

**ACCLPP**  
**Lead and Pregnancy Work Group**  
**Status Report**

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# Today's Presentation

- Review of charge
- Time and progress
- Report Outline
- Recommendations
- Next steps
- What is needed from Advisory Panel

# Charge to the Work Group

Recommendations will be made on:

- prevention of lead exposure for pregnant and lactating women
- risk assessment and screening of pregnant women
- medical, public health and environmental management
- breast feeding
- follow-up of infants and children of mothers with elevated blood lead levels.
- further research and health education needs in this field

# Approach

- Review existing evidence
- Evaluate data and issue recommendations for: prevention, risk assessment, screening, medical & environmental management, breastfeeding, and follow-up of EBLLs
- Describe data gaps
- Prepare recommendations for research and health education needs
- Report

# Work Completed and Revised Estimated Timeline

<b><u>Task</u></b>	<b><u>Estimated Completion</u></b>
• <b>Workgroup Initiated</b>	<b>April 2004</b>
• <b>Literature Reviews</b>	<b>March 2005</b>
• <b>Draft Report on Summary of Literature</b>	<b>September 2005</b>
• <b>Outline of Report</b>	<b>December 2005</b>
• <b>First Draft Report</b>	<b>June 2006</b>
• <b>Circulate Draft Report to ACCLPP</b>	<b>September 2007</b>
• <b>Receive ACCLPP Comments</b>	<b>October 2007</b>
• <b>Final Draft to ACCLPP</b>	<b>December 2007</b>
• <b>Revise and submit for CDC clearance</b>	<b>February 2008</b>

# In-Person Meetings

- July 14, 2004 (New York)
- November 19, 2004 (New York)
- April 15, 2005 (Boston)
- September 16, 2005 (Boston)
- December 14, 2005 (Philadelphia)
- May 12, 2006 (Atlanta)
- July 27-28, 2006 (Boston)
- November 8,-9 2006 (Boston)
- February 1-2, 2007 (San Francisco)
- Next Meeting April 16-17, 2007 (Atlanta)
- Future meetings in July and November 2007

# Revised Chapters

- 1 – Introduction
- 2 – Background and Significance
- 3 – Health Effects of Prenatal Lead Exposure
- 4 – Sources of Lead Exposure in Pregnancy and Lactation
- 5 – Epidemiology and Risk Factors for Elevated Lead Levels in Pregnant Women
- 6 – Blood Lead Screening and Follow-up Testing in Pregnancy and Infancy
- 7 – Environmental, Nutritional, and Behavioral Management
- 8 – Indications, Contraindications, and Adverse Effects of Chelation in the Pregnant Woman, Fetus, and Newborn Infant
- 9 – Breastfeeding
- 10 – Research, Policy, and Health Education Needs
- List of References

# Sources of Lead Exposure During Pregnancy and Lactation

- Lead Paint: Home remodeling, repair and renovations
- Contaminated Soil
- Lead Glazed Ceramic Pottery
- Imported folk remedies, alternative medications, herbal and personal care products
- Consumer Products and Food
- Occupations
- Hobbies and Recreational Activities
- Point Sources
- Leaded Gasoline
- Endogenous Stores
- Drinking Water

# Risk Factors in Pregnant Women

- **Living near a point source of lead**
- **Recent immigrants from an area where ambient lead contamination is high or sources are common**
- **Use of lead-glazed ceramics or imported pottery**
- **Pica behavior**
- **Use of complementary and/or alternative medicines, herbs or therapies**
- **Use imported cosmetics or certain food products**
- **Work in Lead Industries**
  - **Take home exposures**
- **High-risk hobbies or recreational activities**
- **Renovation or remodeling of older homes**
- **Consumption of drinking water with high lead content**
- **History of previous lead exposure**

# Blood Lead Screening

## Key Recommendations

- Universal blood lead testing of pregnant women in the United States is **not** recommended
- Routine blood lead testing is recommended in populations at high-risk for lead exposure
- Venous blood lead levels are the preferred method of biological sampling to determine exposure to lead in pregnant women

# Blood Lead Screening

## Key Recommendations

- State or local public health departments should assist clinicians in determining the need for blood lead testing by identifying high-risk populations
- In clinical settings where routine blood lead testing of pregnant women is not indicated, individual risk assessment with careful attention to the risk factors should be addressed
- When indicated, blood lead testing should take place at the earliest contact with the pregnant patient

# Follow-up Testing

## Key Recommendations

- Follow-up blood lead testing is indicated for all pregnant women and newborns with a BLL  $\geq 5 \mu\text{g/dL}$

# Frequency and Timing of Maternal Blood Lead Follow-Up Testing

<b>Venous BLL</b>	<b>Perform a follow-up test:</b>
5-14	<ul style="list-style-type: none"><li>• Once in each successive trimester and at delivery</li></ul>
15-44	<ul style="list-style-type: none"><li>• Within 2 weeks and then every 1-2 months</li><li>• Obtain a maternal BLL at delivery</li></ul>
$\geq 45$	<ul style="list-style-type: none"><li>• Within 24 hours and then at frequent intervals depending on clinical interventions and trend in BLLs.</li><li>• Consultation with a clinician experienced in the management of pregnant women with BLLs in this range is strongly advised.</li><li>• Obtain a maternal BLL at delivery.</li></ul>

# Initial Follow-Up Blood Lead Testing of the Infant

<b>Initial BLL</b> (UC or Neonatal)	<b>Perform a follow-up test:</b>
<5	•According to local pediatric lead screening guidelines
5-14	•Within 1 month (at first newborn visit)
15-19	•Within 1 month (at first newborn visit)
20-24	•Within 1 month (at first newborn visit)
25-44	•2 weeks-1 month
≥45	•Within 24 hours and then at frequent intervals depending on clinical interventions and trend in BLLs. •Consultation with a clinician experienced in the management of pregnant women with EBLLs in this range is strongly advised.

# Schedule for Follow-Up Blood Lead Testing of Infants (0-6 Months of Age)

<b>Venous blood lead level (µg/dL)</b>	<b>Early follow-up (first 2-4 tests after identification)</b>	<b>Late follow-up (after BLL begins to decline)</b>
<10	In Discussion	In Discussion
10-14	3 months	6-9 months
15-19	1-3 months	3-6 months
20-24	1-3 months	1-3 months
25-44	2 weeks-1 month	1 month
>=45	As soon as possible	Chelation with subsequent follow-up

# Environmental, Behavioral, and Nutritional Interventions

## Key Recommendations

- In homes built before 1978, pregnant and lactating women should not be in the area where home renovations or lead-based paint hazard reduction work is being performed or temporary relocation.
- Pregnant women should avoid occupational or recreational activities that may expose them to lead

# **Environmental, Behavioral, and Nutritional Interventions**

## **Key Recommendations**

- Avoid imported products that may contain lead: herbal medicines; cosmetics; foods; spices; candies
- All pregnant and lactating women should be evaluated for the adequacy of their diets and be provided with appropriate nutritional advice and supplements
- In women with EBLLs, at high risk for lead exposure, or with a history of EBLLs, a dietary calcium intake of 2000 milligrams daily should be maintained, either through diet or supplementation or a combination of both.

# Environmental, Behavioral, and Nutritional Interventions

## Key Recommendations

- Iron supplementation is recommended to correct any deficiency for iron
- Pica behavior is common among women identified with high blood lead levels in pregnancy, therefore it should be assessed
- In homes with lead service pipes, pregnant and lactating women should refrain from drinking unfiltered tap water or using it to prepare infant formula

**TABLE 1. RECOMMENDED ACTIONS BY BLOOD LEAD LEVEL IN PREGNANCY**

<b>BLL</b>	<b>HEALTH CARE PROVIDERS</b>	<b>PUBLIC HEALTH PROVIDERS</b>
0-4	Routine anticipatory guidance and health education to all pregnant women	Collect all blood lead test results
5-9	Routine anticipatory guidance and health education materials to all pregnant women	Develop and disseminate guidelines and health education materials
	Identification of sources Confirmatory and Follow-up testing (see table 2)	Provide health education and prevention materials to clinicians
<b>≥5</b>	<p>There is no threshold It is desirable for BLLs to be &lt;5, but as they get closer to 10, should do more aggressive testing &amp; counseling (use wording from clinical paper*) Detailed risk assessment/source identification and reduction counseling Nutritional assessment and counseling Follow-up testing</p>	
10-14	Call Lead Poisoning Prevention Program	Send out health education materials
15-44	Follow-up testing, source reduction	Exposure assessment, source reduction, non-medical case management
>=45	2 <sup>nd</sup> trimester consider chelation (and inpatient hospitalization if chelating) in consultation with public health dept.	Refer providers with a list of identified lead poisoning experts
>=70	Medical emergency	

\*Reference: ACCLPP clinical implications of BLL<10 paper (forthcoming)

# Recommended Actions by Blood Lead Level in Pregnancy

BLL	Health Care Providers	Public Health Providers
O-4	Routine anticipatory guidance and health  Education to all pregnant women	Collect all blood lead test results  Develop and disseminate guidance materials on prevention and screening

# Recommended Actions by Blood Lead Level in Pregnancy

BLL	Health Care Providers	Public Health Providers
5-9	As above  Review sources with patient  Confirmatory and follow-up testing	As above  Provide health education and prevention materials to clinicians

# Recommended Actions by Blood Lead Level in Pregnancy

BLL	Health Care Providers	Public Health Providers
10-14	As above  Attempt source identification and reduction  Contact LPPP	As above  Send out Health education materials to provider and patient

# Recommended Actions by Blood Lead Level in Pregnancy

BLL	Health Care Providers	Public Health Providers
15-44	As above	As above  Exposure assessment, source reduction, non-medical case management

# Recommended Actions by Blood Lead Level in Pregnancy

BLL	Health Care Providers	Public Health Providers
$\geq 45$	<p>As above</p> <p>Urgent removal of patient from source</p> <p>Consider chelation in second half of pregnancy in consultation with lead and high risk pregnancy experts</p>	<p>As above</p> <p>Exposure assessment, source reduction, non-medical case management</p>

# Recommended Actions by Blood Lead Level in Pregnancy

BLL	Health Care Providers	Public Health Providers
$\geq 70$	Medical Emergency	As above  Exposure assessment, source reduction, non-medical case management

# Chelation

## Key Recommendations

- Confirmation of the blood lead level should be obtained before considering chelation therapy in a pregnant woman or infant
- Encephalopathic pregnant women should be chelated regardless of trimester
- With the above exception, chelation should be delayed until the completion of organogenesis

# Chelation

## Key Recommendations

- Pregnant women with confirmed BLLs  $\geq 45$   $\mu\text{g}/\text{dL}$  should be considered high-risk pregnancies and managed in consultation with an expert in high risk pregnancy and lead poisoning
- Chelation should be considered for pregnant women after the completion of organogenesis with a blood lead  $\geq 45$   $\mu\text{g}/\text{dL}$  and in consultation with a physician with expertise in chelation therapy for lead-poisoned pregnant women.

# Chelation

## Key Recommendations

- Calcium Edetate ( $\text{CaNa}_2\text{EDTA}$ ), although limited, is the agent most frequently used to chelate lead-poisoned pregnant women
- Infants (0-6 months of age) with a confirmed BLL of  $\geq 45 \mu\text{g/dL}$  should be considered as candidates for chelation in consultation with an expert in pediatric lead poisoning

# Key Recommendations for Breastfeeding

- These recommendations are based on decisions balancing benefits and risk and only apply to situations in the United States.
- Lactating women with BLLs  $\geq 5$   $\mu\text{g}/\text{dL}$  should have BLLs monitored
- A woman with a confirmed BLL greater than or equal to 40  $\mu\text{g}/\text{dL}$  should not breastfeed

# Key Recommendations for Breastfeeding

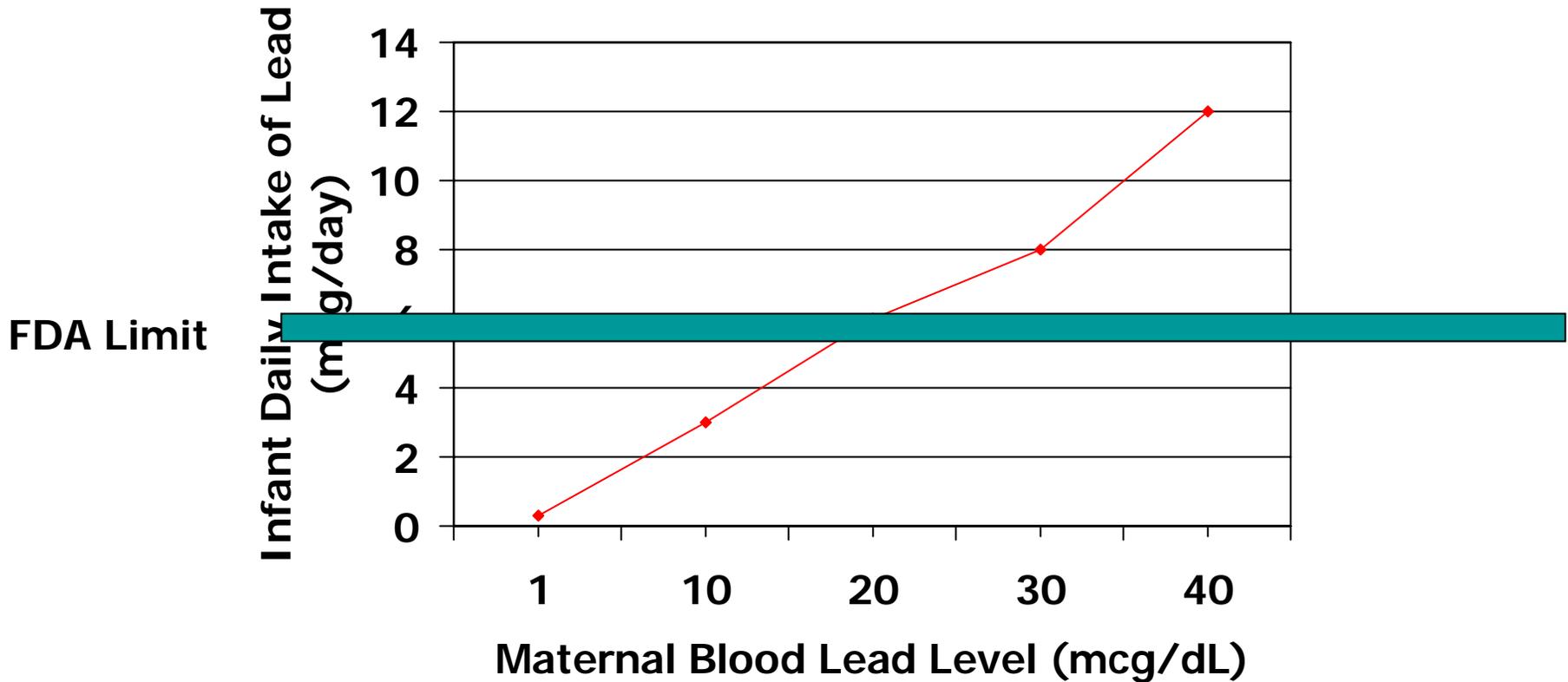
- At maternal blood lead levels between 5-40  $\mu\text{g}/\text{dL}$  breastfeed may continue while sequential BLLs of the mother and infant are performed to monitor trends in blood lead levels
- If these sequential BLLs do not decline as expected, extra attention should be paid to identify ongoing sources of lead in the mother-infant pair.

# Discussion

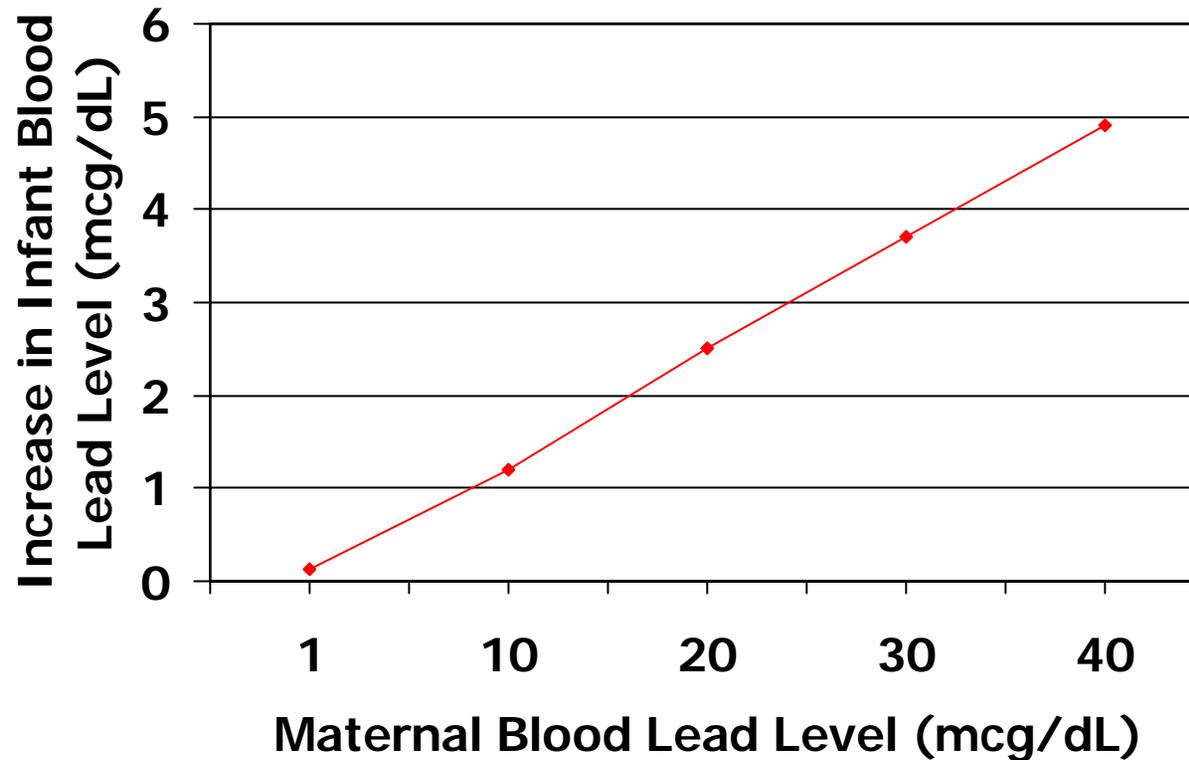
# Issue: Breastfeeding

- Breastfeeding has innumerable benefits to the Mother and the Infant.
- Some Lead does pass from the mother to the infant via breast milk.
- Theoretical calculations of exposure based on evidence in the literature estimate that an exclusively breastfed infant will ingest enough lead to raise the infants BLL.

# Estimate of Daily Intake of Lead in a Breastfed 9 month old Infant



# Estimated increase in Blood Lead Level of an Exclusively Breastfed 1 Month Old Infant



# Issue: Breastfeeding

- Do the benefits of breastfeeding (mortality, immunity, IQ) outweigh the exposure to lead?
- At what maternal BLL (if any) should breastfeeding be discontinued?
- At what increase in a nursing infant's BLL should breastfeeding be discontinued?

# Proposed Recommendation for Breastfeeding

- Discontinue breastfeeding if maternal BLL  $\geq 40$   $\mu\text{g}/\text{dL}$
- Blood lead levels 10-40  $\mu\text{g}/\text{dL}$ :
  - Take wait and see approach
  - Conduct environmental source investigation appropriate to maternal or infant BLL
  - Serial blood lead tests of mother and baby
  - Discontinue breastfeeding if infant BLL rises and no additional source of exposure has been found
  - Continue Calcium supplementation and Prenatal Vitamins

**Table 1. Frequency and Timing of Maternal Blood Lead Follow-Up Testing**

Initial Venous <sup>a</sup> Blood Lead Level (µg/dL)	Perform a follow-up test:
5-14	Once in each successive trimester and at delivery to assess the trend. <sup>b</sup>
15-44	Within 2 weeks and then every 1-2 months to assess trend. Obtain a maternal BLL at delivery. <sup>b</sup>
≥45	Within 24 hours and then at frequent intervals depending on clinical interventions and trend in BLLs. Consultation with a clinician experienced in the management of pregnant women with BLLs in this range is strongly advised. Obtain a maternal BLL at delivery. <sup>b</sup>

a. Venous blood sample is recommended for maternal blood lead testing.

b. Umbilical cord or neonatal blood lead level should be obtained at delivery.

**Table 2. Follow-Up Blood Lead Testing of the Neonate (< 1 month of age)**

<b>Initial Blood Lead Level<sup>a</sup> (µg/dL)</b>	<b>Perform a follow-up test:</b>
<5	According to local pediatric lead screening guidelines
5-14	Within 1 month (at first newborn visit)
15-19	1-3 months <sup>b</sup>
20-24	1-3 months <sup>b</sup>
25-44	2 weeks-1 month
≥45	Within 24 hours and then at frequent intervals depending on clinical interventions and trend in BLLs. Consultation with a clinician experienced in the management of pregnant women with BLLs in this range is strongly advised. <sup>b</sup>

a. The initial blood lead level may be either from an umbilical cord sample at the time of delivery or an infant venous BLL. A venous blood sample is preferred over a capillary sample. Decisions to initiate or stop breastfeeding or initiate chelation therapy should be based on venous blood lead test results.

b. According to pediatric well-baby visit schedule or as clinically-indicated based upon trends in blood lead levels.

The higher the BLL on the screening test, the more urgent the need for confirmatory testing.

c. The frequency of retesting should be based on the clinical interventions performed in consultation with a specialist.

**Table 3. Schedule for Follow-Up Blood Lead Testing**

<b>Venous blood lead level (µg/dL)</b>	<b>Early follow-up (first 2-4 tests after identification)</b>	<b>Late follow-up (after BLL begins to decline)</b>
10-14	3 months <sup>b</sup>	6-9 months
15-19	1-3 months <sup>b</sup>	3-6 months
20-24	1-3 months <sup>b</sup>	1-3 months
25-44	2 weeks-1 month	1 month
>=45	As soon as possible	Chelation with subsequent follow-up

Adapted from: Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention (2002)

- a. Seasonal variation of BLLs exists and may be more apparent in colder climate areas. Greater exposure in the summer months may necessitate more frequent follow ups.
- b. Some case managers or PCPs may choose to repeat blood lead tests on all new patients within a month to ensure that their BLL level is not rising more quickly than anticipated.