, home repair or other level. Responses widely varied within and between groups.

For high BLLs >20 µg/dL, a blood lead test should be obtained on regular basis; treatment should be sought from a physician; and other services should be implemented to reduce exposure to lead. The participants were asked if these actions should be defined as a medical action, medical warning, medical attention or other level. Responses widely varied within and between groups. LPPB will use the health messaging testing system to conduct additional focus groups since this process is two months compared to the six- to nine-month time period for OMB approval. Efforts will be made to reach consensus on terms that will be used to address ranges of BLLs. Future testing will be conducted face-to-face to present pictures to participants and

more effectively identify factors that influence compliance with the recommended actions.

Overview of Lead Exposure at Firing Ranges

Dr. Lynn described an investigation conducted by the Alaska Division of Public Health (ADPH) in response to exposure to lead at indoor firing ranges among school rifle teams. The Alaska LPPP was created in 1996 and Alaska Code established surveillance of EBLLs that requires reporting of all BLLs ≥10 µg/dL within four weeks of receiving test results. ADPH encourages reporting of all lead test results and most laboratories now submit blood lead tests to ADPH. The major sources of lead exposure among adults in Alaska are from occupational exposures, hobbies and recreational activities, particularly mining, stained glass, and re-casting of lead sinkers and bullets. Children are primarily exposed by take-home lead from adults, foreign-born adoptees and new arrivals.

The distribution of BLLs reported in Alaska among persons of all ages from 1995-2001 was fairly low with the highest exposures resulting from mining. During the same time period, nine of 701 children 0-5 years of age had BLLs >10 µg/dL and eight of 514 children 6-15 years of age had BLLs >10 µg/dL. The majority of ADPH's outreach activities are targeted to adults because only 7% of housing in Alaska is pre-1950. ADPH launched an initial investigation in January 2002 when a BLL of 44 µg/dL was reported in an adult male who was a high school rifle team coach. A follow-up investigation showed EBLLs ranging from 21-31 µg/dL among high school students 13-17 years of age who were members of the rifle team. Testing did not reveal EBLLs among any family members.

An environmental investigation conducted by an independent firm showed that the small-bore firing range had six lanes and was housed in a multi-purpose building. The sampling results confirmed lead contamination throughout the facility ranging from 193-9,000 µg/ft^2 from the floor under the carpet, the women's locker room, a rug outside the firing range door and the men's locker room. No written or formal maintenance program for the range had been established. The environmental investigation also confirmed the presence of contamination from lead dust in the ventilation system.

Based on these results, ADPH contacted all 55 school districts in the state and learned that three additional districts used indoor rifle ranges and .22-caliber small-bore and non-air-powered rifles. Of six high schools identified, two used Range A, one used Range B and three used Range C. All six schools were in the Fairbanks area and participated in the fall shooting season from September to December. ADPH tested 36

students 13-19 years of age on six rifle teams in October 2002; the results are summarized below.

BLLs of teams 1 and 2 from firing range A ranged from 1-3 and 3-5 µg/dL, respectively. BLLs of team 3 from firing range B ranged from 3-14 µg/dL. BLLs of teams 4-6 from firing range C ranged from 17-37, 8-18 and 8-17 µg/dL, respectively. ADPH tested siblings and other family members and did not identify lead sources from the home, well water or other activities. ADPH did not suggest medical treatment for the rifle team members, but did recommend that all persons be removed from ongoing lead exposure; range C cease operations for environmental evaluation and remediation; and all shooters receive a follow-up blood lead test at the end of the season.

Range C voluntarily closed and ADPH's follow-up blood lead testing one month after the season ended showed that BLLs of the shooters decreased from 37-17 µg/dL on average. In June 2003, two adults in Alaska with BLLs >25 µg/dL were reported to the state blood lead surveillance system. The adults were employed as range officers at private non-profit indoor firing ranges that taught 4-H clubs and junior shooters rather than school rifle teams. For this investigation, ADPH conducted testing in the middle of the shooting season among 20 junior shooters, six adult shooters, nine range officers, and 11 family members who were non-shooters. The results among all 46 participants showed BLLs ranging from 1-13 µg/dL with range officers having the highest levels due to exposure from cleaning and maintaining the firing ranges. Based on ADPH's dust wipe sampling, significant contamination of 1,700-27,000 $\mu g/ft^2$ was detected throughout the facility.

ADPH's comparison of the four firing ranges is summarized as follows. Range A is a state-of-the-art facility that is regulated by a state agency and operates under a formal maintenance program, written lead monitoring protocols and a $120,000 annual maintenance budget. The mean BLL of eight shooters tested at range A was 2.1 µg/dL. Range B is a multi-purpose room in a school that is used for lunches, physical education, wrestling practice and meetings. The facility has no written protocols and has not performed a lead evaluation since 1991. The environmental evaluation confirmed that the facility had inadequate ventilation and contaminated lead dust. The mean BLL of seven shooters tested at range B was 8.9 µg/dL.

Range C is a private range built in 1950 that has no written protocols and uses dry sweeping to clean empty shell casings. A ventilation system was added in 1982. The environmental assessment confirmed that the facility had extensive lead contamination and inadequate ventilation. The mean BLL of 20 shooters tested at range C was 17.7 µg/dL. Range C is still closed while efforts are being made to leverage funds for the environmental remediation. Range D is an old building >20 years of age with HEPA ventilation systems on the firing lanes. The facility has no written protocols and uses

dry sweeping to clean empty shell casings. The mean BLL of 20 shooters tested at range D was 7.6 µg/dL. ADPH concluded that ranges with no written protocols utilizing dry sweeping are associated with EBLLs. Follow-up environmental testing identified lead contamination due to improper operation of the ranges, inadequate or malfunctioning ventilation systems, and improper cleaning and maintenance procedures.

ADPH recommended that firing ranges take the following actions. Approved "lead-safe" cleaning practices should be used and written protocols should be developed. These guidelines should strongly advise against dry sweeping and recommend use of a HEPA vacuum or squeegee to clean spent shell casings. A lead chelating agent should be used to clean and wet mop the entire facility. Air and ventilation systems should be regularly assessed. Respirators should be used when cleaning bullet traps. Range officers and other users of the range should wear dedicated clothing. ADPH recommended that schools and parents take the following actions. BLLs of all rifle team members should be routinely monitored. Blood lead testing should be performed at the beginning and end of shooting seasons for all children and other persons involved in shooting programs in indoor ranges.

ADPH was aware of several challenges in implementing the recommendations. Both ADPH and Alaska schools are facing significant budget constraints. Regulations established by the Occupational Safety and Health Administration are designed for employees rather than users. The development of lead safety programs as well as the adequate design and operation of volunteer ranges are not legal requirements. Some range personnel and team members are reluctant to be tested because rifle shooting is an extremely competitive sport and lead testing may be perceived as jeopardizing scholarships. In an effort to address these issues, ADPH recommended that public health officials identify indoor firing ranges in jurisdictions with no regulatory oversight and provide education to these facilities on lead hazards. The importance of applying cooperative and collaborative strategies to approach range operators and users was acknowledged.

ADPH identified several data gaps during the investigations. The existing literature primarily focuses on occupational exposures and does not specifically address users. Children 6-18 years of age are a neglected group for which "EBLLs," "level of concern" or "public health intervention level" have not been defined. However, this age group is at risk for lead exposures associated with activities and hobbies. For example, 42 college rifle teams are currently in operation in the United States, but the number of high school teams and junior shooting programs are unknown. Rifle team members and coaches with a high level of expertise in shooting do not necessarily follow or have more knowledge of lead-safe practices. ADPH is currently preparing a manuscript of

the investigations for publication in a journal, but additional details can now be obtained at www.akepi.org.

ACCLPP made several comments about ADPH's investigations. The EPA Office of Solid Waste may serve as a partner in addressing lead exposure from firing ranges. The movement of lead into soil or runoff may result in groundwater contamination and would then fall under the jurisdiction of EPA's solid waste program. CDC should explore the possibility of conducting a broader epidemiologic investigation to determine the extent of lead exposure from fire ranges outside of Alaska at the national level. Some members were in favor of ACCLPP forming a workgroup to address this issue in more detail, but others questioned the need for this effort since lead exposure among children 6-18 years of age has only been reported from one source to date.

Dr. Brown confirmed that she will approach the NCEH Health Studies Branch about the possibility of conducting an epidemiologic investigation of lead exposure from firing ranges. LPPB activities are targeted to children 1-5 years of age, but the Division of Adolescent and School Health or other CDC programs would most likely welcome the opportunity to conduct this study based on ACCLPP's invitation and recommendations. Dr. Brown encouraged ACCLPP to provide LPPB with a solid proposal to support these discussions. A sound rationale and justification for CDC to fund this research will be particularly important since NHANES data show that children 6-18 years of age have the lowest geometric mean BLLs of any group in the country based on age, race/ethnicity or any other factor. NHANES is the only representative study of BLLs in the U.S. population.

Unfinished ACCLPP Business

Dr. Campbell conveyed that ACCLPP needs to reach closure on the clinical paper, executive summary for the >10 WG report, and the public health implications statement. 1) Changes on the clinical paper that ACCLPP submitted in writing and suggested during the meeting will be forwarded to Dr. Binns for review and revision. In terms of the venue, ACCLPP previously agreed to publish the clinical paper in *Pediatrics*, but Dr. Campbell will also contact the *Pediatrics in Review* editors to determine interest in publishing. ACCLPP should also consider other journals to approach if *Pediatrics* does not accept the document for publication. Alternatively, a suggestion was made on the previous day for ACCLPP to publish the clinical paper in a CDC venue with the other <10 documents as a comprehensive package, but this approach may delay publication.

ACCLPP members suggested several options to reach closure on the clinical paper.

- Shorten the clinical paper by placing technical sections into an appendix.

- Consider *Contemporary Pediatrics* as an alternate publication since this journal is well read by both general practitioners and pediatricians.
- Reformat the clinical paper into a case study since general practitioners will be more likely to comply with the guidance if an "actual" patient or scenario is presented.
- Develop effective strategies to widely distribute the clinical paper to family practitioners because survey data show that these providers deliver services to ~20% of children, but lack knowledge of pediatric issues. Obtain assistance from ACCLPP's liaison to the American Association of Nurse Practitioners and LPWG's representative for the American Academy of Family Physicians in dissemination efforts.
- Take specific approaches to distribute the clinical paper to the general public.

Dr. Brown clarified that LPPB will facilitate a press release when the <10 WG report and public implications statement are issued. LPPB will also collaborate with state and local partners prior to the press release to assist in targeting outreach activities to populations that may have no access to the standard press. LPPB will determine from the CDC Committee Management Office (CMO) whether the CDC clearance process is needed if the clinical paper is released as an ACCLPP document in a peer-reviewed journal.

ACCLPP reached closure on the clinical paper with the following motion by Dr. Banner. The abstract should be rewritten with bullet points in a logical sequence to highlight key messages of the clinical paper. The document should be reorganized to reflect the revised abstract. The document should be shortened by focusing on clinical guidance to advise pediatricians; deleting text on the collection of blood samples and laboratory differences; and referring to other CDC documents that have previously addressed these issues. The motion was seconded by Dr. Slota-Varma and **unanimously approved**.

2) For the second outstanding issue, Dr. Brown explained that the executive summary of the >10 WG report was written in response to ACCLPP's recommendation at the previous meeting to reformat the introduction as a short executive summary with conclusions in bullet points. Dr. Banner suggested that the sentence on page 1 of the document be modified as follows. "Although the workgroup was the primary author of this report, the ACCLPP reviewed the document and accepted the report." He pointed out that the current language inaccurately states the document was revised to reflect ACCLPP's comments.

Dr. Banner raised several criticisms about the <10 WG report during the previous meeting: 1) methodologies used in reaching conclusions, 2) approaches applied in citing published data, and 3) potential conflicts of interest among some members. He

stated that these issues were not considered or addressed by the <10 WG and are not reflected in the current report. As a result, he believes that ACCLPP does not have ownership of the document and did not have final authority in conclusions reached by the <10 WG. ACCLPP members' concerns about the report are outlined on pages 20-21 of the March 2004 meeting minutes.

Dr. Banner also objected to another sentence on page 1 of the executive summary that states "ACCLPP unanimously endorsed the findings in this report." He found this language to be inconsistent with the March 2004 minutes that show ACCLPP "accepted the document" and gave provisional approval based on the development of an executive summary and other conditions. The executive summary was distributed to ACCLPP via e-mail, but the members did not review the complete document with the addition of the executive summary, engage in a face-to-face discussion, or take a formal vote to approve or disapprove the revised report. Due to these reasons, he did not intend to vote to approve the <10 WG report as modified with the executive summary. Overall, Dr. Banner underscored the critical need for ACCLPP to reevaluate the process for workgroups to communicate and interact with voting members and revisit procedures for ACCLPP to approve workgroup documents.

Dr. Campbell clarified that the <10 WG made several detailed updates during previous meetings to present proposed changes, outline responses to comments and obtain input from ACCLPP. During the March 2004 meeting, ACCLPP unanimously approved the <10 WG report if an executive summary was developed and other provisions were met. The executive summary was circulated to ACCLPP via e-mail for review and comment after the previous meeting. No members contacted Drs. Brown or Campbell to change their vote or express concerns about the workgroup process. In terms of procedural issues, Dr. Campbell explained that the minutes always reflect many suggestions made by individual members throughout the meeting. ACCLPP's practice is to take action on issues that are formalized by consensus or a vote.

Dr. Brown agreed that the executive summary was developed and then circulated to ACCLPP via e-mail for review and comment for the first time. ACCLPP did not engage in a face-to-face discussion of the document and also did not take a formal vote. To eliminate this concern in the future, ACCLPP could adopt a more formal process to approve documents, address suggestions made by individual members and conduct other business. Alternatively, future agendas could be limited to a specific number of items and discussion periods could be expanded.

ACCLPP members made several comments about procedural issues. Consideration should be given to increasing the number of meetings from two per year or extending the length of meetings. Approval of workgroup documents has been and will continue to be a problem due to the constant rotation of ACCLPP members. For example, terms

have expired for several members who voted to approve the <10 WG report. CDC should contact CMO to determine whether documents that were formally approved by the former membership of a committee can be revisited by the new membership. ACCLPP should establish a clear and formal protocol to approve workgroup documents in the future. There was a suggestion that ACCLPP should take a vote to give final approval of the complete <10 WG report with the executive summary.

ACCLPP reached closure on the executive summary of the <10 WG report with the following motion by Dr. Slota-Varma. The sentences on page 1 should be changed to "Although the workgroup was the primary author of this report, the ACCLPP reviewed the document and it was revised based on their comments. The ACCLPP accepted the findings of this report." The motion was seconded by Dr. Rhoads and **carried with a vote of eight in favor, two opposed and one abstention**.

Dr. Brown announced that Dr. Banner and Ms. Odle, as the dissenting voters, are free to write the reasons for their respective oppositions to the executive summary of the <10 WG report in any format. The preface of the document will note that statements of the two dissenting voters are available upon request.

3) For the third outstanding issue, ACCLPP agreed on the following process. The public health implications paper will be revised based on ACCLPP's comments and circulated via e-mail with a ballot to the voting members for approval, disapproval or approval with changes. Revisions suggested by ACCLPP and responses to these changes will be distributed via e-mail to all members for review. The revised document will be placed on the March 2005 agenda for a face-to-face discussion and vote if comments among members conflict to a significant degree.

New ACCLPP Business

Dr. Campbell led ACCLPP in a review of topics that were proposed over the course of the meeting as future agenda items.

- Presentation by the HHS Administration for Children and Families on the use of Temporary Assistance for Needy Families funding to provide lead-free housing to program recipients.
- Presentation by Ms. McLaine on evaluation results of the HUD lead-based paint hazard control grant program.
- Discussion by ACCLPP on budget constraints of state and local health departments in implementing primary prevention recommendations.
- Status report by CMS, if available, on the Medicaid screening document.

- Presentation by CDC on efforts to investigate lead exposure at firing ranges.
- Discussion by ACCLPP of a formal protocol to review, discuss and approve workgroup documents, including criteria for disclosure and conflicts of interest among outside consultants who serve as workgroup members.
- Progress report on activities to address lead in water in Washington, DC and other areas.

Dr. Brown reported that CDC and the EPA Division of Water Quality are currently reviewing data from 65 cities to determine the impact of lead in water at the national level. She expected that these results would be available for presentation at the March 2005 ACCLPP meeting.

ACCLPP suggested other topics to address at future meetings. ACCLPP should change its name to the "Advisory Committee on Childhood Lead Exposure Prevention." ACCLPP's name was appropriate in the past, but the focus has now shifted to BLLs <10 µg/dL. "Poisoning" and other adverse effects have not been observed at these low levels. However, another view was expressed for ACCLPP to retain its name because the emphasis on "lead poisoning prevention" is still appropriate. ACCLPP generally agreed to obtain information from HHS on the process to change its name and discuss these findings at a future meeting. The possibility of expanding ACCLPP's mission from children 1-5 years of age to grades K-9 or higher should be explored as well.

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 planning, organizing and making other logistical arrangements for a successful meeting. The next ACCLPP meeting will be held on March 22-23, 2005 in New Orleans, Louisiana.

With no further discussion or business brought before ACCLPP, Dr. Campbell adjourned the meeting at 12:50 p.m. on October 20, 2004.

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

1/12/05
Date

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