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

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

CENTERS FOR DISEASE
CONTROL AND PREVENTION

Advisory Committee on
Childhood Lead Poisoning Prevention
September 18-19, 2007
Minneapolis, Minnesota

DRAFT Record of the Proceedings

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List of Participants

ACCLPP Members
Dr. George Rhoads, Chair
Ms. Magaly Angeloni
Dr. Valerie Charlton
Dr. Deborah Cory-Slechta
Dr. Sher Lynn Gardner
Ms. Linda Kite
Dr. Michael Kosnett
Dr. Jessica Leighton
Dr. Megan Sandel
Dr. Gail Wasserman

Designated Federal Official
Dr. Mary Jean Brown,
Executive Secretary

***Ex-Officio* and Liaison Members**
Dr. Walter Alarcon (NIOSH)
Dr. Helen Binns (AAP)
Dr. Warren Friedman (HUD)
Dr. Benjamin Gitterman (APHA)
Mr. Brian Goodroad (AANP)
Mr. Steve Hays (AIHA)
Ms. Melita Jordan (ASTHO)
Dr. Ezatollah Keyvan-Larijani (CSTE)
Ms. Jane Malone (AFHH)
Ms. Jacqueline Mosby (U.S. EPA)
Dr. George Rodgers, Jr. (AAPCC)
Dr. Phyllis Stubbs-Wynn (HRSA)
Mr. Jonathan Wilson (NCHH)

CDC Representatives
Ms. Wendy Blumenthal
Mr. Barry Brooks
Ms. Joy Gulliksen
Ms. Samantha Harrykissan
Dr. David Homa
[via conference call]
Mr. Jeff Jarrett
Mr. Michael Jensen
Ms. Claudine Johnson
Ms. LaToria Whitehead

Minnesota State and Local Agency Representatives
Ms. Becky Bernauer
Mr. Jack Bradham
Ms. Megan Ellingson
Mr. Tom Hogan
Ms. Melisa Illies
Commissioner Gretchen Musicant
Dr. Daniel Symonik
Mr. James Yannarelly
Dr. Erik Zabel
Mr. Kenneth Zurian

Guest Presenters and Members of the Public
Ms. Tina Brank (CLEARCorps USA)
Ms. Megan Curran
(Sustainable Resources Center)
Dr. Adrienne Ettinger (Harvard School of Public Health)
Mr. Jeff Gladis
(Western Community Action)
Ms. Sue Gunderson
(CLEARCorps USA)
Dr. David Jacobs
(National Center for Healthy Housing)
Ms. Tara Jordan-Radosevich
(U.S. Department of Housing and Urban Development)
Ms. Mardi Kleus (U.S. Environmental Protection Agency Region 5)
Ms. Tammy Moore (US. Environmental Protection Agency Region 5)
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(Halleland, Lewis, Nilan & Johnson, P.A.)
Dr. Patrick Parsons (New York State Department of Health)
Ms. Sarah Rudolf (Coalition to End Childhood Lead Poisoning)
Dr. P.J. Ford Slack (Alaska Department of Education and Early Development)
Ms. Rosalind Volpe (International Lead Zinc Research Organization)

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ADVISORY COMMITTEE ON
CHILDHOOD LEAD POISONING PREVENTION
September 18-19, 2007
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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 September 18-19, 2007 at the Radisson Plaza Hotel in Minneapolis, Minnesota.

Opening Session

Dr. George Rhoads, Chair of ACCLPP, called the meeting to order at 8:45 a.m. on September 18, 2007 and welcomed the attendees to the proceedings.

Dr. Mary Jean Brown, Executive Secretary of ACCLPP and Chief of the CDC Lead Poisoning Prevention Branch (LPPB), announced that voting members with a real or perceived conflict of interest related to any item on the September 18-19, 2007 ACCLPP agenda would be responsible for identifying these issues and recusing themselves from voting on these topics or participating in these discussions.

Dr. Brown opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Dr. Brown was pleased to introduce and summarize the achievements of an honored guest. Ms. Gretchen Musicant, Health Commissioner of the City of Minneapolis, has made strong efforts to create a public health focus on youth violence in the city. As a result of these activities, Minneapolis is allocating special violence prevention grants and convened a task force to address youth violence from a public health intervention perspective. Commissioner Musicant was recently awarded with a public health achievement award in recognition of her distinguished service to promote and protect the health of individuals, families and the community in Minneapolis.

Commissioner Musicant emphasized that she was honored ACCLPP selected Minneapolis as its meeting site. Childhood lead poisoning in general and the *Healthy People 2010* goal of reaching all children to reduce lead poisoning in particular are extremely important issues throughout the city. Although Minneapolis increased the number of children tested for lead, the number of children identified with elevated blood lead levels (EBLLs) has decreased. Despite these efforts, however, Minneapolis reported 335 cases of EBLLs in children in 2006.

Commissioner Musicant described several citywide measures in which Minneapolis is incorporating the issue of lead to reduce its current burden. In its "Sustainability Effort," Minneapolis designated lead testing and 21 additional indicators to measure its status as a sustainable community. The lead testing indicator includes a map of locations where EBLLs most frequently were detected. The report of the Sustainability Effort is available on the city of Minneapolis web site.

In its "Results Minneapolis" initiative, city departments are being held accountable for lead and other specific indicators. Minneapolis established a new partnership with Section 8 low-income housing because this agency conducts systematic risk assessments and makes referrals for remediation. Minneapolis passed a new Lead-Safe Work Practice Ordinance in January 2007 that requires certification for repair of any homes identified with chipping and peeling paint.

Lead outreach and education activities in Minneapolis include collaborative efforts with the Sustainable Resource Center and agencies at state and county levels. Minneapolis and its partners have leveraged resources from federal agencies and other sources to conduct innovative activities, particularly the "Leady Eddie Van" that is used to provide community education.

Commissioner Musicant described one of the most significant challenges in lead that Minneapolis is facing at this time. Many providers are hesitant about counseling families of children who have positive test results for lead exposure, but are below the federal "lead poisoned" threshold. Minneapolis is reviewing its existing lead standards to collaborate with providers and families in addressing this need. Commissioner Musicant emphasized that the city of Minneapolis looked forward to reviewing the guidance and recommendations ACCLPP provided during its meeting.

Dr. Brown informed Commissioner Musicant that ACCLPP's clinical paper on adverse health effects of BLLs <10 µg/dL would be co-published by the *Morbidity and Mortality Weekly Report* (*MMWR*) and *Pediatrics*. The city of Minneapolis particularly would find this information useful because the paper describes actions healthcare providers can take in counseling families of children with BLLs <10 µg/dL. The paper would be available to the public on both the CDC and *Pediatrics* web sites on November 1, 2007.

The participants joined Dr. Brown in applauding the outstanding contributions of Dr. Helen Binns, the ACCLPP liaison to the American Academy of Pediatrics, who served as the primary author of the paper over a four-year period.

Update on LPPB Activities

Dr. Brown covered the following areas in her update. The Consumer Product Safety Commission (CPSC) recalled 44 different toys or 12.2 million units from January 5-September 5, 2007 due to dangerous levels of lead. Data indicate that as much as 50% of recalled items are not removed from shelves and even fewer recalled items are disposed of once sold.

At this time, Connecticut is the only state requiring toy manufacturers to certify that recalled toys have been disposed of as hazardous waste. CPSC's silence on this issue is extremely important because recalled toys could be sold elsewhere or recycled and placed into new products. Dr. Brown raised the possibility of ACCLPP addressing CPSC's silence on the disposal of recalled toys.

Dr. Brown reported that LPPB took several actions in response to this public health issue. First, a new fact sheet was developed and posted on the CDC web site with links to CPSC and the National Center for Healthy Housing (NCHH). The fact sheet contains the following key messages to consumers. The toy should be immediately removed if parents suspect their child has been exposed to a toy containing lead. Most children with EBLLs have no symptoms. A blood lead test is the only definitive method to confirm whether the child has an EBLL. A healthcare provider can assist the parent in deciding whether a blood lead test is needed and also can recommend treatment if the child has been exposed.

Second, specific recommendations were developed for pediatric healthcare providers. Providers who contact LPPB requesting assistance are informed that a blood lead test is a fairly straightforward medical procedure covered by Medicaid and most private health insurance. Providers also are advised to perform blood lead tests in cases with extremely anxious or persistent parents.

Third, ASTM International develops worldwide standards and has established a subcommittee in response to CPSC's request to draft standard specifications for lead content in vinyl plastics used in children's consumer products. CDC, the U.S. Environmental Protection Agency (EPA), NCHH, and toy manufacturers and sellers are represented on the subcommittee.

Dr. Brown highlighted the key points of ASTM's draft standards. The language is limited to vinyl products that are specifically marketed to children. A threshold of 600 ppm is

proposed for lead in children's vinyl products. Testing methodologies that are destructive and laboratory-based are proposed.

Dr. Brown conveyed that CDC and other members of the ASTM subcommittee made several comments in response to the draft standards. Plastics in products that are commonly used by children should be included in the standards along with vinyl products. The threshold of 600 ppm was established based on available good manufacturing practices and also when children's BLLs were higher in the past. Studies should be conducted to determine a lower level that is achievable in the current manufacturing environment.

The standards should be modified with an explicit statement to clarify that lead is NOT to be added to plastic products commonly used by children. X-ray fluorescence should be investigated as an analytic method and included as an acceptable testing method if performed. Dr. Brown announced that ASTM would hold its next subcommittee meeting in October 2007 and would release the draft standards for public comment over the next few months.

Dr. Brown was pleased to report that LPPB recently developed a Healthcare Effectiveness Data and Information Set (HEDIS) measure for lead screening of children enrolled in Medicaid. HEDIS is one of the most widely used sets of healthcare performance measures in the United States and serves as a report card for health plans. The National Committee for Quality Assurance maintains HEDIS and will include 70 measures across eight domains of care in the 2008 HEDIS measures.

Dr. Brown summarized the key features of the lead screening HEDIS measure. The description of the HEDIS measure is the percentage of Medicaid-enrolled children two years of age who have had $\geq$1 blood lead tests by their second birthday. The denominator of the HEDIS measure is children who are two years of age during the measurement year in 2008 and who are continuously enrolled for 12 months prior to their second birthday. However, one gap of 30 days is permitted.

The hybrid measure of the HEDIS measure allows health plans to report both immunization status and lead screening and also use the same sample for both measures. Dr. Brown confirmed that she would inform ACCLPP of any differences in blood lead testing for children who are continuously enrolled in Medicaid with only one 30-day gap versus children who have gaps in enrollment for >30 days.

Dr. Brown emphasized that the lead screening HEDIS measure would not significantly increase the current cost of collecting or analyzing data. At the end of 2008, aggregate data would be produced on the status of children enrolled in Medicaid and their blood lead testing results by two years of age for the entire country. The performance of a particular health plan would not be known in the first year of the lead screening HEDIS measure, but the second year of the measure would be plan-specific.

Dr. Brown informed ACCLPP that in support of the lead screening HEDIS measure, LPPB drafted recommendations on blood lead screening of young children enrolled in Medicaid. LPPB's draft guidance is consistent with ACCLPP's long-standing efforts and focus on this issue since 2000. LPPB expects to publish the recommendations in the *MMWR* over the next year after the CDC clearance process is completed.

Table 1 of LPPB's recommendations describes specific action steps for state and local officials to (1) update blood lead screening policies for Medicaid-enrolled children; (2) improve rates of blood lead screening for Medicaid-enrolled children at increased risk; and (3) design and implement updated surveillance and evaluation strategies.

Table 2 of LPPB's recommendations outlines strategies for healthcare providers to provide blood lead screening and follow-up care. Dr. Brown confirmed that she would provide ACCLPP with the entire document of LPPB's draft recommendations on blood lead screening of young children enrolled in Medicaid. ACCLPP would be asked to review and submit comments on the draft recommendations in a one-month period of time.

Dr. Brown announced that LPPB is continuing its international lead activities in Kosovo. After the war in the former Yugoslavia, refugee camps were built in the 1990s on three sites that are heavily contaminated with lead from smelting and other sources. The three refugee camps are a significant industrial concern and house ~300 children. CDC became involved in this effort in 2005 because previous testing indicated that all of the children had BLLs $\geq$65 µg/dL and some children died as a result of receiving inappropriate forms of chelation.

Dr. Brown summarized LPPB's key findings and recommendations based on its site visits to the Kosovo camps. From 2005-2007, 30% of children who were tested had capillary BLLs $\geq$45 µg/dL. Few if any of the children living in the camps have maintained BLLs <10 µg/dL for their entire childhood.

Cesman Lug is the most highly contaminated camp and should be immediately closed. The situation in the Cesman Lug camp is made more critical because Roma living in Serbia and Montenegro are now moving into vacant dwellings in the camp. Dwellings that are currently vacant should be immediately demolished due to lead contamination and a clear and present fire hazard.

The lack of data has hampered decision-making and resulted in confusion on the part of Roma and others as to the seriousness of the problem and the extent of environmental contamination. A periodic and systematic data review would provide important information about the quality of the children's clinical care. Perhaps as many as 90 children are candidates for therapy, but only 39 children reportedly have been chelated to date. The actual number cannot be determined at this time.

The United Nations Mission in Kosovo or the U.S. Agency for International Development should attempt to identify a donor nation that would be willing to build more lead-free apartment complexes. Lead exposure should be a priority for repatriation to the Roma Mahala. Plans should be developed for continued medical surveillance of these children during their repatriation to Roma Mahala. LPPB is attempting to establish a strong presence in Kosovo to address issues related to mining, smelting and informal smelting.

Dr. Brown informed ACCLPP that LPPB also is continuing its international lead activities in Peru. LPPB conducted an investigation in response to an EpiAid request in Cerro de Pasco where the main economic activity is lead mining. From 1996-2002, 520 children were tested with mean BLLs ranging from 14-37 µg/dL. In 2005, 85% of children 1-10 years of age had EBLLs.

LPPB's site visit to Cerro de Pasco in 2007 showed EBLLs in children 1-12 years of age that were similar to those identified in 2005. LBBP hopes to convene an international conference possibly in October 2008 with the International Lead Zinc Research Organization, World Bank, World Health Organization (WHO) and other groups to formally go on record with solid international lead recommendations.

Discussion

Ms. Jacqueline Mosby, ACCLPP's *ex-officio* member for EPA, announced that EPA and CPSC have been discussing the development of a campaign or formal statement regarding the disposal of recalled toys. EPA is collaborating with its Office of Solid Waste on creating an appropriate approach to assist parents in identifying lead-containing toys. Ms. Mosby confirmed that an EPA staff member with expertise in solid waste and Resource Conservation and Recovery Act regulations would attend the next interagency task force meeting to address this issue.

ACCLPP commended LPPB on its diligent efforts and outstanding activities following the March 2007 meeting. Several members suggested actions that LPPB and ACCLPP should take to advance childhood lead poisoning prevention and elimination efforts.

- LPPB's guidance to providers on recalled toys should emphasize that the risk of lead exposure from toys would be highest in younger children with mouthing behaviors. Specific recommendations might minimize the number of unnecessary blood tests in older children.
- LPPB's lead screening HEDIS measure should contain clear guidance to providers on financial penalties if Medicaid rules are not completely followed. For example, LPPB's advice would be extremely important in determining whether Medicaid would pay for a child's visit in which a local Women, Infants and Children (WIC) clinic tested a provider's patient for lead, forwarded the test results to the provider, and the provider had no other reason to repeat the test.

- ACCLPP should formally address CPSC's policy of "re-gifting" children's jewelry, toys and other products to countries outside of the United States with less scrutiny.
- ACCLPP should develop and distribute a strong position paper with two clearly defined terms. First, ACCLPP should define "trace levels" of lead in children's products because a solid threshold has not established to date. CPSC's definition of an "acceptable" trace level of lead in children's jewelry is <600 ppm or 7.8 µg/dL over a one-month period of time. Second, ACCLPP should define "children's products." The definition of children's products in legislation that was recently introduced is extremely problematic, such as "products intended for children ≤6 years of age."
- ACCLPP should explore strategies with CPSC to establish a certification process in which "lead-free" tags would be placed on children's toys and jewelry.
- ACCLPP should discuss the possibility of developing educational materials and providing web-based technical assistance to countries where lead-containing products for children have been exported. The materials and technical assistance could be made available to Ministries of Health to assist in informing consumers in these countries about the dangers of recalled toys and other products and the harm to children.

In addition to ACCLPP's suggestions, Dr. Kosnett made a formal proposal for the members to consider. ACCLPP should recommend that international trade organizations address public health issues related to trade. This approach could promote the development of a worldwide agreement in which no country that permitted the manufacture of lead-containing children's jewelry and toys or allowed significant or unacceptable amounts of lead-based paint in the manufacture of toys to be a part of the international trading community.

Dr. Kosnett explained that ACCLPP's role in this effort could be to promote collegial educational interactions between the public health communities in the United States and developing countries. For example, an international conference could be held in China in 2008 to take advantage of the tremendous amount of global attention, visitors and media coverage of China at that time due to the Olympics.

The overarching purpose of the international conference would be for ACCLPP to educate and interact with Chinese public health officials. Overall, Dr. Kosnett's position was that the United States should offer its support and raise awareness of China's concerns regarding international trade of lead-containing products to children.

Dr. Brown made a number of comments and clarifying statements in response to ACCLPP's comments, concerns and suggestions. A "Safe Imports" Task Force was recently established under a Presidential Executive Order. HHS is the lead agency on the task force, but CDC does not serve as a member.

Dr. Brown outlined several potential approaches for ACCLPP to take in its future direction. ACCLPP could issue formal recommendations to the Safe Imports Task Force due to its charter to advise both the HHS Secretary and CDC Director. ACCLPP could communicate with WHO about the importation of lead-safe products to children. Dr. Brown and the ACCLPP members could identify and discuss their collective contacts with health officials, governmental agencies, academia and other colleagues in China to determine the feasibility and cost of convening an international conference in China.

Individual ACCLPP members could contact their respective Congressional representatives and health legislative aides on this issue as well. To assist ACCLPP in identifying its future direction and strategies, Dr. Brown confirmed that copies of recently introduced legislation on lead-containing children's products would be distributed to the voting members.

Dr. Brown was aware of ACCLPP's strong concerns about CPSC's legal authority to "re-gift" or export children's jewelry, toys and other products to other countries. She informed ACCLPP that CPSC is a member of the Presidential Task Force on safe importation. If ACCLPP decided to write a letter to the HHS Secretary on this issue, this communication could be used as a platform to make recommendations directly to CPSC.

Dr. Brown advised the members that rapid actions would need to be taken on the order of weeks to months if ACCLPP decided to communicate with the HHS Secretary on the issue of safe imports. She pointed out that the Presidential Executive Order only provided the task force with 60 days to develop a framework for safe imports. The task force's framework would be released for public comment and also distributed to ACCLPP.

Actions

ACCLPP concluded the discussion by agreeing to take action on two issues. First, a new workgroup would be established to draft a letter outlining ACCLPP's major concerns regarding the import, export and disposal of lead-containing toys and other products to children. After ACCLPP's review, comments, revisions and formal approval, the letter would be finalized and sent to the HHS Secretary. ACCLPP's cleared letter would be widely distributed to CPSC, WHO and other organizations.

Based on Dr. Brown's clarification, the workgroup would not be charged with defining "trace levels" of lead in consumer products because this effort is under the purview of CPSC or other regulatory agencies rather than CDC.

The following ACCLPP members, liaisons and *ex-officios* volunteered to serve on the new workgroup: Ms. Angeloni, Dr. Cory-Slechta, Dr. Gitterman, Mr. Hays, Ms. Kite, Dr. Kosnett, Ms. Malone, Ms. Mosby, Dr. Sandel and Dr. Stubbs-Wynn. Ms. Wendy Blumenthal, of LPPB, would provide staff support to the workgroup and contact the members over the next two weeks. During its first conference call, the workgroup would discuss strategies to most effectively convey ACCLPP's comments and concerns to the HHS Secretary.

Second, a motion was properly placed on the floor and seconded by Dr. Sandel and Ms. Kite, respectively, for ACCLPP to make comments on ATSM's draft standards when the public comment period is opened over the next few months. ACCLPP **unanimously approved** the motion.

Overview of the Minnesota Childhood Lead Poisoning Prevention Program (CLPPP)

Dr. Daniel Symonik, Program Director of the Minnesota CLPPP, reported that the Minnesota Department of Heath (MDOH) developed its "2010 Childhood Lead Poisoning Elimination Plan" to create a lead-safe state in which all children have BLLs <10 µg/dL by the year 2010. The elimination plan focuses on primary prevention. The governor of Minnesota approved the plan in 2004, but MDOH is collaborating with partners to update the document.

Dr. Symonik outlined the key components of MDOH's elimination plan. Lead poisoning almost always has no immediate symptoms except in severe cases. Blood testing is the only method to identify EBLLs. Developmental effects of lead in children are permanent. Prevention is a critical component in preventing EBLLs from occurring, keeping EBLLs from becoming higher, and reducing EBLLs as quickly as possible.

Dr. Symonik explained that the Minnesota Blood Lead Information System was established by statute and authorizes four major activities. BLLs in children and adults will be monitored. Screening services will be provided to high-risk populations. Follow-up services will be provided for children with EBLLs. Information on primary prevention programs will be distributed.

MDOH's blood lead guidelines are categorized into several distinct groups. The "screening" guidelines address children and pregnant women, routine screening and periodic evaluation based on state -specific risk factors. Assessment agencies with appropriate jurisdiction in Minnesota have statutory authority to visit the home and write an enforceable lead cleanup order if a pregnant woman is identified with a BLL >10 µg/dL. However, the statute does now allow Minnesota to gather data on pregnancy status. The "case management" guidelines address public health interventions based on lead levels. The guidelines were reissued in 2005 with a new format and additional language from CDC's <10 µg/dL data.

The "clinical treatment" guidelines address medical evaluation, management and follow-up to provide guidance to physicians. MDOH developed the guidelines in collaboration with a group of local physicians. The "screening guidelines" were issued in 2000 and will be comprehensively reviewed and updated by an expert panel to reflect current data, trends and rates. MDOH currently recommends universal screening in Minneapolis, St. Paul and the remainder of the state based on risk factors. The expert panel will be charged with

determining whether universal screening is still warranted in Minneapolis and St. Paul based on current rates.

Dr. Symonik was pleased to announce that MDOH increased its screening rates from 1998-2006 and nearly tripled the number of children tested over this period of time. MDOH's blood lead guidelines, solid efforts at the local level, and the "withhold" clause in MDOH's annual contract with health plans to provide public health services played a significant role in the success of increasing screening throughout the state.

The withhold clause allows MDOH to pay health plans 1% of the state contract that is initially withheld only if certain performance goals are met. This provision is extremely significant in terms of incentives because one health plan was not paid $3 million in one year for not meeting performance goals. The withhold clause also has prompted health plans to pursue data matching agreements with MDOH to identify positive lead test results for specific children.

In terms of children with EBLLs, MDOH's environmental intervention level is a single venous test of 15 µg/dL. MDOH has continued to make progress in decreasing the number of EBLLs in children throughout the state. Despite these efforts, a fatal lead case occurred in Minnesota in February 2006 after a child swallowed a piece of jewelry and developed influenza-like symptoms. The child had a BLL of 180 µg/dL based on blood lead testing and died the same day as the initial report.

Tests revealed that the piece of jewelry swallowed by the child contained 60%-90% of lead, but other similar jewelry was tested and showed <0.06% of lead. MDOH coordinated its response to the media and public with CDC, CPSC, the Minneapolis health department, and the governor and mayor. The case was published in the *MMWR*.

Dr. Symonik described MDOH's recent studies and other activities. MDOH published a countryside lead prevalence study in 2005 to address the prevalence of lead in rural areas. From 2001-2002, 70% of all children in three counties were tested. Rural rates were found to be similar to national estimates. The main contributors to lead in rural areas were WIC status, residence in pre-1950 housing, and other risk factors established by MDOH. The study is available to the public on the MDOH web site.

MDOH recently analyzed data to determine differences between WIC and refugee status as a risk factor for lead. WIC clinic screening was performed in three separate projects targeting high-risk areas. Of 2,772 persons screened, only 8 had BLLS $\geq$10 µg/dL and only one child had an EBLL >20 µg/dL. Of 305 pregnant women tested in Hennepin County, only one had an EBLL.

MDOH performed refugee screening with 150 children in St. Paul in 2006 to evaluate CDC's new guidelines. Of all screened children, 93% received a second blood test. The source of

lead in these children most likely was outside of the United States. MDOH plans to publish these data over the next year.

For its housing-based activities, MDOH has been successful in receiving HUD lead hazard reduction grants for lead hazard control. MDOH has used these funds for primary prevention to enter homes and also to educate contractors and homeowners on lead-safe practices. MDOH has made strong efforts to promote coordination between health and housing agencies. Annual resources to MDOH for lead poisoning prevention include $4 million from HUD, $590,000 from CDC, $500,000 from a state general fund, $200,000 from EPA, and additional funding from private sources and nonprofit organizations.

Mr. James Yannarelly, of the Ramsey County Department of Public Health (RCDPH) in St. Paul, Minnesota, provided a local perspective on housing-based activities. RCDPH is focusing on this issue through a number of solid partnerships with local and state agencies and private organizations. RCDPH has received a significant amount of funding since the early 1990s to change its secondary prevention lead program to a housing-based primary prevention program. Although ~87% of houses in Ramsey County have lead, a significant portion of the lead causes no problems due to appropriate maintenance, management and control.

RCDPH has taken several actions to target primary prevention efforts to problem areas, such as developing strategies, collaborating with national organizations, implementing effective models, delivering benchmarks, and sharing lessons learned. RCDPH also partners with private contractors that implement lead-safe work practices (LSWP), adhere to HUD guidelines and follow CDC/ACCLPP recommendations. RCDPH performs ~2 rehabilitation projects each week that require paint stabilization, ~17 window replacements, and overnight relocation of the family to a local hotel.

RCDPH paid for ~5 contractors to undergo a four-day supervisory course. The respective crews of each contractor were trained in the LSWP program. RCDPH performed a complete clearance process on initial projects the contractors completed following training. The contractors were shown their strengths and weaknesses in rehabilitation work. Overall, RCDPH's training resulted in positive changes in behaviors and practices among the contractors during rehabilitation of housing units, such as the purchase and use of HEPA vacuums and improved cleanup. Mr. Yannarelly commended CDC for its stronger focus on housing-based primary prevention.

Update by the Blood Lead Laboratory Workgroup

Dr. Patrick Parsons, of the New York State Department of Health and chair of the workgroup, conveyed that the workgroup includes representatives from CDC, ACCLPP and external groups with expertise in the subject matter. The workgroup has held three

conference calls to date and circulated its first draft report among the members in July 2007. The workgroup expects to distribute the document to ACCLPP for review and comment in the near future. Key issues on the workgroup's agenda are outlined below:

- Current laboratory capabilities for blood lead.
- Criteria for acceptable blood lead laboratory performance in Clinical Laboratory Improvement Amendments (CLIA) approved proficiency testing (PT) programs.
- The impact of more stringent criteria for PT performance based on the use of reference methods by centralized laboratories and the use of the LeadCare device by point-of-care laboratories.
- Misclassification of children based on laboratory errors.

Dr. Parsons described current methods for blood lead testing. The highly complex and automated graphite furnace atomic absorption spectrometry (GFASS) system is one of the most widely used reference methods for measuring lead in blood and has a detection limit of 1 µg/dL. The cost of GFASS ranges from $30,000 for a basic unit to $50,000 for a more robust and well-equipped unit. Anodic stripping voltammetry (ASV) is a modestly complex and non-automated bench-top unit that is based on electrochemistry. ASV has a detection limit of ~2-3 µg/dL and costs $10,000-$15,000.

Inductively coupled plasma mass spectrometry (ICP-MS) is an extremely complex and automated system that has a detection limit of ~0.5 µg/dL. The cost of ICP-MS ranges from $180,000-$250,000. The old LeadCare device is a handheld and non-automated ASV technology that is based on electrochemistry and is considered to be moderately complex under CLIA. LeadCare II is the new waived and non-automated device that has a detection limit of ~2-3 µg/dL and costs $2,000-$3,000. However, LeadCare II will be problematic because the device is different than reference method technologies. Moreover, the performance of LeadCare II in the field has not been definitively assessed to date.

Dr. Parsons summarized the history and current environment of regulating clinical laboratories in the United States. The federal government has regulated clinical laboratories through the Occupational Safety and Health Administration (OSHA) since the 1970s and CLIA '88 since 1992. These regulations drove the standardization of laboratory performance across the entire spectrum of clinical laboratory medicine. At the state level, oversight of clinical laboratories greatly varies by state.

Laboratory oversight is achieved through mandatory proficiency testing except when waived, laboratory standards and laboratory inspections. PT is used to determine laboratory testing performance via inter-laboratory comparisons in the United States, while external quality assessment schemes (EQAS) are used in Europe and elsewhere.

PT programs in the United States and EQAS programs in Europe and Canada have philosophical differences. For example, laboratories in the United States that fail PT might

receive a letter from the regulatory agency to cease patient testing. EQAS is a voluntary activity and laboratories that fail this program have less serious consequences than PT failure in the United States.

PT testing under CLIA '88 covers the entire spectrum of clinical laboratory medicine of three test events per year and five challenges or PT samples per test event. Laboratories must score 80% or receive four correct challenges out of five on each blood lead test event to earn "satisfactory" PT performance for the test event.

For cumulative performance under CLIA '88, laboratories must maintain $\geq$80% on at least two out of three blood lead test events to earn "successful" PT performance. An "unsuccessful" PT performance is two consecutive failures out of three. Consequences for unsuccessful PT performance could include a letter from a state agency or a CLIA regional office instructing the laboratory to investigate the source of the error or cease patient testing. The laboratory would need to remediate the errors and demonstrate proficiency before resuming patient testing.

Requirements for unsuccessful laboratories to resume patient testing vary based on standards established by the accrediting agency in the region, the vigor of the local office in pursuing poor performance, and the level of oversight in each state. However, one of the most important components in laboratory performance is capacity for rapid turnaround of results to ensure that laboratories are quickly made aware of problems.

Several factors play an important role in deciding the total error level that is acceptable for blood lead testing, such as clinical and public health needs, method performance, laboratory capabilities and capacity, and the most effective tools for a specific purpose. In addition to these factors, data were published in 2000 to inform the decision-making process.

The study compared procedures for evaluating laboratory performance in EQAS for lead in blood and aluminum in serum. The study also demonstrated the need for common quality specifications. The study was based on a proposed approach that used clinical inputs to establish targets for analytical imprecision, bias and the total allowable error level. Quality specifications were elaborated as well.

The study suggested that the CLIA '88 recommendations for $\pm$4 or $\pm$10% of the target concentration, whichever would be greater, could be used as a quality specification. However, the study recommended a revision of $\pm$3 or $\pm$10%. Current blood lead performance criteria include the CLIA '88 standard of $\pm$4, the OSHA standard of $\pm$6, and the average standard in European countries of $\pm$3.

Dr. Parsons reported that the workgroup discussed potential impacts on U.S. laboratories if the current performance limits for blood lead testing were changed. In this effort, the workgroup evaluated data from two PT programs. The New York State (NYS) Department

of Health PT Program for Blood Lead is a state regulatory program that is mandatory for all clinical laboratories serving NYS. Of 108 laboratories that serve NYS, 49% use GFASS, 19% use bench-top ASV, 21% use ICP-MS, and 11% use the LeadCare analyzer.

The Wisconsin State Laboratory of Hygiene PT Program for Blood Lead is a voluntary program that is supported by federal grants and does not require a fee to participants. Of 469 laboratories that serve Wisconsin, 61% use the LeadCare analyzer.

The standard deviation between laboratories showed that ICP-MS was the best technology of the four with BLLs of 6 and 11 µg/dL. An analysis of data showed that NYS PT reference methods, excluding LeadCare laboratories, were fairly stable up to 20 µg/dL depending on whether the criteria were ±3 or ±4. Performance decreased to below 90% with BLLs 30-38 µg/dL regardless of whether criteria were ±1-3. The analysis showed that this change would have consequences for laboratories at BLLS 10-30 µg/dL.

An analysis of NYS LeadCare laboratories showed that these laboratories had significant difficulties in maintaining proficiency >20%, particularly at criteria of ±1 µg/dL. The analysis showed that any change in criteria would impact laboratories that use the LeadCare technology.

An analysis of data showed that Wisconsin PT refereed methods, excluding LeadCare laboratories, began to decrease in performance with criteria of ±2 at BLLs >15 µg/dL. The analysis showed that these laboratories would be impacted by a change in performance criteria. An analysis of Wisconsin LeadCare laboratories showed decreased performance with criteria of ±3.

Federal regulations contain language stating that in cases with a lack of consensus on a particular PT sample, samples would be ungradable and would be scored with 100%. The NYS PT Program has avoided this provision by using a select group of 15 reference laboratories to establish target values. The Wisconsin PT Program is unable to grade its LeadCare laboratories against established referee target values because the LeadCare technology is extremely sensitive to the age of blood and can only be used with fresh whole blood. The practice of the Wisconsin PT Program in freezing blood before an event causes a discrepancy in the target value.

Data were reviewed from the NYS PT Program to determine the impact of changing blood lead performance limits on laboratory permit status. The analysis showed that with current criteria of ±4/±10%, 10%-15% of laboratories would be at risk of failure and <6% would be unsuccessful and fail PT. With criteria of ±3/±10%, 15% of laboratories would be at risk of failure and ~6% would be unsuccessful and fail PT. The minimal difference between these two results demonstrates that a change to criteria of ±3/±10% could be implemented without serious unintended consequences for laboratory capacity.

With criteria of ±2/±10%, 25% of laboratories would be at risk of failure and nearly 10% would be unsuccessful and fail PT. This finding indicates that caution should be taken in recommending a change to these criteria due to the strong potential for undesirable and unintended consequences. With criteria of ±1/±10%, 33% of laboratories would be at risk of failure and 15% would be unsuccessful and fail PT.

Based on these findings, Dr. Parsons supported an incremental approach to improving laboratory performance by changing criteria to ±3/±10% initially and ±2/±10% in the future. An initial change in criteria to ±2/±10% could result in serious consequences due to the decertification of large commercial laboratories.

Dr. Parsons noted that one of the workgroup members analyzed data from nine commercial laboratories to determine the impact of changing blood lead PT criteria on internal quality assurance practices. The two control levels used in the analysis were BLLs of 9 and 25 µg/dL. The study demonstrated the need to analyze differences in methodologies to meet these standards.

Dr. Parsons highlighted the workgroup's key findings to date. Better laboratory performance is needed, particularly at low blood lead concentrations. A change in the current performance standard should not result in unintended consequences in the future. Laboratories have the capacity to enhance performance.

Dr. Parsons emphasized that all of the workgroup members have not agreed on the following proposed approach. A phased approach is recommended to tighten the standard one step at a time. Implementation of a more stringent standard of ±3/±10% at this time is desirable, feasible and consistent with current European standards. The impact of this change would be revisited in 12-24 months to determine whether laboratory performance improved as a result of the first change. Consideration would then be given to adopting a new standard of ±2/±10% at that time.

The workgroup also identified a number of problems in changing the current performance criteria for laboratories. Efforts to modify the current federal regulation will be extremely difficult. The old LeadCare system might be unable to meet new standards. The new LeadCare system is waived and is not subject to federal PT oversight. Some states might demand satisfactory PT performance. Users should be educated on the limitations of various technologies.

Overall, Dr. Parsons emphasized the need for ACCLPP to issue an explicit charge to the workgroup in terms of making specific recommendations on error limits. ACCLPP also could instruct the workgroup to expand its charge to provide guidance on handling LeadCare for screening.

Ms. Blumenthal announced that the workgroup reviewed preliminary BLL sensitivity and specificity data from National Health and Nutrition Examination Survey (NHANES) statistical

analyses. The workgroup performed this data review due to its interest in identifying cases where children were misclassified as "false-positive" or "false-negative." The workgroup took this approach because of the need to make evidence-based recommendations that reflect a public health need to lower the current performance criteria.

The sensitivity and specificity analyses were based on simulations of various EBLL prevalence rates and the following assumptions. BLLs in NHANES represented the true BLL for a child. BLLs generated for the analysis included a given fixed error level that was added to or subtracted from the "true" value. The error value was randomly added or subtracted. The ratio of a high to low error level was ~50/50 and might not be accurate in terms of actual laboratory experience.

In the analysis, 100 iterations were run and each iteration differed in terms of assigning error levels. The limitations of the analysis included a simulation design that would result in a hypothesis of "potential" outcomes versus "actual" laboratory performance. The sensitivity and specificity values used in the analysis were mean values.

Ms. Blumenthal outlined key findings of the analysis. The percentage of children who were truly positive based on blood lead testing and would be appropriately offered intervention was significantly impacted as the error level tightened. The error level dramatically increased from 34 with criteria of $\pm$3 to ~51 with criteria of $\pm$4.

The expected numbers of false-positives in a hypothetical population of 100,000 children were significantly impacted when criteria were tightened from $\pm$4 to $\pm$3. False-negatives were similarly impacted with a population prevalence of 10%. These findings caused one of the workgroup members to express concern about a rapid shift from the current criteria of $\pm$4 to $\pm$2. A quick change could drive more laboratories to consider using the LeadCare II instrument that would not be subject to PT standards.

Several ACCLPP members made suggestions to assist the Blood Lead Laboratory Workgroup in conducting future activities.

- CDC should include language in future program announcements that requires states to perform PT testing.
- ACCLPP should recommend decoupling performance limits for blood lead testing from current regulations. With this approach, a non-regulatory expert panel could issue guidance on the standards that would be relevant to public health needs and consistent with existing laboratory capacity.
- ACCLPP should strongly promote voluntary standards in addition to mandatory standards. For example, a laboratory that exceeds mandatory standards could advertise its performance as a "gold star" lead laboratory.
- ACCLPP should expand the workgroup's charge to advise clinical laboratories to standardize or generalize interpretations that are routinely provided with blood lead tests.

Dr. Rhoads suggested that ACCLPP could formally address its comments by writing a letter to the appropriate entity and emphasizing three key points. First, the current performance standard should be changed from ±4 to ±3 as soon as practicable. Second, ACCLPP recognizes the need for a change in laboratory performance criteria to ±2 at this time, but this change should be implemented over the next two years if possible. Third, ACCLPP supports decoupling current standards from federal regulations into a more flexible administrative process.

The following motion was properly placed on the floor and seconded by Dr. Sandel and Dr. Gardner, respectively. ACCLPP should expand the charge of the Blood Lead Laboratory Workgroup to analyze reference methods and LeadCare issues and make recommendations in this regard. This guidance will have tremendous implications for the practice and detection of BLLs. ACCLPP **unanimously approved** the motion.

Dr. Parsons made several comments in response to ACCLPP's discussion. The workgroup would support Dr. Rhoads' suggestion for ACCLPP to write a letter on the need to change current laboratory performance criteria. In response to Dr. Sandel's motion that ACCLPP unanimously approved, a representative of the LeadCare manufacturer would need to be invited to join the workgroup. This approach would make it more likely that the manufacturer would support and endorse the workgroup's recommendations.

Update on CDC's Healthy Homes Initiative

Dr. Brown reported on actions that have been taken to shift LPPB's sole focus on childhood lead poisoning prevention to a more holistic housing approach. CDC is making strong efforts to complete LPPB's entire transformation over the next year. The *Healthy People 2010* goal for childhood lead poisoning is to prevent BLLs ≥10 µg/dL as a public health problem.

The *Healthy People 2010* goal related to housing is to reduce the number of housing units with moderate or severe physical problems by 50%. To achieve this goal, the number of housing units with moderate or severe problems would need to be decreased from ~6,500 to ~3,200 million units. Data collected by the American Housing Survey from 1995-2005 showed minimal improvement over this time in the number of occupied housing units in the United States with "moderate or severe" or "moderate and severe" physical problems.

CDC is developing a "Healthy Housing Framework for Action" in preparation of a "Surgeon General's Call to Action" to organize general contractors, architects, urban planners and other groups in the United States around this public health issue. A clear distinction will be made between "housing" and "home" in this initiative. A "healthy house" is defined as one

that is sited, designed, built, maintained and renovated in ways that support the health of its occupants. LPPB is focusing on the interaction between the actual structure and residents.

Dr. Brown summarized the five guiding principles of the healthy housing framework for action. One, public awareness will be increased by creating a national dialogue on healthy housing and promoting health literacy about housing. A national dialogue will improve public understanding of the relationship between housing and health. Health literacy will be increased in many contexts and settings, including individual families, academia, professionals, and stakeholders involved in the housing industry and community planning. Greater knowledge about key health issues will provide persons with capacity to make informed, evidence-based and compassionate housing decisions.

Two, actions will be taken to ensure that all Americans have access to healthy, safe and affordable housing. Housing design and construction can hamper ease of mobility within a home and interfere with reasonable access to important features of the house, such as toilets, shelving in cupboards, and closets for elderly and disabled persons. Of all U.S. families, 13 million spend >50% of their income on housing and might not be able to purchase health care, medicines or adequate food. Living in a neighborhood with a concentrated poverty level increases emotional stress and exposure to intentional injury.

Three, the physical and mental health of individuals will be promoted through evidence-based healthy housing interventions. Lowering hot water temperature, installing window guards and implementing other safety measures result in less pediatric burns and falls. The risk of death is decreased by 40%-50% when a fire occurs in a home with a working smoke alarm.

Lead paint abatement reduces the likelihood that more children will be lead poisoned in homes where children have been poisoned in the past. Radon testing and carbon monoxide monitors reduce deaths in the home. Integrated pest management and use of the least toxic baits and insecticides result in fewer insect pests and less reliance on chemical pesticides. Involuntary exposure to secondhand tobacco smoke can be prevented by making homes, workplaces and public places smoke-free.

Four, investments will be made in research to advance current knowledge of strategies for healthy housing and improve physical and mental health. Additional housing factors that can harm or promote and protect the health of individuals will be identified. Understanding of causal sequences of events leading to specific injuries will be strengthened. The physiologic pathway that links the housing environment and mental health will be described. Understanding of building practices that improve the health of residents will be enhanced. Scientific and analytic methods that are available to researchers who conduct formative studies in this area will be improved.

Five, investments will be made in research that enhances understanding of the long-term economic benefits of healthy housing. Additional studies are needed to quantify the relative

benefits and cost-savings of modern construction practices, such as increasing the width of stairs and traction on floor surfaces, improving home lighting, and installing handrails. Investments also should be made in energy conservation, green construction and renovation practices, and similar improvements that result in improved health of residents, cost-savings and other benefits.

Dr. Brown noted that reuniting public health and housing policy is not a new concept and is simply a matter of restoring a once vital link. This activity is feasible because the course is increasingly clear and well mapped. Moreover, key participants have been identified and initial steps have been taken. Strengthening and widening these efforts is an urgent matter.

Dr. Brown described CDC's ongoing and future activities to support the effort of reuniting public health and housing policy. A new plenary module on "Principles of Healthy Housing" will be incorporated into the Lead Poisoning Prevention Training Center (LPPTC) in the fall of 2007. Lead poisoning prevention training will be included in the Healthy Housing Training Center Network. LPPB will be responsible for managing both of these contracts. The next LPPTC session will be held on October 15-19, 2007.

An article linking household mold to depression will be published in the October 2007 issue of the *American Journal of Public Health*. The eight-city study has been the largest research project of its kind to date to demonstrate an association between mold and mood. The study also was the first investigation conducted outside of the United Kingdom.

A Healthy Housing Expert Panel with ~35-40 scientists will be convened in December 2007 with the following charge. State-of-the-art science on housing interventions that affect the health of residents will be identified and summarized. A consensus-based white paper will be developed that places interventions in one of three categories for action: (1) implement immediately, (2) conduct applied and evaluative research, or (3) conduct basic or formative research. A policy meeting is expected to be held within six months of the expert panel's publication to discuss and identify actual implementation strategies.

CDC awarded LPPB discretionary funds of $167,000 to expand the Baltimore Lead Poisoning Prevention Program to include asthma, injuries, primarily burns, and deaths from house fires and carbon monoxide. Baltimore also will focus on sudden infant death syndrome, cabinet locks, safety gates, and the development of partnerships with non-profit organizations. These activities will be conducted as part of Baltimore's existing assessment and intervention during home visits to children with EBLLs.

Most of Baltimore's efforts will be designed to improve infrastructure. A database will be developed and training will be provided. A regulatory framework and curriculum will be created for sanitarians, code enforcement officials and other local officials. A "cookbook for transformation" will be developed and provided to LPPB with guidance for other lead programs that are considering a transition to healthy housing.

Dr. Brown described LPPB's future activities to support its transition to a more holistic housing approach. For "budget-related" activities, LPPB made a request for report language in the 2008 budget to allow flexibility in using lead funds for healthy housing activities. LPPB hopes to increase the lead/healthy housing budget by $9.5 million in 2009 to implement new strategies at state and local levels. LPPB also hopes to increase its personnel for the development of training curriculum and programs and more emphasis on healthy housing research projects.

For "science-related" activities, an interagency Healthy Housing Surveillance Workgroup will be established with representation by CDC, the Agency for Toxic Substances and Disease Registry, EPA, HUD and the National Institutes of Health to identify data elements, determine existing data sources, and develop collaborative mechanisms. The workgroup plans to hold its first meeting in October 2007. CDC is continuing the Green Buildings Study to determine levels of common allergens and environmental toxics in green built housing. CDC has conveyed its interest to HUD in evaluating health effects related to greening of tenant-based Section 8 properties.

For "partnership-related" activities, the Tri-Agency Healthy Housing Conference will be held in October 2008 with CDC, EPA, HUD, and funded state and local programs. A meeting will be convened in the spring of 2008 with healthy homes grantees. Dr. Brown and CDC's Healthy Homes Goal Team Leader have been meeting with various groups to enlist new partners, including the Red Cross, Healthy Grandparents Programs and Meals on Wheels. Dr. Brown emphasized that the healthy homes activities will broaden and not replace LPPB's strong focus on the *Healthy People 2010* goal for childhood lead poisoning.

Update on HUD's Healthy Homes Initiative

Dr. Warren Friedman, ACCLPP's *ex-officio* member for EPA, reported that HUD focuses on a number of healthy homes issues, including lead poisoning, asthma and allergens, and indoor air quality. HUD takes a holistic and comprehensive approach to address multiple environmental health and safety hazards in housing. HUD designed this cost-effective approach to include preventive measures for reducing hazards, particularly in homes of low- and very low-income families.

HUD uses three mechanisms to implement its healthy homes activities. Under "grants and cooperative agreements," HUD has made 92 awards through FY'07 at a total of $72 million to its grantees throughout the country. HUD's grant programs include healthy homes demonstration projects for assessments, interventions, evaluation, and the development of assessment protocols and a weatherization assessment tool.

Several healthy homes technical studies have been conducted under HUD's grants programs focusing on a characterization of housing stock; development of a methodology to

detect and quantify mold spores; a cockroach cleaning protocol; and construction issues associated with Native American housing.

Under "interagency agreements," HUD has produced a number of healthy homes documents, outreach materials and other products in partnership with CDC, the National Institute of Standards and Technology, and the U.S. Department of Agriculture. The *Help Yourself to a Healthy Home* booklet is one of HUD's most popular documents for consumers and can be downloaded in its entirety from the HUD web site.

Under "contracts," HUD has contracted a variety of organizations to conduct healthy housing projects, such as research topic papers, technical documents, a listing of mold professionals, laboratory analysis of household dust allergen levels, and an evaluation of healthy housing initiatives.

Dr. Friedman pointed out that HUD outreaches to communities in a number of its healthy homes activities to forge public-private partnerships. For example, HUD provided technical assistance and developed best practice documents to help CLPPP staff and other state and local personnel in shifting from a sole focus on lead to a broader healthy homes approach. HUD provided integrated pest management training to public health authorities and environmental safety training to contractors following Hurricane Katrina.

Dr. Friedman summarized a number of HUD's healthy homes initiatives. HUD will continue to support the Surgeon General's Call to Action for Healthy Housing. HUD will continue to participate in healthy homes conferences and also will increase regional and local collaborations. The HUD Office of Affordable Housing Program has a green initiative that is being piloted in Lawton, Oklahoma. The project is designed to incorporate green principles into housing construction and assess practices in the home after green construction.

HUD launched a campaign in April 2006 to outreach to 30 cities throughout the country over a three-year period. In this campaign, HUD collaborates with local groups to display its "Healthy Homes Pavilion" at local events. The interior of the pavilion contains signs that identify potential housing conditions, such as moisture problems from freestanding water and lead hazards from deteriorated paint.

Dr. Friedman outlined HUD's future strategies to enhance its healthy housing initiatives. Programs will be expanded to increase the focus on healthy, energy efficient and affordable housing. Demonstration projects and other healthy housing activities will continue to be research-based with more formal analyses and assessments to ensure the application of these projects in the future. Interagency collaboration will be expanded as well.

Dr. Friedman pointed out that HUD issued a press release on September 13, 2007 announcing its allocation of $143 million in grants to protect children from dangerous lead and other health and safety hazards in the home. The press release was distributed to ACCLPP for review.

ACCLPP commended CDC on expanding LPPB's focus from childhood lead poisoning prevention to include a broader healthy housing approach. ACCLPP also was pleased that CDC, HUD and other federal agencies have established a true partnership in this effort.

Several ACCLPP members made suggestions for the federal agencies to consider in ongoing efforts to strengthen and expand healthy housing initiatives.

- The federal agencies should make better use of local data in the healthy housing initiatives because some of this information is not available at the federal level. For example, local data can include information on rodents, mold and pesticide use in small geographic areas of certain jurisdictions.
- The federal agencies should assist local jurisdictions in developing model legislation on healthy housing.
- The federal agencies should attempt to develop and reach consensus on one definition of "green" during the ongoing healthy housing collaborative efforts.
- The federal agencies should engage non-traditional partners in the healthy housing initiatives, such as AARP and large insurance companies that can play an important role in prevention, advocacy and policy development.
- The federal agencies should use valuable environmental data that will be generated from the National Children's Study to inform the healthy homes initiatives.
- CDC should conduct formal clinical trials in addition to observational research as progress is made on the healthy homes initiative. For example, a study could be performed on the remediation of mold with no other improvements made in the home. These findings could be used to determine whether the sole remediation of mold in the home made an impact on depression.

Dr. Brown made several remarks in response to specific questions posed by the ACCLPP members. First, the new interagency Healthy Housing Surveillance Workgroup will begin to identify existing data sets during its first meeting in October 2007. This effort will allow the workgroup to propose healthy homes benchmarks in the future.

Second, Dr. Brown provided guidance to states with an interest in incorporating the five guiding principles of the healthy housing framework for action into existing programs. Training should be provided to staff in local and state lead programs and other agencies beyond local and state health department personnel. To facilitate this effort, the Healthy Housing Training Center Network offers a 2.5-day training session in nine academic settings across the country.

Dr. Brown also pointed out that states and local jurisdictions must seriously consider the regulatory framework, costs and other important issues associated with incorporating a healthy housing framework into existing programs.

Third, Dr. Brown confirmed that she would give some thought to potential strategies for CDC to obtain external advice on the healthy homes initiative. However, she emphasized that several important issues would need to be considered. On the one hand, ACCLPP is federally chartered to provide guidance and recommendations to the HHS Secretary and CDC Director on childhood lead poisoning prevention. An expansion of ACCLPP's focus to include healthy homes issues would require a new charter.

On the other hand, an entirely new healthy homes advisory committee could be established in addition to ACCLPP. However, CDC is more interested in convening expert panels to provide advice on specific issues rather than forming new federal advisory committees.

Overall, Dr. Brown clarified that decisions on this issue would be premature at this point because the healthy homes initiative is in its infancy. However, she thanked ACCLPP for raising this important issue at this time because the terms of several members would expire in 2008. The healthy homes initiative would provide ACCLPP with an opportunity to determine whether potential candidates in 2008 should be recruited based on their expertise in lead, healthy homes, or a combination of both disciplines.

The Role of Low-Income Housing Tax Credits (LIHTC) in Childhood Lead Poisoning

Dr. David Jacobs, of NCHH, explained that the LIHTC program is operated by the Department of Treasury and is the federal government's largest program for new housing construction and rehabilitation of low-income properties. In 2007, each state received $1.95 per person under the LIHTC program or a total of $500 million. Private investors, syndicators and developers contributed additional leveraged funds on the order of hundreds of millions of dollars.

The LIHTC program requires units to have a "low-income" status for 15-30 years. Since 1986 when the program was established, 1.9 million units have been rehabilitated or constructed. Slightly less than 500,000 units were built before 1978 and are likely to have lead paint.

Dr. Jacobs summarized an evaluation of the LIHTC program. Processes widely vary for states to administer the LIHTC and address lead paint issues. Each state and some large cities develop qualified allocation plans (QAPs) to determine strategies to award credits. Of 52 QAPs, only 15 explicitly address lead-based paint (LBP). Of these 15 QAPs, only four specifically state that LBP hazards are required to be eliminated or controlled during rehabilitation of older housing units. These findings indicate that 74% of rehabilitated housing units under the LIHTC program do not have LBP requirements.

States have the option of administering the LIHTC program through state housing codes or HUD Uniform Physical Condition Standards (UPCS). Private underwriting standards do not provide specific LBP requirements. Federal Housing Authority regulations cover LBP, but are limited to multi-family mortgage insurance and HUD-owned single-family dwellings sold with a HUD-insured mortgage. Single-family mortgage insurance regulations covering single-family units not being sold were not updated in HUD's most recent LBP regulations in 2000.

The Internal Revenue Service (IRS) recently issued guidance materials noting that HUD's lead-safe housing rule applied to each state that used UPCS as its inspection standard. However, no specific details were provided on applicable parts of the regulation, such as rehabilitation. States that do not select UPCS are not under an affirmative responsibility to follow any lead-safe procedures unless another federal or state local authority requires compliance. The IRS has not issued any training materials on lead-safe practices.

In 2003, the IRS failed to execute a proposed memorandum of understanding (MOU) with HUD and the Department of Agriculture to clarify LBP issues in the low-income housing tax credit program. However, HUD and the Department of Treasury had previously executed an MOU regarding fair housing requirements. As a result, fair housing is now addressed in all QAPs. The IRS provides written instructions for persons to complete and submit Form 8823, "Low-Income Housing Credit Agencies Report of Noncompliance or Building Disposition," with their tax returns.

A formula was developed to estimate the number of housing units in the LIHTC program that would have been at risk for LBP hazards from 1986-2006. The formula projected that 193,000 housing units might have been rehabilitated with no lead requirements over this six-year period of time and that 14,200 housing units would have been at risk annually for each of the six years.

Dr. Jacobs informed ACCLPP that CDC administered a survey to CLPPP grantees with the following questions: (1) What is the number of programs that are aware of the LIHTC? (2) Are programs aware of QAPs? (3) Do these QAPs address lead? (4) What is the program's relationship with HUD and local housing agencies in administering the LIHTC? (5) What are the next steps regarding the inclusion of lead elements in QAPs in your project? (6) When will the QAP be drafted and finalized for the upcoming final project year?

The survey to CLPPPs showed the following results. Of 42 respondents, only 23 programs were aware of the LIHTC; 13 programs that were not aware of the LIHTC performed research to investigate this issue; six programs had no knowledge of the LIHTC; and nine programs had knowledge of QAP strategies to specifically address lead. The survey also showed that several states had limited relationships with HUD and state housing agencies.

CLPPPs should be educated on the possible use of the LIHTC for lead poisoning prevention. Property owners, developers, investigators, syndicators and local housing

agencies should incorporate specific lead requirements in QAPs and award additional points for lead hazard control, particularly for low-income eligible populations. Communications should be improved with state and local housing agencies and between CLPPPs and HUD.

A template should be developed to incorporate lead poisoning prevention language into all QAPs. The model for Fair Housing requirements should be reviewed in this effort. Federal rules should be clarified to include lead as a requirement in QAPs. States should closely partner with state housing agencies to draft, establish and document lead paint requirements into appropriate QAPs. CLPPPs and state and local housing agencies should collaborate to review and modify QAPs on an annual basis.

EPA, HUD, and state and local housing agencies should be included in existing or upcoming coalitions, partnerships, and strategic advisory committees. QAPs should consider dust, soil, ventilation, moisture and other non-paint issues due to the transition toward healthy homes. A listing of state and city QAPs that award points for green rehabilitation and construction should be developed and widely distributed.

Dr. Jacobs asked ACCLPP to consider several key questions during its ongoing discussions on healthy housing: (1) What strategies should be implemented to address non-paint issues? (2) Should non-paint issues be included in QAPs? (3) Who has responsibility of non-paint issues? (4) Who is responsible for assuring that LSWPs are used in LIHTC rehabilitation? (5) Should contractors be required to show proof of LSWP training? Dr. Jacobs informed ACCLPP that the entire LIHTC report is available to the public on the Alliance for Healthy Homes web site at: www.afhh.org/res/res_pubs/lihtc_cdc_report_final.pdf.

Study Designs Related to Adverse Health Effects of BLLs <10 µg/dL

Dr. Rhoads explained that he structured his presentation with three major objectives. First, recent results concerning the effects of low-level lead exposures would be reviewed in the context of changes in BLLs in U.S. children over the past few decades. Second, study design issues would be reviewed to identify sources of possible bias. Third, strategies would be proposed for studies that might resolve some of the ambiguities in what is known about the effects of BLLs <10 µg/dL.

Several studies have been conducted that relate childhood blood lead at levels < 10 µg/dL to developmental outcomes. A prominent finding has been that the relationship between blood lead at these low levels is more strongly related to outcomes, such as IQ and reading scores, than was reported from older studies conducted when children had higher BLLs. Thus, according to these findings, a change in blood lead from 10 µg/dL to 5 µg/dL would

make more difference to developmental outcomes than would a change from 15 µg/dL to 10 µg/dL.

This somewhat unexpected result may not be fully consistent with the U.S. national experience. NHANES data showed a dramatic decrease in BLLs among U.S. children 1-5 years of age from 15 µg/dL in 1976-1980, to 3.6 µg/dL in the early 1990s, and to 1.9 µg/dL in 1999-2002. Based on coefficients reported by Canfield *et al.*, IQ was predicted to improve in children three years of age by 1.5 points with a decrease from 15 to 10 µg/dL BLL and by a striking 8.7 IQ points with a decrease from 10 to 3.6 µg/dL BLL.

On a population basis in the United States, coefficients from this study would predict a nationwide improvement of 10.2 IQ points by the early 1990s with further improvement since that time. This is a very large predicted improvement, but no consensus has been reached among psychologists and educators that such a remarkable change occurred.

A cross-sectional analysis was performed in 2000 with NHANES III data. This national sample included 4,816 children 6-16 years of age. Venous blood lead was collected and the children completed several measures of psychological function and school achievement. The analysis showed that the coefficient relating reading scores on the Wide Range Achievement Test-Revised (WRAT-R) to BLL were 0.99 for all children and 1.53 for those who had never had a BLL >7.5 µg/dL.

The arithmetic subtest coefficient was 0.70 in all children and 1.06 in children with peak BLLs <7.5 µg/dL. When these coefficients were applied to the change in BLL that was actually documented for the United States between 1976-1980 and the early 1990s, they implied an improvement of 13.4 points on the WRAT-R reading score. However, actual tracking of reading scores in children nine years of age by the National Educational Assessment Survey revealed no sign of such a change.

Dr. Rhoads described sources of possible bias in the studies. All studies relating blood lead to neurodevelopment of children were observational and could be biased by differences between highly exposed and less exposed children. Although many such factors were taken into account, elimination of all of the important differences cannot be assured in observational studies.

Points of particular concern are whether children with less intellectual and academic potential might, on average, have more hand-to-mouth activity as toddlers or whether parents who organize their homes and childrearing practices in ways that minimize lead exposure might also provide more developmental stimulation for their children. These types of confounding could account for the steeper BLL-IQ curves that have been recently reported as was noted in the 2005 CDC document on this topic.

The finding of reverse causality based on an IQ relationship at 10 µg/dL was not widely predicted when the level of concern was established at 10 µg/dL. Exact predictions could

not be made with scenarios where children with less IQ potential had more hand-to-mouth activity or more opportunity to ingest non-foods.

Dr. Rhoads then outlined some possible future directions regarding this issue. Despite the caveats outlined above, recent studies are worrisome. Better research is needed to address existing uncertainty and determine whether the relationship between IQ and low BLLs is real and is of substantial magnitude. IQ-blood lead slopes reported in recent low-level studies appear to be too steep to be entirely credible. Steeper blood lead or an IQ curve at low BLLs suggests possible reverse causality. However, these considerations should not rule out an important IQ effect at low BLLs.

More observational studies adhering to the same basic designs that have been previously used are likely to be subject to the same biases as those recently reported and might never provide a basis for deciding when BLLs are low enough. A randomized primary prevention trial would be the best strategy to clarify these issues, but might be difficult to implement. Observational studies with different designs might be helpful.

New observational studies should be designed with a measure of exposure that is independent of ingestion, such as a study on the IQs of siblings raised in different housing with different levels of lead exposure. Non-lead markers should be identified to assess non-food ingestion and control for the association between blood lead and IQ. Genomic approaches should be used to identify single nucleotide polymorphisms or haplotypes that place children at risk.

To conduct a randomized prevention trial, a situation where phased housing intervention is being implemented to reduce lead exposure should be located. Families should be assigned to the improved housing in a fair and random manner. Differences in blood lead should be measured between the two groups. Developmental measures in children raised in new housing with low lead levels should be compared to children raised in old housing.

ACCLPP extensively discussed the advantages and disadvantages of lowering the BLL of concern. Most members agreed with Dr. Rhoads' proposal to conduct a randomized prevention trial. The members made two key suggestions that should be considered as ACCLPP continues this discussion in the future.

First, CDC should maintain, clarify and strengthen its focus and investments on primary prevention and healthy housing for community interventions to be implemented at BLLs <10 µg/dL. No interventions are available at this time to support public interest in lowering the BLL of concern to <10 µg/dL. Second, CDC should eliminate its language of a "BLL of concern" because the agency has no regulatory authority to mandate a threshold for lead.

In its future discussion on this issue, Dr. Brown encouraged ACCLPP to consider lowering the BLL of concern to <10 µg/dL from both public health and pragmatic perspectives.

Public Comment Session

Dr. Jacobs advised CDC to define BLLs 1-10 µg/dL as "above average." This approach would eliminate public confusion about "levels of concern" or specific interventions to implement.

Mr. Jack Bradham, of the Hennepin County Health Department, announced that Hennepin County would meet the *Healthy People 2010* objective of "0 EBLLs" if current trends in BLLs continued and the BLL threshold continued to be defined at 10 µg/dL. Due to the difficulty in defining "0 EBLLs," Mr. Bradham asked ACCLPP to provide guidance on a pragmatic definition, particularly in light of newly arrived immigrant children and rare fatal lead cases.

Dr. Brown explained that CDC has proposed the following definition of achieving the *Healthy People 2010* goal for childhood lead as a public health problem based on NHANES. NHANES would be administered as currently constructed. If the prevalence of BLLs >10 µg/dL was low enough so that no child would be identified with a BLL ≥10 µg/dL in 95 out of 100 trials, this result would be consistent with achieving the *Healthy People 2010* goal for childhood lead as a public health problem.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 5:35 p.m. on September 18, 2007.

Update by the Lead and Pregnancy Workgroup (LPWG)

Dr. Rhoads reconvened the ACCLPP meeting at 8:33 a.m. on September 19, 2007 and yielded the floor to the first presenter.

Dr. Jessica Leighton, an ACCLPP member and chair of LPWG, provided a status report on LPWG's activities following the March 2007 meeting. Because LPWG located only a minimal amount of data to support some of the recommendations, she asked ACCLPP to extensively critique the recommendations for each chapter of the lead and pregnancy report. She confirmed that the lack of data would be highlighted as a caveat in the report.

Dr. Leighton pointed out that since LPWG's update to ACCLPP in March 2007, the chapters of the lead and pregnancy report were revised as follows:

- Chapter 1: Introduction
- Chapter 2: Adverse health effects of exposure to lead
- Chapter 3: Biokinetics and biomarkers of lead in pregnancy and lactation
- Chapter 4: Sources and pathways of lead exposure in pregnant women
- Chapter 5: Identification and follow-up of EBLLs in pregnancy and infancy
- Chapter 6: Environmental, behavioral, nutritional and medical management

- Chapter 7: Indications, contraindications and adverse effects of chelation in the pregnant woman, fetus and newborn infant
- Chapter 8: Breastfeeding
- Chapter 9: Research, policy and health education needs

Dr. Leighton summarized key points and recommendations in the chapters of the lead and pregnancy report. The following points are emphasized in Chapter 1: "Introduction." Lead exposure remains a public health problem for women of childbearing age, the developing fetus and nursing infant. Evidence has been produced on the effects of lead on maternal and infant birth and neurodevelopment outcomes.

Bone lead stores were previously considered to be inert, but are mobilized in pregnancy and lactation. Certain population subgroups are at high risk for exposure, including workers in high-risk occupations, foreign-born recent immigrants, and persons practicing pica and other high-risk behaviors. Medical and public health providers have sought guidance for the identification, treatment and follow-up of lead-exposed pregnant and lactating women and prenatally exposed infants.

The following points are emphasized in Chapter 2: "Adverse health effects of exposure to lead." Lead exposure is associated with increased risk of hypertension. However, a magnitude of effect, exposure level at which risk increases, and association between risk and acute or cumulative exposure have not been established to date. Some evidence has been produced to support an association between moderate levels of maternal lead exposure and spontaneous abortion.

Inconsistent associations have been seen between maternal lead exposure and risk of preterm delivery. Data are inadequate to establish the presence or absence of an association between maternal lead exposure and major congenital anomalies in the fetus. Epidemiologic cohort studies suggest that even with maternal BLLs <10 µg/dL, prenatal exposure to lead is inversely related to fetal growth and neurobehavioral development independent of effects of postnatal exposure.

The following points are emphasized in Chapter 3: "Biokinetics and biomarkers of lead in pregnancy and lactation." No accurate measure of total body lead has been established to date. Biological markers are used to estimate lead body burden and assess lead dose to the fetus during pregnancy and to the infant during lactation. BLLs are the most well validated and widely available measure of lead exposure. However, a single blood lead measure at a given point in time will not provide an accurate indication of cumulative exposure or risk to the fetus or infant. Repeat testing might be necessary.

Bone is a potential source of endogenous lead exposure. Cumulative maternal bone lead stores are mobilized during pregnancy and lactation. However, bone lead measurement is a research tool that is not available for routine clinical application. Lead readily crosses the placenta by passive diffusion and has been measured in the fetal brain as early as the end

of the first trimester. As a result, primary prevention of exposure is particularly important to reduce risk. Given the difficulty of accurately and precisely measuring trace amounts of lead in human breast milk, routine measures of breast milk lead should not be used for routine clinical application.

The following recommendations are highlighted to prevent or reduce lead exposure in pregnant women in Chapter 4: "Sources and pathways of lead exposure in pregnant women." Clay, soil, pottery, paint chips and other non-food items should never be eaten. Jobs or hobbies that might involve contact with lead should be avoided, such as construction work, home renovation or repair, furniture refinishing, and work involving firearms, arts and crafts, ceramics, stained glass, metals or color pigments.

Imported clay pots and dishes should not be used to cook, serve or store food. Chipped or cracked pottery should not be used. Repair work and remodeling on homes built before 1978 should be avoided. Health remedies and kohl, kajal, surma and other eye cosmetics from other countries should be avoided. Caution should be taken when consuming candies, spices and snack foods made in other countries. A balanced diet should be eaten with adequate intakes of iron and calcium. Table 4-1 contains an extensive list of risk factors for EBLLs in pregnant women.

The following recommendations are highlighted for blood lead screening in Chapter 5: "Identification and follow-up of EBLLs in pregnancy and infancy." Universal blood lead testing of all pregnant women in the United States is not recommended. Routine blood lead testing of pregnant women is recommended in clinical settings serving populations at high-risk for lead exposure. In clinical settings where routine blood lead testing of pregnant women is not indicated, healthcare providers should consider the possibility of lead exposure in all pregnant women by evaluating risk factors for exposure.

The presence of specific risk factors indicates the need for blood lead testing. When indicated, blood lead testing should take place at the earliest contact with the pregnant patient and also should be performed using venous blood lead tests. State or local public health departments should identify high-risk populations of pregnant women to guide clinicians in determining the need for blood lead testing. Follow-up blood lead testing is indicated for pregnant women with BLLs $\geq$5 µg/dL and their infants.

Pregnant women with confirmed BLLs $\geq$45 µg/dL should be considered as high-risk pregnancies and managed in consultation with an expert in lead poisoning and high-risk pregnancies. Tables 5-1 through 5-4 contain the following information: (1) recommended actions by BLL in pregnancy; (2) frequency of maternal blood lead follow-up testing during pregnancy; (3) follow-up of initial blood lead testing of the neonate <1 month of age; and (4) schedules for subsequent follow-up blood lead testing in infants <6 months of age.

The following recommendations are highlighted for avoidance of lead exposure in Chapter 6: "Environmental, behavioral, nutritional and medical management." Point sources of

exposure should be identified and eliminated or controlled. Occupational exposures should be avoided. Personal protective equipment should be used.

Recreational activities that might involve lead exposure should be avoided. Drinking of lead-contaminated tap water should be avoided either by using bottled or filtered water or flushing the tap. Pica behavior is common among women identified with high BLLs in pregnancy and should be assessed and discouraged.

If renovation, remodeling or repairs are undertaken in homes built before 1978 with lead paint or paint with unknown lead content, pregnant and lactating women should be protected from lead exposure by adhering to EPA's LSWPs, including isolation from the work area. Products that might contain lead should be avoided, including culturally-specific products produced outside of the United States and ceramics, herbal medicines, cosmetics, foods, spices and candies.

The following nutritional recommendations are highlighted in Chapter 6. All pregnant and lactating women should be evaluated for the adequacy of their diets and should be provided with appropriate nutritional advice and prenatal vitamins. Adequate nutrition should be maintained throughout pregnancy and lactation.

The following actions should be taken for pregnant and lactating women with EBLLs or a history of EBLLs. A dietary calcium intake of 2,000 mg daily should be maintained either through diet or supplementation or a combination of both. Iron status should be evaluated and supplementation should be provided to correct any iron deficiency.

The following medical management recommendations are highlighted in Chapter 6. Pregnant women with confirmed BLLs $\geq$45 µg/dL should be considered as "high-risk" and managed in consultation with lead poisoning and high-risk pregnancy experts. Pregnant women with confirmed BLLs <45 µg/dL should be retested according to the schedules in Chapter 5 and Chapter 8 if breastfeeding. Table 6-1 contains a list of suggested factors to assess and characterize pica behavior.

The following recommendations are highlighted for chelation therapy in Chapter 7: "Indications, contraindications and adverse effects of chelation in the pregnant woman, fetus and newborn infant." Chelation treatment should be considered for pregnant women with BLLs >45 µg/dL and if organogenesis is complete (i.e., after the first trimester). The decision to chelate should be performed in consultation with an expert.

Pregnant women with life-threatening lead encephalopathy should be chelated regardless of trimester. Before considering chelation therapy in the pregnant woman or infant, BLLs should be repeated and confirmed using an additional venous blood lead sample collected within 24 hours. Chelation treatment must occur in a lead-free environment. As a result, the patient should be removed from further lead exposure prior to initiating chelation therapy.

Pregnant women with confirmed BLLs ≥45 µg/dL should be considered as "high-risk" and managed in consultation with lead poisoning and high-risk pregnancy experts. Infants 0-6 months of age with confirmed BLLs ≥45 µg/dL should be considered as candidates for chelation in consultation with a pediatric expert in lead chelation therapy. Tables 7-1 and 7-2 contain the following information: (1) chelating agents used to treat lead poisoning and (2) published experience with chelating agents during pregnancy in humans.

The following recommendations are highlighted for breastfeeding in Chapter 8. Due to the possibility of an increase in BLLs during lactation, a woman with BLLs ≥20 µg/dL identified during pregnancy should have BLLs monitored during lactation. Women with confirmed BLLs ≥40 µg/dL should not breastfeed unless the mother and baby are closely monitored.

At maternal BLLs between 20-40 µg/dL, data do not exist to accurately weigh the risks of lead exposure from breast milk against the benefits of breastfeeding. At these levels, the woman may continue to breastfeed if sequential BLLs of the mother and infant are performed to monitor trends in BLLs. If these sequential BLLs do not decline as expected, extra attention should be paid to identifying ongoing sources of lead in the mother-infant pair. Specifically, a thorough investigation of the child's environment should be performed to evaluate the possibility of additional lead sources.

Tables 8-1 through 8-4 contain the following information: (1) frequency of maternal blood lead follow-up testing during lactation to assess risk of infant lead exposure from maternal breast milk; (2) recommended values estimated for breast milk intake by age in months; (3) estimated daily intake of lead from breast milk at different maternal blood lead concentrations; and (4) estimated infant blood lead concentration associated with different maternal blood lead concentrations.

LPWG will develop key recommendations for research, policy and health education needs for Chapter 9 during its next meeting.

ACCLPP commended Dr. Leighton and the other LPWG members for developing a document on an extremely complex issue. ACCLPP acknowledged that LPWG has been challenged in creating the lead and pregnancy report due to the lack of data to support certain recommendations.

Several ACCLPP members made suggestions for LPWG to consider in its ongoing efforts to revise the report.

- Chapter 1: New language should be added to the introduction to outline the anticipated impact of screening pregnant women on clinical practice.
- Chapter 2: "Moderate" should be characterized with a specific range because laboratories do not define BLLs as elevated until 25 µg/dL.

- Chapter 3: Language should be added to clarify that x-ray and breast milk are not practical at this point in time because both of these factors could change in the future.
- Chapter 4: More emphasis should be placed on hand-to-mouth activities related to pica in addition to actual consumption of non-food items.
- Chapter 4: A recent paper that quantifies tobacco use as a source of lead in pregnant women should be referenced. Dr. Binns will provide LPWG with the citation of the paper.
- Chapter 4: Language should be added to explicitly identify a "child" as another individual with an EBLL who lives with a pregnant woman.
- Chapter 5: A general statement should be added to advise pre-conceptual care providers to consider risk factors.
- Chapter 5: Language should be added to clarify that if the provider uses a questionnaire, the questions should be modified to be relevant and specific to local needs.
- Chapter 5: Language should be added for states to develop strategies to identify and track patients through blood lead reporting systems.
- Chapter 5: Papers in the literature that recommend medical removal of pregnant women from occupational lead exposure should be cited, such as the article on *Recommendations for Medical Management of Adult Lead Exposure* that was published in March 2007. Although the OSHA threshold for medical removal is 50 µg/dL, a proviso in the OSHA regulations authorizes physicians to recommend medical removal at any BLL if a woman has a health condition that places her at increased risk of lead exposure. Dr. Kosnett will provide LPWG with language to address this issue.
- Chapter 5: LPWG should discuss and reconsider the threshold of 5 µg/dL for screening of pregnant women. Laboratory capacity is not sufficient to quantify lead at BLLs <10 µg/dL in pediatric screening and a considerable amount of uncertainty exists with BLLs <10 µg/dL. This outcome would be the same for screening pregnant women. Dr. Parsons will provide LPWG with language to address this issue.
- Chapter 5: The first BLL columns in Tables 5-1 through 5-4 should all be "<5" for consistency.
- Chapter 5: The "≤4" column in Table 5-1 should be revised as follows: "Healthcare providers should routinely give anticipatory guidance to all pregnant women who work in industries where they could be exposed to lead and whose BLLs are low or unknown."
- Chapter 5: "Source reduction" should be moved from the "15-44" column in Table 5-1 and placed in the "5-9" column to clarify "identification of lead sources and reduction."
- Chapter 5: Language in the "15-24" column of Table 5-2 should be changed as follows. "At the next visit or in one month, a blood lead test between 15-14 should be repeated."

- Chapter 5: The title of Table 5-4 should be clarified to ensure that the guidance is not interpreted to mean blood lead testing in infants <6 months of age should be performed.
- Chapter 5: The guidance should be changed in Table 5-4 to advise referral to a specialist earlier than BLLs ≥45 µg/dL.
- Chapter 6: Language should be added to the nutritional recommendations to emphasize that adequate vitamin D is necessary for calcium absorption.
- Chapter 6: LPWG should engage obstetricians in a dialogue regarding potential changes to the two medical management recommendations. For example, the first recommendation should clearly define the BLL that should be considered as a high-risk pregnancy. "High-risk pregnancy" should be clearly defined to mean a physician-to-physician consultation rather than a referral of the patient to a high-risk obstetrician. Language in the second recommendation should be changed to "retested and advised."
- Chapter 6: The medical management section should advise pregnant women to seek additional advice by consulting with lead poisoning experts. The types of providers that can provide expertise in lead poisoning should be described.
- Chapter 6: A new column should be added to Table 6-1 to specify whether actions should be taken based on outcomes in assessing and characterizing pica behavior.
- Chapter 6: Headers should be added to Table 6-1 to clarify and distinguish among "personal pica," "substances consumed," and "community context."
- Chapter 7: The term should be changed to "lead-safe environment" in the chelation therapy recommendations.
- Chapter 7: Language should be added to the chelation therapy section to clarify that sufficient data are not available to make a recommendation on chelating infants 0-6 months of age at BLLs <45 µg/dL. The provider should be advised to consult with a medical toxicologist.
- Chapter 7: The second and third breastfeeding recommendations should be switched to discuss BLLs 20-40 µg/dL first, followed by BLLs ≥40 µg/dL.
- LPWG should add a new appendix with three sections on "understanding BLLs in pregnancy." One, expected BLL patterns in pregnancy should be clearly described. Two, language on interpreting laboratory uncertainties should be extracted from ACCLPP's <10 clinical paper. Three, the false-negative/false-positive table at a threshold of <5 µg/dL that Ms. Blumenthal presented during the meeting should be replicated. Dr. Parsons will assist LPWG in developing the new appendix.

Dr. Leighton thanked ACCLPP for providing LPWG with valuable feedback. She asked the members to submit additional comments in writing by November 1, 2007 in preparation of LPWG's next meeting on November 8, 2007. An electronic version of the report and references would be circulated to ACCLPP to facilitate the submission of comments. Dr.

Leighton planned to present the full lead and pregnancy report during the March 2008 ACCLPP meeting.

Dr. Brown described CDC's next steps in the lead and pregnancy report. CDC would draft policy and research recommendations for Chapter 9. As a scientifically influential document from a federal agency, the report would be required to undergo separate clearance processes at CDC, HHS and the Office of Management and Budget. The cleared document would then need to be peer reviewed by three outside experts with no conflicts of interest in the subject matter.

Dr. Brown estimated that after ACCLPP formally approved the final draft, the report would not be published for two years due to the clearance, peer review and final editing processes. However, the two-year lag would provide an opportunity for CDC and the authors of the report to incorporate new data produced during this time. CDC also would coordinate efforts with OSHA and the National Institute for Occupational Safety and Health to ensure that the lead and pregnancy report was consistent with guidance documents produced by these agencies. Alternatively, CDC would need to provide a strong rationale for any inconsistencies between the documents.

At a future meeting, Dr. Brown planned to engage ACCLPP in a discussion about publication options. For example, the lead and pregnancy report could be published as a standalone document, in the *MMWR*, or in an obstetric or pediatric journal. She confirmed that CDC has informed state health departments about the timeline for the upcoming publication of the document.

Update by the Model Codes Workgroup (MCWG)

Ms. Jane Malone, chair of MCWG and the ACCLPP liaison to the Alliance for Healthy Homes (AFHH), provided a status report on MCWG's activities following the March 2007 meeting. MCWG discussed and reviewed proposals to submit to the International Code Council (ICC) on international property maintenance codes (IPMCs). MCWG distributed and received comments from ACCLPP on its draft position statement to improve IPMCs to prevent exposure to LBP hazards.

ICC adopted several proposals in its 2006-2007 code change cycle that ended in May 2007, but none of MCWG's proposals were accepted. MCWG's proposals focused on expanding language in the IPMCs from "ensuring no peeling paint" to include "appropriately addressing deteriorated LBP." MCWG's proposals also explicitly defined LSWPs and added a clearance requirement.

Ms. Malone announced that ICC initiated its new code change cycle with the first hearings to be held in March 2008. ICC will consider changes to the IPMCs that AFHH and NCHH

jointly submitted in August 2007 during the first hearing in March 2008. The AFHH/NCHH changes focus on painted surfaces in interior properties and clearly define practices that are prohibited in repairing deteriorated LBP. The AFHH/NCHH changes were distributed to ACCLPP for review.

Dr. Brown reminded the members that at a previous meeting, ACCLPP unanimously approved sending a letter to ICC. The draft letter highlights ACCLPP's recommendations for the IPMCs to explicitly and effectively prohibit the creation of LBP hazards and also to enforce LSWPs. The letter references AFHH's web site for readers to obtain more information on specific standards.

Dr. Brown informed ACCLPP that the draft letter was submitted to the CDC clearance process and is expected to be approved over the next 30 days. The CDC-cleared letter will then be forwarded to the HHS Secretary for informational purposes only. After the 30-day period expires, Drs. Brown and Rhoads will sign and send the letter to ICC. The draft letter was distributed to ACCLPP for review.

In response to specific questions posed by ACCLPP members, Dr. Brown confirmed that the letter could be circulated to trade association publications in addition to ICC. She clarified that after CDC's formal approval and clearance, the letter would be in the public domain and could be reprinted in any venue. The letter also would be posted on ACCLPP's web page on the CDC web site.

New ACCLPP Business

Dr. Rhoads opened the floor for the members to revisit outstanding items or propose new topics that need action by ACCLPP.

Dr. Kosnett asked ACCLPP to consider developing language on the interpretation of clinical laboratory report forms for blood lead testing. He pointed out that ACCLPP's guidance could assist in minimizing variability and enhancing consistency among clinical laboratory forms in interpreting lead concentrations.

Dr. Kosnett proposed that the laboratory workgroup's charge could be expanded to address these issues. However, the workgroup's membership would need to be broadened to include persons with experience and expertise in interpretation issues. Alternatively, an entirely new "Interpretation Workgroup" could be established.

Dr. Brown asked ACCLPP to delay taking action on Dr. Kosnett's proposal until Dr. Parsons submits clinical laboratory language to LPWG. ACCLPP could make a decision at that time on whether a new "Interpretation Workgroup" would be needed or if the voting members would simply need to vet Dr. Parsons' language. Overall, Dr. Brown reminded ACCLPP of

its federal charter to provide advice on lead poisoning prevention of children and not adults. She also emphasized the resource constraints in forming a new ACCLPP workgroup.

ACCLPP extensively discussed Dr. Kosnett's proposal to address the interpretation of clinical laboratory report forms for blood lead testing. Although ACCLPP agreed with Dr. Kosnett on the importance of addressing this issue, the majority of voting members were unable to reach consensus due to the caveats and limitations outlined by Dr. Brown in undertaking this effort.

Dr. Brown proposed the following process to resolve ACCLPP's dilemma. She would consult with CDC's laboratory staff to identify contacts in commercial laboratories and determine whether an easy mechanism could be implemented to address the interpretation of clinical laboratory report forms for blood lead testing. After Dr. Brown reported her findings to ACCLPP during the March 2008 meeting, the voting members could discuss and make a decision on the feasibility of developing and distributing model statements to commercial laboratories. None of the ACCLPP members expressed opposition to Dr. Brown's proposed approach.

Ms. Mosby informed ACCLPP that she learned EPA has not developed an explicit definition of "green." However, green building is closely linked to EPA's pollution prevention activities, including the reduction or elimination of waste at the source by modifying production processes and promoting the use of non-toxic or less toxic substances. Ms. Mosby conveyed that EPA's pollution prevention activities could be used as a mechanism to define "green."

Ms. Mosby announced that EPA recently approved 15 of 80 applicants that submitted proposals in response to the new Community-Based Grant Program. The 15 awarded applicants are located throughout the country and will forge partnerships between national and community-based organizations to address infrastructure building, ordinance issues, outreach and education, and training. EPA expects to post a notice of approval of the 15 awarded applicants on its web site by the end of September 2007. The total grant award is ~$3.3 million.

Dr. Friedman confirmed that both he and Ms. Mosby would follow-up on ATSM standards for laboratory projects and report their findings to ACCLPP at a future meeting.

Dr. Brown reported that Ms. Valarie Johnson, an ACCLPP member, and Ms. Cassandra Archie, were scheduled to make a presentation on the previous day on educational services of lead poisoned children. Because the two speakers were unable to attend the meeting, this topic would be placed on ACCLPP's March 2008 agenda.

Dr. Brown acknowledged the strong interest of CDC, ACCLPP and other national groups in developing recommendations for early childhood and early elementary education of lead poisoned children. She pointed out that CDC, ACCLPP and other organizations have made

Closing Session

The participants applauded Mr. Barry Brooks, Ms. Charlotte Cloud-Williams, Ms. Joy Gulliksen and Ms. Claudine Johnson, of LPPB, for providing outstanding administrative support and making logistical arrangements for the meeting. The next ACCLPP meeting would be held on March 18-19, 2008 in Atlanta, Georgia.

With no further discussion or business brought before ACCLPP, Dr. Rhoads adjourned the meeting at 11:50 a.m. on September 19, 2007.

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

1/31/08
Date

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