09-OH-02

Submission Date:

Committee: Occupational and Environmental Health

Title: Public Health Reporting and National Notification for Elevated Blood Lead Levels

I. Statement of the Problem

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support "automated case reporting from electronic health records or other clinical care information systems." In July 2008, CSTE identified sixty-eight conditions with existing Position Statements that warranted inclusion on the official list, each of which now requires a standardized reporting definition to support the surveillance case definition.

In addition to the Position Statement revisions necessitated by the above, some conditions, including elevated blood lead, were also identified as needing substantive revisions to their surveillance case definitions.

II. Background and Justification

Background¹

Inorganic lead is a bluish gray metal that has been used since ancient times because of its useful properties, such as low melting point, pliability, and resistance to corrosion. The ancient Romans and Greeks first discovered its toxic effects. Lead is ubiquitous in the U.S. environment because of the widespread use of lead compounds in industry, gasoline, and paints during the past century. Lead is not an essential element nor does it serve any useful purpose in the body. It adversely affects multiple organ systems and can cause permanent damage. Research shows that lead has adverse health effects, including neurotoxicity and adverse renal and reproductive effects at much lower levels than once believed safe.

Human exposure to inorganic lead occurs when dust and fumes are inhaled and when lead from lead-contaminated hands, food, water, cigarettes, and clothing is ingested. Lead absorbed from the respiratory and digestive systems into the blood is distributed to tissues throughout the body. More than 90 percent of total body lead content eventually accumulates in the bones, where it has a half-life of years to decades. Lead stored in bones continues to be released, via the

¹ Most of the material in the background is directly quoted from CSTE position statement 1999-ENV-2. See the References for further information on this source.

bloodstream, to tissues throughout the body long after the external environmental exposure has ceased.

There are several biological measures of lead exposure. Elevation of protoporphyrin (free or zinc protorporphyrin) concentration in red blood cells can indicate inhibition of heme synthesis by lead, but it is an insensitive biomarker of lead exposures in individuals with blood lead concentrations below 25 µg/dL. Additionally, there are other causes (e.g., iron-deficiency anemia and inflammatory conditions) of elevated protoporphyrin levels. Lead concentrations in urine, teeth, and hair have been used as biological indicators of current or past lead exposure. Urine lead is less validated than blood lead as a biomarker of external lead exposure, while laboratory analysis for lead in hair is not standardized. For these reasons, there is rarely any value in measuring lead in urine or hair. Measurement of bone lead levels, via K-shell X-ray fluorescence (K-XRF), provides an accurate method for determining cumulative lead exposure and the total body burden of lead. Currently, K-XRF remains largely a research tool. At present, the best method for monitoring biological exposure to lead is measurement of the blood lead level (BLL) in whole blood. Blood lead levels provide a readily available, standardized, and relatively low cost method to assess lead exposure. The frequency and severity of symptoms associated with lead exposure generally increase as the BLL increases although there is much individual variability. No such relationship between symptoms and the other measures of lead exposure has been established.

An elevated BLL has been defined by CSTE and CDC since 1998 as 10 μ g/dL or greater for a child, and, since 1999, as 25 μ g/dL or greater in an adult. Recent research has documented adverse health effects at BLLs well below these defined levels. There is now increasing concern over the toxicity of lead for adults at low doses and its association with hypertension, adverse effects on renal function, cognitive dysfunction, and adverse female reproductive outcome. Current recommendations are to maintain adult BLLs less than 10 μ g/dL to avoid long-term health risks and less than 5 μ g/dL to avoid spontaneous abortion. It should also be noted that, with decreases in environmental lead sources (e.g., gasoline and paint), the lead burden in the U.S. population has been steadily declining as evidenced by the NHANES Third National Report on Human Exposure to Environmental Chemicals, which estimated that the mean (geometric) blood lead concentration in 2001-2002 was 1.45 μ g/dL for the U.S. population aged 1 year and older. Based on scientific research, public health concerns, and geometric mean BLLs in the U.S., this position statement recommends lowering the definition of elevated blood lead in adults from 25 to 10 μ g/dL.

The leading cause of elevated blood lead in children is exposure to lead-based paint in older houses. The leading cause in adults is occupational exposure to lead; employers are required to monitor blood lead levels of their employees when airborne lead is known to exceed certain levels. Other sources of lead exposure include hobbies such as sport shooting and stained glass making, use of lead-contaminated alternative medicines, and renovation of old homes.

Some states require reporting of lead poisoning by health care providers. However, reporting of elevated BLLs by clinical laboratories to state childhood and adult/occupational lead surveillance systems has been shown to be the most complete and effective reporting source. Surveillance built on laboratory reporting of elevated BLL has led to a wide variety of public health

prevention and intervention activities. Reporting of *all* BLL by laboratories, which is required in many states, is essential for determining true prevalence in the tested population.

Justification

An elevated BLL meets the following criteria for a nationally and **standard** notifiable condition, as specified in CSTE position statement 08-EC-02:

- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the U.S. population—have laws or regulations requiring **standard** reporting of elevated BLLs to public health authorities.
- CDC requests standard notification of elevated BLLs to federal authorities.
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

III. Statement of the desired action(s) to be taken

CSTE requests that CDC adopt this standardized definition for an elevated BLL to facilitate more timely, complete, and standardized local and national reporting of this condition. This definition includes a newly revised case definition for elevated BLL in adults and a recommendation that laboratories report *all* blood lead test results, not just ones defined here as elevated.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of elevated BLLs to facilitate their prevention and control.

V. Methods for Surveillance

Surveillance for elevated BLLs should use the sources of data and the extent of coverage listed in Table V below.

Table V. Recommended sources of data and extent of coverage for ascertaining cases of elevated BLLs.

	Coverage					
Source of data for case ascertainment	Population-wide	Sentinel sites				
clinician reporting	X					
laboratory reporting	X					
reporting by other entities (e.g., hospitals, veterinarians, pharmacies)						
death certificates						

nospital discharge or outpatient records	
extracts from electronic medical records	
telephone survey	
school-based survey	
other: <u>See comment below.</u>	

Comment

Although not useful for individual case ascertainment, the National Health and Nutrition Examination Survey (NHANES) has provided national estimates of blood lead levels in the U.S. civilian population since the 1970s. These estimates have proven invaluable in monitoring the human impacts of efforts to reduce environmental sources of lead. In 2004, New York City undertook a survey based on NHANES, which provided local, population-based estimates of blood lead levels. See the References for additional information about these sources of surveillance data for elevated BLL.

VI. Criteria for Reporting

Reporting refers to the process of healthcare providers or institutions (e.g., clinicians, clinical laboratories, hospitals) submitting basic information to governmental public health agencies about cases of illness that meet certain reporting requirements or criteria. The purpose of this section is to provide those criteria that should be used by humans and machines to determine whether a specific condition should be reported.²

A. Narrative description of criteria to determine whether a blood lead level (BLL) should be reported to public health authorities

Laboratories should report any BLL to public health authorities. Health care providers should report elevated BLLs.

A BLL that meets either of the following criteria should be considered an elevated BLL case:

- A person < 16 years of age with a lead concentration in a capillary blood specimen $\geq 10 \mu g/dL$ (0.48 $\mu mol/L$).
- A person of any age with a venous blood lead concentration, as determined by a CLIAcertified facility, ≥10 μg/dL (0.48 μmol/L).

Other recommended reporting procedures

² "Human-based" criteria (described below under "A. Narrative") can be applied by medical care providers and laboratory staff based on clinical judgment and clinical diagnosis. Machine-based criteria (described below under "B. Table") can be applied using computerized algorithms that operate in electronic health record systems, including computerized records of laboratory test orders and laboratory test results.

- Reporting should be on-going and routine.
- Frequency of reporting should follow the state health department's routine schedule.

B. Table of criteria to determine whether a case should be reported to public health authorities

Table VI-B. Proposed Table of criteria to determine whether a case should be reported to public health authorities. <u>Note</u>: The following criteria are proposed for evaluation before general implementation. For purposes of currently implementing reporting the narrative description in VI-A, should be used. (*Note: This table of reporting criteria applies only to clinicians. Laboratories should report lead exposure test results to public health authorities regardless of concentration.*)

Criterion		Reporting			
Clinical Presentation					
person < 16 years of age	Ν	N			
person ≥ 16 years of age			N		
Laboratory findings					
lead concentration $\geq 10 \ \mu g/dL \ (0.48 \ \mu mol/L)$ in a capillary blood specimen	Ν				
lead concentration $\geq 10 \ \mu g/dL \ (0.48 \ \mu mol/L)$ in a venous blood specimen		N	N		
<i>Epidemiological risk factors</i> exposure to lead-based paint in housing built prior to 1978	C	C			
work in an occupation with exposure to lead (e.g., battery manufacturing and recycling, nonferrous foundries, radiator repair shops, lead smelters, construction sites (during activities such as lead-based paint removal), demolition sites, firing ranges, ceramics, and scrap metal processing)			С		
avocation with exposure to lead (e.g., making pottery or stained glass, casting ammunition or fishing weights, sport shooting, and renovating or remodeling homes containing lead paint)			С		
history of retained bullets (gunshots), pica, or taking alternative medicines (e.g., Ayurvedic)	C	C	С		

Notes:

N = This criterion in conjunction with all other "N" and any "O" criteria in the same column is required to report a case.

C = This finding <u>c</u>orroborates (i.e., supports) the diagnosis of—or is associated with—an elevated BLL, but is not included in the case definition and is not required for reporting.

C. Disease Specific Data Elements:

Disease-specific data elements to be included in the initial report are listed below.

For persons age less than age 16:

Specimen type	Venous Capillary
Parent/guardian	Name Street address Second address line City State Zip code Phone

For persons age ≥ 16 years:

Current Occupation Job title

Current Employer Name Street address Second address line City State Zip code Phone Employer's industry type

VII. Case Definition

A. Narrative description of criteria to determine whether a case should be classified as confirmed, probable (presumptive), or suspected (possible) is provided below:

Elevated Blood Lead Levels Among Children (adopted 1998)

Laboratory criteria for diagnosis

Blood lead concentration, as determined by a CLIA-certified facility, $\geq 10 \ \mu g/dL$ (0.48 $\mu mol/L$) in a child (person < 16 years of age)

Case classification

Suspected: a single capillary blood specimen with elevated lead concentration

Probable: two capillary blood specimens, drawn greater than 12 weeks apart, both with elevated lead concentration

Confirmed: one venous blood specimen with elevated lead concentration, or two capillary blood specimens, drawn within 12 weeks of each other, both with elevated lead concentration

Comment

Elevated blood lead levels, as defined above, should be used for the purposes of surveillance only to apply standard criteria for case classification and may not correspond to action levels determined by individual programs or providers.

Adult Blood Lead Levels to be Reported to the National Public Health Surveillance System (revised 2009) Laboratory Criteria for Reporting

An adult blood lead level that should be maintained under surveillance by the NPHSS is defined as an adult (≥ 16 years) with a venous (or comparable) blood lead level $\geq 10 \ \mu g/dL$ (0.48 $\mu mol/L$) of whole blood.

B. Classification Tables

Table VII-B lists the criteria that must be met for a case to be classified as confirmed, probable and suspected.

Table VII-B. Proposed table of criteria to determine whether a case is classified. <u>Note</u>: The following criteria are proposed for evaluation before general implementation. For purposes of current notification, the narrative description in VII-A, should be used.

	Case Definition			on	
Criterion	Cor	nfirr	ned	Probable	Suspected
Clinical Presentation					
person < 16 years of age	Ν	N		N	Ν
person ≥ 16 years of age			N		
Laboratory findings					
lead concentration $\geq 10 \ \mu g/dL \ (0.48 \ \mu mol/L)$ in a capillary blood specimen		N		Ν	Ν

	Case Definition Confirmed Probable Suspect			tion	
Criterion				Suspected	
lead concentration $\geq 10 \ \mu g/dL$ (0.48 $\mu mol/L$) in a capillary blood specimen drawn within 12 weeks of another capillary blood specimen with a lead concentration $\geq 10 \ \mu g/dL$ (0.48 $\mu mol/L$)		N			
lead concentration $\geq 10 \ \mu g/dL$ (0.48 $\mu mol/L$) in a capillary blood specimen drawn more than 12 weeks after another capillary blood specimen with a lead concentration $\geq 10 \ \mu g/dL$ (0.48 $\mu mol/L$)				N	
lead concentration $\geq 10 \ \mu g/dL \ (0.48 \ \mu mol/L)$ in a venous blood specimen	N		N		

Notes:

N = This criterion in conjunction with all other "N" and any "O" criteria in the same column is required to classify a case.

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

Expectations for sharing case data

- State and territorial health agencies will submit individual reports of all BLLs in adults (≥16 years) to CDC **twice per year**.
- State and territorial health agencies will submit individual reports of all BLLs in children (≤16 years) to CDC **quarterly**.

Limitations on releasing case data

• CDC may release fully de-identified individual case data to appropriate non-CDC researchers or other government agencies through special-use agreements, as long as the data release does not compromise federal or state privacy or confidentiality policies or regulations, proprietary interests, national security interests, or law enforcement activities. Refer to the *CDC-CSTE Intergovernmental Data Release Guidelines Working Group Report: CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data* for further information.

Restrictions on printing counts of case data

• CDC will only publish data on **confirmed** cases of elevated BLLs. Provisional data will not be used until verification procedures are complete.

Publications

- Data will be analyzed and findings will be disseminated through peer-reviewed publications, MMWR articles, at meetings, and the CDC web site, to guide intervention and prevention strategies. Cell sizes less than 5 are withheld from release.
 - For adult blood lead data: A national summary aggregated de-identified data set will be made available to the public through the NIOSH/ABLES website,18 months after the close of the calendar year (e.g., 2007 data will be available by July 2009). Deidentified case data will be shared with the US Occupational Safety and Health Administration (OSHA) in the Department of Labor, which is the agency responsible for the federal regulation and enforcement of the OSHA Lead Standards 1910.1025 and 1926.62, to help target the National Emphasis Program on Lead.
 - For child blood lead data, data will be made available on the CDC website by state and county. Data will also be used to generate ad hoc analyses of temporal trends in blood lead levels.
- Analytic findings will be shared with state partners before the findings are submitted for peer review and before the findings are made publicly available.

X. References

- AOEC. 2007. Medical management guidelines for lead-exposed adults. In: Association of Occupational and Environmental Clinics. Washington, DC: Association of Occupational and Environmental Clinics. Available from: http://www.accupational.clinics.acc
 - http://www.aoec.org/documents/positions/MMG_
- 2. FINAL.pdf. Accessed: 2008 August 29.
- 3. Centers for Disease Control and Prevention [Internet]. Lead. Atlanta: CDC. Available from: http://www.cdc.gov/lead/. Accessed: 2008 Aug 12.
- Centers for Disease Control and Prevention [Internet]. National Health and Nutrition Examination Survey. Atlanta: CDC. Available from: http://www.cdc.gov/nchs/nhanes.htm Last updated: 2008 Aug 8. Accessed: 2008 Aug 12.
- 5. Council of State and Territorial Epidemiologists (CSTE). CSTE official list of nationally notifiable conditions. CSTE position statement 07-EC-02. Atlanta: CSTE; June 2007. Available from: http://www.cste.org.
- 6. Council of State and Territorial Epidemiologists (CSTE). Criteria for inclusion of conditions on CSTE nationally notifiable condition list and for categorization as immediately or routinely notifiable. CSTE position statement 08-EC-02. Atlanta: CSTE; June 2008. Available from: http://www.cste.org.
- 7. Council of State and Territorial Epidemiologists [Internet]. Proposal to adopt new or amended surveillance definitions for four environmental conditions. CSTE position statement 1998-EH-1. Atlanta: CSTE; June 1998. Available from: http://www.cste.org.

- Council of State and Territorial Epidemiologists [Internet]. Surveillance case definition for adult blood lead levels to be reported to the National Public Health Surveillance System, NPHSS. CSTE position statement 1999-ENV-2. Atlanta: CSTE; June 1999. Available from: http://www.cste.org.
- 9. Council of State and Territorial Epidemiologists, Centers for Disease Control and Prevention. CDC-CSTE Intergovernmental Data Release Guidelines Working Group (DRGWG) Report: CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data. Atlanta: CSTE; 2005. Available from: http://www.cste.org/pdffiles/2005/drgwgreport.pdf or http://www.cdc.gov/od/foia/policies/drgwg.pdf.
- Schwartz BS, Hu H. (2007) Adult Lead Exposure: Time for Change Environ Health Perspect 115: 451–454. Available from: <u>http://www.ehponline.org/members/2006/9782/9782.html</u>
- 11. Hu H, Shih R, Rothenberg S, and Schwartz BS. (2007) The Epidemiology of Lead Toxicity in Adults: Measuring Dose and Consideration of Other Methodologic Issues Environ Health Perspect 115:455–462. Available from: <u>http://www.ehponline.org/members/2006/9783/9783.html</u>
- Kosnett M, Wedeen R, Rothenberg S, Hipkins K, Materna B, Schwartz BS, Hu H, Woolf A. (2007). Recommendations for Medical Management of Adult Lead Exposure. Environmental Health Perspect, 115(3):463-471. Available from: http://www.ehponline.org/members/2006/9784/9784.html.
- Navas-Acien A, Guallar E, Silbergeld EK, and Rothenberg S. (2007) Lead Exposure and Cardiovascular Disease—A Systematic Review Environ Health Perspect 115:472–482. Available from: <u>http://www.ehponline.org/docs/2006/9785/abstract.html</u>
- 14. Shih R, Hu H, Weisskopf MG, Schwartz BS. (2007) Cumulative Lead Dose and Cognitive Function in Adults: A Review of Studies That Measured Both Blood Lead and Bone Lead Environ Health Perspect 115:483–492. Available from: <u>http://www.ehponline.org/members/2006/9786/9786.html</u>
- 15. National Health and Nutrition Examination Survey, 1999-2002. Table 16. Lead in blood. Geometric mean and selected percentiles of blood concentrations (in μg/dL) for the U.S. population aged 1 year and older. Available at http://www.cdc.gov/exposurereport/pdf/thirdreport.pdf.
- 16. New York City Department of Health and Mental Hygiene [Internet]. New York City Health and Nutrition Examination Survey. New York: NYCDHMH; 2008. Available from: http://www.nyc.gov/html/doh/html/hanes/hanes.shtml. Accessed: 2008 Aug 12.

XI. Coordination:

Agencies for Response:

- (1) Howard Frumkin, MD, MPH NCEH/ATSDR Director Centers for Disease Control and Prevention CDC/CCEHIP/NCEH/OD, MS F61 Chamblee, GA 30341 (770) 488-0604 howard.frumkin@cdc.hhs.gov
- (2) Christine Branche, PhD, MSPH Acting Director, NIOSH 395 E Street, S.W. Suite 9200 Patriots Plaza Building Washington, DC 20201 (202) 245-0625 Email: <u>Cbranche@cdc.gov</u>
- (3) Jordan Barab
 Acting Assistant Secretary
 U.S. Department of Labor
 Occupational Safety & Health Administration
 200 Constitution Avenue
 Washington, D.C. 20210

XII. Submitting Author:

(1) Martha Stanbury, MSPH
Michigan Department of Community Health
Division of Environmental Health
PO Box 30195
Lansing, MI 48909
(517)335-8364
stanburym@michigan.gov