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## Screening for Elevated Blood Lead Levels in Children and Pregnant Women

#### **US Preventive Services Task Force**

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The US Preventive Services Task Force (USPSTF) is redesigning its recommendation statement in response to feedback from primary care clinicians. The USPSTF plans to release, later in 2006, a new, updated recommendation statement that is easier to read and incorporates advances in USPSTF methods. The recommendation statement below is an interim version that combines existing language and elements with a new format. Although the definitions of grades remain the same, other elements have been revised.

#### **SUMMARY OF RECOMMENDATIONS**

#### Children

- 1. The US Preventive Services Task Force (USPSTF) concludes that evidence is insufficient to recommend for or against routine screening for elevated blood lead levels (BLLs) in asymptomatic children aged 1 to 5 who are at increased risk (I recommendation) (see "Clinical Considerations" for a discussion of risk).
- 2. The USPSTF recommends against routine screening for elevated BLLs in asymptomatic children aged 1 to 5 years who are at average risk (D recommendation).

#### **Pregnant Women**

3. The USPSTF recommends against routine screening for elevated BLLs in asymptomatic pregnant women (D recommendation).

#### **RATIONALE**

#### **Importance**

BLLs in children have declined dramatically in the United States over the past 2 decades. However, segments of the population remain at increased risk for higher BLLs. Even relatively low BLLs are associated with neurotoxic effects in children. Severely elevated BLLs in symptomatic pregnant women are associated with poor health outcomes; however, BLLs in this range are rare in the US population.

2514

There is good evidence that venous sampling accurately detects elevated BLLs and fair evidence that validated questionnaires are modestly useful in identifying children at increased risk for elevated BLLs.

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#### **Key Words**

lead levels, evidence-based medicine, screening

#### **Abbreviations**

USPSTF—US Preventive Services Task Force

BLL—blood lead level

CDC—Centers for Disease Control and

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#### Benefits of Detection and Early Intervention

The USPSTF found good-quality evidence that interventions do not result in sustained decreases in BLLs and found insufficient evidence (no studies) evaluating residential lead hazard-control efforts (ie, dust or paint removal, soil abatement, counseling, or education) or nutritional interventions for improving neurodevelopmental outcomes in children with mildly-to-moderately elevated BLLs. The USPSTF found no studies examining the effectiveness of screening or interventions in improving health outcomes in asymptomatic pregnant women. Given the low prevalence of elevated BLLs in children at average risk and asymptomatic pregnant women, the magnitude of potential benefit cannot be greater than small.

A theoretical benefit of screening is that identification may prevent lead poisoning of other individuals in a shared environment, but the magnitude of this theoretical benefit is uncertain.

#### **Harms of Detection and Early Treatment**

There is good-quality evidence that chelation treatment in asymptomatic children does not improve neurodevelopmental outcomes and is associated with a slight diminution in cognitive performance. Chelation therapy may result in transient renal, hepatic, and other toxicity, mild gastrointestinal symptoms, sensitivity reactions, and rare life-threatening reactions. Residential leadbased paint and dust hazard-control treatments may lead to acutely increased BLLs from improper removal techniques. Potential harms of screening are false-positive results, anxiety, inconvenience, work or school absenteeism, and financial costs associated with repeated testing. Although the exact magnitude of these known and potential harms is uncertain, the overall magnitude is at least small.

No studies have directly addressed the harms of screening and interventions for pregnant women. Although there is little specific evidence concerning the potential harms of interventions for pregnant women with elevated BLLs, the magnitude of harms from such interventions is also at least small.

#### **USPSTF Assessment**

The USPSTF concludes that the evidence is insufficient to assess the balance between potential benefits and harms of routine screening for elevated BLLs in children at increased risk. Given the significant potential harms of treatment and residential lead hazard abatement, and no evidence of treatment benefit, the USPSTF concluded that the harms of screening for elevated BLLs in children at average risk and in asymptomatic pregnant women outweigh the benefits.

#### **CLINICAL CONSIDERATIONS**

- This USPSTF recommendation addresses screening for elevated BLLs in children aged 1 to 5 years who are at both average and increased risk and in asymptomatic pregnant women.
- The highest mean in the United States occurs in children aged 1 to 5 years (geometric mean: 1.9  $\mu$ g/dL). Children under 5 years of age are at greater risk for elevated BLLs and lead toxicity because of increased hand-to-mouth activity, increased lead absorption from the gastrointestinal tract, and the greater vulnerability of the developing central nervous system. Risk factors for increased BLLs in children and adults include minority race/ethnicity; urban residence; low income; low educational attainment; older (pre-1950) housing; recent or ongoing home renovation or remodeling; pica exposure; use of ethnic remedies, certain cosmetics, and exposure to lead-glazed pottery; occupational and paraoccupational exposures; and recent immigration. Additional risk factors for pregnant women include alcohol use, smoking, pica, and recent immigration status.
- BLLs in childhood, after peaking at  $\sim$ 2 years of age, decrease during short-term and long-term follow-up without intervention. Most lead is stored in bone. High bone lead levels can be present with normal BLLs, so that BLLs often do not reflect the total amount of lead in the body. This could explain the lack of effect of BLL-lowering measures on reducing neurotoxic effects.
- Screening tests for elevated BLLs include free erythrocyte (or zinc) protoporphyrin levels and capillary or venous BLLs. Erythrocyte (or zinc) protoporphyrin is insensitive to modest elevations in BLLs and lacks specificity. Blood lead concentration is more sensitive than erythrocyte protoporphyrin for detecting modest lead exposure, but its accuracy, precision, and reliability can be affected by environmental lead contamination. Therefore, venous BLL testing is preferred to capillary sampling. Screening questionnaires may be of value in identifying children at risk for elevated BLLs but should be tailored for and validated in specific communities for clinical use.
- Treatment options in use for elevated BLLs include residential lead hazard-control efforts (ie, counseling and education, dust or paint removal, and soil abatement), chelation, and nutritional interventions. In most settings, education and counseling are offered for children with BLLs from 10 to 20  $\mu$ g/dL. Some experts have also recommended nutritional counseling for children with BLLs in this range. Residential lead hazard control is usually offered to children with BLLs  $\geq$ 20 µg/dL, whereas chelation therapy is offered to children with BLLs ≥45  $\mu$ g/dL.

• Community-based interventions for the primary prevention of lead exposure are likely to be more effective, and may be more cost-effective, than office-based screening, treatment, and counseling. Relocating children who do not yet have elevated BLLs but who live in settings with high lead exposure may be especially helpful. Community, regional, and national environmental lead hazard-reduction efforts, such as reducing lead in industrial emissions, gasoline, and cans, have proven highly effective in reducing population BLLs.

#### DISCUSSION

#### **Burden of Illness**

The prevalence of BLLs  $\geq 10 \mu g/dL$  among children 1 to 5 years of age in the United States has declined from 9% between 1988 and 1991 to 1.6% between 1999 and 2002. The decline is attributable primarily to significant reductions of lead in gasoline, air, dietary sources, and residential paint. However, the prevalence varies substantially among different communities and populations: mean BLLs of black children (2.8 µg/dL) remain significantly higher than those of Mexican American (1.9  $\mu g/dL$ ) and non-Hispanic white children (1.8  $\mu g/dL$ ). Approximately 24 million housing units still contain substantial lead hazards, with 1.2 million of these units occupied by low-income families with young children. An estimated 310 000 children remain at risk for exposure to harmful levels of lead. Population mean BLLs in women of childbearing age and pregnant women have decreased over the past 2 decades. In 1992, 2 large surveys of low-income pregnant women found that between 0% and 6% of these women had BLLs >15  $\mu$ g/dL. In a recent sample of respondents to the National Health and Nutrition Examination Survey (NHANES) including 4394 women of childbearing age, the geometric mean BLL was 1.78 μg/dL.<sup>1,2</sup>

Elevated amounts of lead in the body affect various organ systems, including the cardiovascular, renal, and hepatic, with most symptoms occurring with BLLs ≥50  $\mu$ g/dL. Very high levels of inorganic lead exposure may result in death or long-term neurologic sequelae in children. However, neurodevelopmental dysfunction is associated with BLLs as low as 10  $\mu$ g/dL in young children. The adverse effects of very high maternal BLLs during pregnancy include abortion, stillbirth, preterm delivery, decreased neonatal head circumference, and decreased birth weight. Studies also suggest that mildly elevated maternal BLLs may be associated with increased risk for spontaneous abortion, hypertension in pregnancy, and adverse effects on fetal growth.3 Although very high BLLs during pregnancy are harmful, the adverse effects of antepartum lead levels on the fetus in the range typically found in the United States have not been established.

#### Scope

The USPSTF examined new evidence published since it addressed the following overarching question in its 1996 recommendation: Does screening children and pregnant women for elevated BLLs result in improved neurodevelopmental outcomes? With this update, the USPSTF also reviewed the evidence on the accuracy of screening tests and the harms of screening and treatment.

#### **Accuracy of Tests**

Blood tests or questionnaires may be used to screen for elevated BLLs. Blood lead concentration is more sensitive and specific than free erythrocyte protoporphyrin levels but can be affected by environmental lead contamination and laboratory analytic variation. Erythrocyte (or zinc) protoporphyrin is insensitive to modest elevations in BLL and lacks specificity. Capillary blood lead sampling has false-positive rates of 3% to 9% and false-negative rates of 1% to 8%. The sensitivity and specificity of questionnaires vary considerably with the prevalence of elevated BLLs in the population surveyed and the cutoff BLL that is used. In urban and suburban populations, Centers for Disease Control and Prevention (CDC) screening questionnaires detected 64% to 87% of children with BLLs  $\geq 10 \mu g/dL$ ; higher sensitivities (81%–100%) were reported for BLLs ≥15 to 20  $\mu$ g/dL. Specificity of these questionnaires ranged from 32% to 75%. False-negative results were low (0.2%-3.5%) in lower-prevalence populations (2%–7%) for BLLs of  $\geq$ 10 μg/dL but increased to 19% when the population prevalence of elevated BLLs was higher (17%-28%).4-6

#### Intervention-Treatment

Treatment options for elevated BLLs include residential lead hazard-control efforts (ie, dust or paint removal, soil abatement, counseling, and education), chelation, and nutritional interventions. Most studies of asymptomatic children evaluate the effects of these interventions on BLLs instead of on clinically relevant neurocognitive outcomes. The USPSTF found no studies evaluating neurocognitive outcomes after residential lead hazard-control efforts or nutritional interventions. These interventions were found to have small, inconsistent, or unsustained effects on BLLs in asymptomatic children with mildly-to-moderately increased BLLs ( $<45~\mu g/dL$ ).

There is good evidence that chelating agents benefit children with symptomatic lead poisoning, but there is little evidence available to demonstrate a clinical benefit from chelation therapy for children with BLLs <45  $\mu$ g/dL. A large, multicenter, randomized, controlled trial assessed the effect of oral chelation therapy with succimer on IQ in children with venous BLLs of 20 to 45  $\mu$ g/dL. At 36 months' follow-up, no statistically significant differences were found between treatment and control groups in mean IQ, parental rating of behavior, or tests of learning ability. In this trial, BLLs decreased in

both the treatment and placebo groups, and by 24 months the difference between the treatment and placebo groups was not statistically significant.8,9

The USPSTF found no studies that examined the effectiveness of interventions in pregnant women.

#### **Harms of Screening and Treatment**

No new evidence was found regarding the harms of screening in children or pregnant women. The most common harms of screening for elevated lead levels are false-positive capillary results, anxiety, inconvenience, work or school absenteeism, and financial costs associated with return visits and repeated tests. In a randomized, controlled trial, succimer was associated with a slight decrease in cognitive performance.8,9 No studies have directly addressed the harms of interventions for pregnant women.

#### **Research Needs**

Community-based interventions for the primary prevention of lead exposure are likely to be more effective, and may be more cost-effective, than office-based screening, treatment, and counseling. Evaluation of the effectiveness of community-based interventions and recommendations regarding their use are important areas of future research.

#### **Recommendations of Others**

The CDC recommends universal screening in communities where ≥12% of children aged 1 to 3 years have elevated blood levels, or, in communities that do not have prevalence data, if ≥27% of the housing was built before 1950. The CDC recommends targeted screening for all other children based on an individual risk assessment, including whether children receive Medicaid, Supplemental Food Program for Women, Infants and Children (WIC), or other forms of governmental assistance. This approach is also supported by the American College of Preventive Medicine.

The American Academy of Pediatrics recommends that pediatricians learn whether city or state health departments provide guidance for screening children who are not eligible for Medicaid. If no such guidance is available, the American Academy of Pediatrics recommends that pediatricians consider screening all children. Children should, ideally, be tested at 1 and 2 years of age.12

The American Academy of Family Physicians recommends screening 12-month-old infants for lead poisoning if they live in communities in which the prevalence of lead levels requiring intervention is high or undefined; if they live in or frequently visit a home built before 1950 that has dilapidated paint or recent or ongoing renovations or remodeling; if they have close contact with a person who has an elevated BLL or who lives near lead industry or heavy traffic; or if they live with

someone whose job or hobby involves lead exposure, uses lead-based pottery, or takes traditional remedies that contain lead.13

Medicaid's Early and Periodic Screening, Diagnostic, and Treatment Program (EPSDT) requires that all children receive a screening blood lead test at 12 and 24 months of age; children between the ages of 36 and 72 months of age must receive a screening blood lead test if they have not previously been screened for lead poisoning. 14,15

No national organizations currently recommend screening pregnant women for elevated BLLs.

#### **APPENDIX 1: USPSTF RECOMMENDATIONS AND RATINGS**

The task force grades its recommendations according to 1 of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

- A. The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.
- B. The USPSTF recommends that clinicians provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.
- C. The USPSTF makes no recommendation for or against routine provision of [the service]. The USP-STF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.
- D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.
- I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

#### **APPENDIX 2: USPSTF STRENGTH OF OVERALL EVIDENCE**

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from welldesigned, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

#### **USPSTF MEMBERS**

The following were the members of the USPSTF at the time this recommendation was finalized (for a list of current USPSTF members, go to www.ahrq.gov/clinic/ uspstfab.htm): Ned Calonge, MD, MPH, USPSTF Chair (chief medical officer and state epidemiologist, Colorado Department of Public Health and Environment, Denver, CO); Diana B. Petitti, MD, MPH, USPSTF Vice-chair (senior scientific advisor for health policy and medicine, Regional Administration, Kaiser Permanente Southern California, Pasadena, CA); Thomas G. DeWitt, MD (Carl Weihl professor of pediatrics and director of the Division of General and Community Pediatrics, Department of Pediatrics, Children's Hospital Medical Center, Cincinnati, OH); Leon Gordis, MD, MPH, DrPH (professor, Epidemiology Department, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD); Kimberly D. Gregory, MD, MPH (director, Women's Health Services Research and Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Cedars-Sinai Medical Center, Los Angeles, CA); Russell Harris, MD, MPH (professor of medicine, Sheps Center for Health Services Research, University of North Carolina School of Medicine, Chapel Hill, NC); Kenneth W. Kizer, MD, MPH (president and chief executive officer, National Quality Forum, Washington, DC); Michael L. LeFevre, MD, MSPH (professor, Department of Family and Community Medicine, University of Missouri School of Medicine, Columbia, MO); Carol Loveland-Cherry, PhD, RN (executive associate dean, Office of Academic Affairs, University of Michigan School of Nursing, Ann Arbor, MI); Lucy N. Marion, PhD, RN (dean and professor, School of Nursing, Medical College of Georgia, Augusta, GA); Virginia A. Moyer, MD, MPH (professor, Department of Pediatrics, University of Texas Health Science Center, Houston, TX); Judith K. Ockene, PhD (professor of medicine and chief, Division of Preventive and Behavioral Medicine, University of Massachusetts Medical School, Worcester, MA); George F. Sawaya, MD (associate professor, Department of Obstetrics, Gynecology, and Reproductive Sciences and Department of Epidemiology and Biostatistics, University of California, San Francisco, CA); Albert L. Siu, MD, MSPH (professor and chairman, Brookdale Department of Geriatrics and Adult Development, Mount Sinai Medical Center, New York, NY); Steven M. Teutsch, MD, MPH (executive director, Outcomes Research and Management, Merck & Company, Inc, West Point, PA); and Barbara P. Yawn, MD, MSc (director of research, Olmstead Research Center, Rochester, MN).

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