

22-EH-01**Committee:** Environmental Health**Title:** Public Health Reporting and National Notification for Lead in Blood

Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: 15-EH-01.

Synopsis: This position statement updates 15-EH-01 by changing the name of the condition under surveillance from ‘elevated blood lead level’ to “lead in blood” and updating the criteria for reporting, the case definition, and case classifications.

I. Statement of the Problem

“Lead, elevated blood lead levels” has been on the list of nationally notifiable conditions since 2010. CSTE adopted position statements on public health surveillance for lead exposure for children and adults in 1995 (1,2) and made revisions in 1999, 2009, and 2015.(3-5)

The 2015 updated case definition for “elevated blood lead levels” was intended to identify young children with blood lead levels \geq 97.5th percentile level of blood lead in the general population, and this was based on the most recent data available from the National Health and Nutrition Examination Survey (NHANES). This threshold was referred to as the blood lead reference value (BLRV).(6) 15-EH-01 also recommended that laboratories report all blood lead test results to public health. The 2015 updated definition of 5 $\mu\text{g}/\text{dL}$ for adults was based on guidelines from the CSTE Occupational Health Subcommittee and was subsequently adopted by the National Institute for Occupational Safety and Health (NIOSH).(7,8)

In 2021, the Centers for Disease Control and Prevention (CDC) updated the BLRV, decreasing it from 5 to 3.5 $\mu\text{g}/\text{dL}$ for children based on NHANES data from its 2015-2016 and 2017--2018 cycles.(9) In recognition that there is no safe level of lead, CDC noted that the agency will no longer use the term “elevated blood lead level” and, instead, use “at or above the BLRV” in reference to children. Subsequently, CDC calculated the 97.5% percentile level in adults in NHANES as 3.49 $\mu\text{g}/\text{dL}$.(10) In concurrence with the reference value concept that there is no safe level of lead in blood, the CSTE Occupational Health Subcommittee approved lowering the blood lead threshold from 5 to 3.5 $\mu\text{g}/\text{dL}$ for adults.(11)

In light of these changes, 15-EH-01 needs to be revised.

II. Background and Justification

Lead adversely affects multiple organ systems and can cause permanent damage, including neurotoxicity and adverse cardiovascular, renal, and reproductive effects. Lead in blood is the best biomarker of lead exposure. No safe blood lead level in children has been identified.(12,13) Detection of very low levels of lead in blood is limited by laboratory methods.(14)

Lead is absorbed primarily by inhalation or ingestion.(13) The leading exposure source in children in the United States is lead-based paint dust in houses built before 1978.(13) The leading exposure source in adults is from work.(15)

Reporting of blood lead test results by clinical laboratories to public health departments is the basis for surveillance for lead exposure. It is mandated in all states, although states’ reporting requirements vary related to age and blood lead level.(16)

An “elevated blood lead level” was defined by CSTE in 2009 as ≥ 10 $\mu\text{g}/\text{dL}$ for children and adults.(4) In 2012, because of research showing adverse health effects of lead at low levels in blood, CDC’s Advisory Committee on

Childhood Lead Poisoning Prevention (ACCLPP) recommended that the threshold for “elevated blood lead level” be defined as the 97.5th percentile of the blood lead distribution of children age 1 - 5 based on the NHANES, which at that time was 5 µg/dL, and that this threshold be called the BLRV. The BLRV is not a toxicity threshold; rather it is a policy tool to identify children at the upper end of the population blood lead distribution and a public health benchmark to determine which communities may have exposure to lead. This threshold can be used as a guide to trigger lead education, environmental investigations, additional medical monitoring, and other interventions.(6) Research also provided evidence for the toxicity of lead for adults at low doses.(12) A 2013 CSTE publication, subsequently adopted by the Association of Occupational and Environmental Clinics, recommended that adults with blood lead levels (BLLs) of ≥ 5 µg/dL be monitored.(7) Thus, in 2015 CSTE lowered the surveillance case definition of “elevated blood lead level” in children and adults from ≥ 10 µg/dL to ≥ 5 µg/dL.(5)

On 10/28/2021, the CDC lowered the BLRV from 5 to 3.5 µg/dL for children based on updated NHANES data and encouraged public health and health care providers to adopt this threshold for triggering interventions.(9) This publication noted “there is no safe blood lead level” based on scientific evidence cited by the Agency for Toxic Substances and Disease Registry.(13) CDC also replaced “elevated blood lead level” with “lead in blood at or above the BLRV” throughout the CDC website.

The 97.5th percentile for adults in NHANES was calculated as 3.49 µg/dL for adults.(10) Accordingly, the CSTE Occupational Health Subcommittee updated their *Management Guidelines for Blood Lead levels in Adults* to include the same reference value threshold as for children.(11)

This position statement proposes:

- changing the name of the condition under surveillance from “elevated blood lead level” to “lead in blood” and
- updating the case classification definitions to lower the definition of ≥ 5 µg/dL for “elevated blood lead level” to “blood lead levels at or above the reference value of ≥ 3.5 µg/dL.”

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

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for “*lead in blood*”.
 - A. Utilize standard sources (e.g., reporting*) for case ascertainment for surveillance for *lead in blood*. It should use the recommended sources of data to the extent of coverage presented in Section V.
 - B. Utilize standardized criteria for case ascertainment for *lead in blood* presented in Section VI and Table VI in Technical Supplement.
 - C. Utilize standardized criteria for case classification for *lead in blood* presented in Section VII and Table VII in Technical Supplement.
 - D. Change the name of the condition under surveillance from “elevated blood lead levels” to “lead in blood.”
2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for ***lead in blood*** and **update *lead in blood*** on the *Nationally Notifiable Conditions (NNC) List*. Condition name on *NNC List* should be updated from “elevated blood lead levels” to “lead in blood”.
 - Immediately notifiable, extremely urgent (within 4 hours)
 - Immediately notifiable, urgent (within 24 hours)
 - Routinely notifiable
 - No longer notifiable

3. CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.
4. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: the National Notifiable Diseases Surveillance System (NNDSS) is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends a new condition be made nationally notifiable, CDC must obtain Office of Management and Budget Paperwork Reduction Act (OMB PRA) approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new *MMWR* year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.
5. CDC should publish data on *lead in blood* as appropriate (see Section IX). CSTE recommends the following case statuses be included in the CDC Print Criteria:
 - Confirmed
 - Probable
 - Suspect
 - Unknown
6. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority to conduct public health surveillance follow the recommended methods outlined in this standardized surveillance position statement.

*Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance to local, state, or territorial public health.

**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the *Nationally Notifiable Conditions List* to CDC.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of *lead in blood* to facilitate and evaluate prevention and control of lead exposure; and to identify individuals and communities at the upper end of the population distribution for interventions.

V. Methods for Surveillance: Surveillance for *Lead in blood* should use the recommended sources of data and the extent of coverage listed in Table V.

The primary reporting source is clinical laboratories.(12) Almost all clinical laboratories have established infrastructure or automated electronic reporting systems for transmitting results of tests for all reportable conditions. Blood lead testing using “point-of-care” (POC) technologies[‡] is used in medical provider offices that provide care to children. POC testing poses challenges to surveillance because of incomplete compliance with reporting requirements and technologic challenges with electronic reporting. In addition, POC instruments measure blood lead levels on capillary blood, necessitating the need for venous blood specimen testing by graphite furnace atomic absorption spectrometry (GFAAS) or inductively coupled plasma mass spectrometry (ICP/MS) where the capillary result is at or above the reference value. Capillary blood specimens are not appropriate for measuring adult blood lead levels.

The completeness of testing of children depends on the state testing requirements and recommendations, with most only targeting high-risk populations. Blood lead testing of adults is required by federal and state occupational safety and health laws/regulations for employees meeting certain lead exposure criteria; compliance with these requirements may not be complete.

Table V. Recommended sources of data and extent of coverage for ascertainment of cases of Lead in blood.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting		
Laboratory reporting	X	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers), specify: N/A		
Death certificates		
Hospital discharge or outpatient records	X	
Data from electronic medical records	X	
Telephone survey		
School-based survey		
Other, specify: N/A		

[‡]Currently, the only FDA approved POC instrument is “LeadCare®II Blood Lead System” manufactured by Magellan Diagnostics. For more information see “Guidelines for measuring lead in blood using point of care instruments. Advisory Committee on Childhood Lead Poisoning Prevention of the CDC. 10/14/2013. http://www.cdc.gov/nceh/lead/ACCLPP/20131024_POCguidelines_final.pdf”

VI. Criteria for case ascertainment

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

Report any *lead in blood* that meets the following criteria:*

A1. Clinical Criteria for Reporting

N/A

A2. Laboratory Criteria for Reporting

- All blood lead test results that are at or above the laboratory’s limit of quantification; the result should be expressed as the integer value of the result without rounding to the nearest whole number.
- All blood lead test results that are below the laboratory’s limit of quantification; the result should be expressed as below the laboratory’s limit of quantification.**

A3. Epidemiologic Linkage Criteria for Reporting

N/A

* If provider reporting is also mandated by the state, then it is recommended that providers only need to report children with laboratory results of ≥ 3.5 $\mu\text{g/dL}$, to include the specific lab result and whether from capillary or venous blood. They should only need to report venous BLLs ≥ 3.5 $\mu\text{g/dL}$ for individuals age 16 and older because the state adult blood lead surveillance programs generally do not include capillary results, and adults are rarely tested with capillary blood.

** Should be determined by a CLIA-compliant or CLIA-waived facility.

Additional specifications for reporting:

- Reporting should be on-going and routine.
- Frequency and urgency of reporting should follow the state health department’s regulations.
- Laboratory reporting should be electronic.

B. Disease-specific data elements to be included in the initial report

Specimen type	Venous (whole blood) Capillary (whole blood)
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Some states require data elements in the initial laboratory report of a blood lead test result that are not included in the standardized reporting data structures for electronic initial case reporting (eICR). These data elements have been incorporated into the state-specific electronic reporting systems and/or included in non-electronic reporting formats. At a minimum, the following data elements, which are not in the current standardized data structure for eICR, should nevertheless be included in the initial case reports to all states.

<u>For persons < 16 years of age:</u>		<u>For persons ≥16 years of age:</u>	
Parent/guardian	Name Street address Second address line City State Zip code Phone Laboratory reporting limit Laboratory analytical method (i.e., Point of Care, GFAAS., ICP/MS)	Current Occupation	Occupation
		Current Employer	Name Street address Second address line City State Zip code Phone Employer's industry type

VII. Case Definition for Case Classification
A. Narrative: Description of criteria to determine how a case should be classified.

Any detection of lead in blood is evidence of exposure to lead, and there is no safe level of lead in blood. The population-based "reference value" is used here to indicate individuals with more exposure than most in the population. A confirmed "case" identifies individuals *who have blood lead levels at or above the reference value*, because these individuals are most in need of medical and environmental interventions; it does not delineate those with and without lead toxicity. This position statement uses 3.5 µg/dL as the reference value, based on national population data as described above. In children, specimens from capillary blood at or above the reference value need to be confirmed with a venous specimen tested by GFAAS or ICP/MS because they are prone to false positive results due to contamination during specimen collection.

A1. Clinical Criteria

N/A

A2. Laboratory Criteria

Confirmatory laboratory evidence:

- Detection of lead in a venous blood specimen, tested by GFAAS or ICP/MS, that is at or above the reference value of 3.5 µg/dL.
- Detection of lead in two capillary^{††} blood specimens from a child less than 16 years old at or above the reference value of 3.5 µg/dL that are collected within 12 weeks of each other.

Presumptive laboratory evidence:

N/A

Supportive laboratory evidence:

- Detection of lead in a single capillary blood specimen from a child less than 16 years old that is at or above the reference value of 3.5 µg/dL, OR
- Detection of lead in two capillary blood specimens from a child less than 16 years old at or above the reference value of 3.5 µg/dL that are collected after 12 weeks of each other.

††If specimen type is unknown, it should be considered capillary for persons <16 years of age and venous for persons ≥16 years of age, for the purpose of case classification.

A3. Epidemiologic Linkage

N/A

A4. Case Classifications

Confirmed:

- Meets the confirmatory laboratory evidence.

Probable: N/A

Suspect:

- Meets the supportive laboratory evidence.

B. Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance

Many individuals receive more than one blood lead test over time. Individuals who meet the confirmed case classification criteria should be counted as a case only once annually. To distinguish which are new cases to be enumerated annually from those that persist or recur for more than one year, the following should be applied:

- For children (less than age 16) and adults (age 16 years or older): A confirmed case based on a venous test should be enumerated once per calendar year as a new case if the case was not enumerated as a confirmed case in the previous calendar year.

OR

- For children (less than age 16): A confirmed case based on two capillary tests within 12 weeks of each other should be enumerated once per calendar year as a new case if the case was not enumerated as a confirmed case in the previous calendar year.
 - If the collection date of the second of the two capillary tests occurred in the subsequent calendar year, the case should be counted in the year of the first collection date.

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

CSTE recommends the following case statuses* be included in the 'case' count released outside of the public health agency:

- Confirmed
- Probable
- Suspect
- Unknown

* Which case statuses are included in the case counts constitute the "print criteria."

Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format.

Production of national data summaries and national data re-release for non-NNCs:

- Prior to release of national data summaries, CDC should follow the CDC/ATSDR Policy on Releasing & Sharing Data, issued on April 16, 2003 and referenced in 11-SI-01 and custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report (www.cste2.org/webpdfs/drgwreport.pdf) which contains data release guidelines and procedures for CDC programs re-releasing state, local, or territorial-provided data.
- CDC programs have a responsibility, in collaboration with states, localities, and territories, to ensure that CDC program-specific data re-release procedures meet the needs of those responsible for protecting data in the states and territories.

Expectations for sharing case data with CDC:

This position statement encourages notification of all blood lead test data to CDC for children and to NIOSH for adults regardless of blood lead level, including results below the laboratory's limit of detection. However, this position statement recognizes that jurisdictions may not have the resources to collect and process all blood lead laboratory reports, and thus at a minimum, jurisdictions should share case data on all confirmed and suspect cases in children (less than age 16) with blood lead levels at or above the reference value ($\geq 3.5 \mu\text{g/dL}$) and all confirmed cases in adults (age 16 years or greater) at or above the reference value ($\geq 3.5 \mu\text{g/dL}$).

At a minimum:

- State and territorial health agencies should submit individual reports of adults (age 16 years and greater) to CDC/NIOSH at least once a year.
- State and territorial health agencies should submit individual reports of children (<16 years of age) to CDC quarterly or as requested.

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-ATSDR data release guidelines on re-release of state-provided data (17,18) for further information.

Restrictions on printing counts of case data

- 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. Data suppression in publications should comply with state requirements and CDC guidelines to protect the confidentiality of personal identifying information.

- 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.
- De-identified adult 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 CDC websites by state and county. Data will also be used to generate analyses of temporal trends in blood lead levels and other studies.
- Analytic findings by CDC will be shared with state partners before the findings are submitted for peer review and before the findings are made publicly available.

X. Revision History

Previous PS ID	Section of Document	Revision Description
15-EH-01	22-EH-01	Changed the name of the condition from “elevated blood lead levels” to “Lead in Blood”.
15-EH-01	V. Methods for surveillance	Deleted reporting by clinicians as a source of data for case ascertainment.
15-EH-01	VI. Criteria for case ascertainment	Deleted clinical criteria for reporting. Added two additional data elements for initial case reporting: the laboratory’s reporting limit and the laboratory’s analytical method
15-EH-01	VII.A. Case definition for case classification	Changed case classification for confirmed by lowering the blood lead level to “3.5 µg/dL”. Renamed “unconfirmed” to “suspect” and changed “elevated” to “BLL ≥3.5 µg/dL”. Moved these definitions to A.2, laboratory criteria, as definitions for confirmatory and supportive laboratory, and changed section A.4 to refer back to laboratory criteria for confirmed and suspect.
15-EH-01	VII.B. Case definition for case classification: B - criteria to distinguish a new case	Established criteria to distinguish a new case from reports that should not be enumerated as new cases.
15-EH-01	IX. Data sharing and print criteria	Changed “5 µg/dL” to “3.5 µg/dL”; deleted clauses related to “unconfirmed cases <10 µg/dL”.
09-OH-02	15-EH-01	Reduced the “elevated” blood lead level from 10 µg/dL to 5 µg/dL or greater in adults and children.
N/A	09-OH-02	Updated standardized surveillance case definition for elevated blood lead levels to comply with new position statement template requirements and added elevated blood lead levels as a nationally notifiable condition.

XI. References

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

Criterion	Lead in Blood
<i>Clinical Criteria for Reporting</i>	
N/A	
<i>Laboratory Criteria for Reporting</i>	
All blood lead test results at or above the laboratory's limit of quantification*	S
All blood lead test results below the laboratory's limit of quantification**	S
<i>Epidemiologic Linkage Criteria for Reporting</i>	
N/A	

Notes:

S = This criterion alone is SUFFICIENT to report a case.

* Results should be expressed as the integer value of the result without rounding to the nearest whole number.

** Results should be expressed as below the laboratory's limit of quantification.

Table VII. Classification Table: Criteria for defining a case of Lead in Blood

Criterion	Confirmed		Suspect
	N	S	O
<i>Clinical Evidence</i>			
Person < 16 years of age	N		N
<i>Laboratory Evidence</i>			
Detection of lead in a venous blood specimen, tested by GFAAS or ICP/MS, that is at or above the reference value of 3.5 µg/dL		S	
Detection of lead in two capillary blood specimens at or above the reference value of 3.5 µg/dL that are collected within 12 weeks of each other		N	
Detection of lead in a single capillary blood specimen that is at or above the reference value of 3.5 µg/dL			O
Detection of lead in two capillary blood specimens at or above the reference value of 3.5 µg/dL that are collected after 12 weeks of each other			O
<i>Epidemiologic Linkage Evidence</i>			
N/A			
<i>Criteria to distinguish a new case:</i>			
Counted once per year where the individual did not have BLLs meeting the case confirmation criteria in the immediately preceding year.	N	N	N

Notes:

S = This criterion alone is SUFFICIENT to classify a case.

N = All "N" criteria in the same column are NECESSARY to classify a case.

O = At least one of these "O" (ONE OR MORE) criteria in **each category** (categories=sets of clinical evidence, laboratory evidence, epi linkage evidence) **in the same column**—in conjunction with all "N" criteria in the same column—is required to classify a case.