

Recommendation for a Revised Blood Lead Reference Value (August 10, 2021)

Prepared for: The Lead Exposure and Prevention Advisory Committee

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Disclaimer: The findings and conclusions in this report are those of the BLRV workgroup and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC). This document has not been revised or edited to conform to agency standards.

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Acronym Table

AAP	American Academy of Pediatrics
ACCLPP	CDC’s Advisory Committee on Childhood Lead Poisoning Prevention
APHL	Association of Public Health Laboratories
ASV	anodic stripping voltammetry
ATSDR	Agency for Toxic Substances and Disease Registry
BD	Becton, Dickinson and Company – in terms of blood tubes

BLL	Blood lead levels
BLRV	Blood lead reference value
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CLIA	Clinical Laboratory Improvement Amendments
CLIAC	Clinical Laboratory Improvement Advisory Committee
CMS	Centers for Medicare and Medicaid Services
DHHS	U.S. Department of Health and Human Services
DLS	Division of Laboratory Sciences
EBLL	Elevated blood lead levels
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
FRN	Federal Register Notice
GFAAS	Graphite Furnace Atomic Absorption Spectrometry
HUD	U.S. Housing and Urban Development Agency
ICPMS	Inductively Coupled Plasma-Mass Spectrometry
LEPAC	Lead Exposure and Prevention Advisory Committee
NCEH	National Center for Environmental Health
NHANES	National Health and Nutrition Examination Survey
OMB	Office of Management and Budget
POC	Point of care – in terms of testing instruments
WIC	Women, Infants, and Children Nutrition Program

Executive Summary

No safe level of lead exposure has been identified for children. Protecting children from childhood lead poisoning requires the collective work of many partners, including but not limited to a range of federal, state, territorial, and local agencies, as well as homeowners, landlords, and clinical providers. The CDC blood lead reference value (BLRV), defined as the 97.5th percentile of blood lead level (BLL) concentrations for U.S. children aged 1 to 5 years, is an important tool guiding the efforts of these stakeholders, but is not a clinical reference level defining an acceptable range of blood lead levels in children, nor is it a health-based toxicity threshold, and it cannot be used to predict the health outcome for any particular child. The BLRV is also not an action level in most states or localities; however, it does provide vital information to healthcare providers and parents that a child has been exposed to lead and has a BLL that is higher than most children, paving the way for early intervention and the prevention of additional exposure and associated harm. The BLRV is also a useful tool for targeting services, identifying racial and other disparities in lead exposure, monitoring progress in reducing lead exposure, and informing policies to eliminate childhood lead poisoning at the federal, state, and local levels.

Ultimately, primary prevention by eliminating lead exposure before children are exposed and harmed is the goal; revising the BLRV downward is consistent with that aim. However, the Workgroup also considered and acknowledged a variety of potential challenges associated with lowering the BLRV. Notably, this includes the need for enhanced manufacturing, specimen collection and testing practices, and that POC technologies improve analytical sensitivity and precision. We also recognize concerns about messaging for parents, healthcare providers, and other stakeholders, particularly in instances where local action levels (and related follow-up services) do not align with a lowered BLRV. Lowering the BLRV may also impact governmental agencies at the federal, state, and local levels, necessitating increased capacity or resources to address a larger and more varied case load. Potential challenges and risks were evaluated and weighed against the potential benefits of lowering the BLRV and the workgroup offers several recommendations to address and overcome these and other identified barriers.

The Blood Lead Reference Value Workgroup recommends that the CDC Lead Exposure and Prevention Advisory committee adopt a revised reference value of 3.5 micrograms of lead per deciliter of blood ($\mu\text{g}/\text{dL}$) (based upon most recent NHANES cycles 2015-2018) and implement a plan to address barriers associated with specimen collection, testing, messaging, and capacity of affected agencies and stakeholders at the federal, state, and local levels. These implementation challenges and recommendations to address them are outlined in detail in this document. Some of these barriers exist even at the current BLRV, but all deserve priority consideration as CDC moves forward with their lead poisoning prevention efforts. To create stability and consistency for stakeholders, the Workgroup also recommends that the CDC reaffirm their commitment to regular and timely monitoring of the 97.5th percentile of the NHANES blood lead levels and clarify that although this statistic may increase or decrease over time, that the BLRV will only ever be maintained or decreased, but never increased.

Purpose of Report

The purpose of this report is as follows:

1. Define the Blood Lead Reference Value (BLRV);
2. Provide information regarding how the BLRV is currently used by the Center for Disease Control (CDC) and other entities;
3. Present the current status of the BLRV; and,
4. Present the BLRV Workgroup's recommendations.

Historical Background

The Centers for Disease Control and Prevention (CDC) first defined the threshold for childhood lead poisoning in the 1960s as any amount in blood ≥ 60 micrograms per deciliter ($\mu\text{g}/\text{dL}$) [1-3]. Subsequently, research showed that far lower levels could impact IQ, speech, attention, and classroom performance even without inducing clinical symptoms, the CDC's threshold was incrementally lowered. By 1976, when the average blood lead level of children in the United States was approximately ≥ 15 $\mu\text{g}/\text{dL}$, the maximum acceptable threshold was 40 $\mu\text{g}/\text{dL}$ [1-3]. Since the 1970s, the United States has made tremendous progress in lowering children's blood lead levels. In 1991, the CDC set the "level of concern" to ≥ 10 $\mu\text{g}/\text{dL}$ for children under age six years and maintained ≥ 10 $\mu\text{g}/\text{dL}$ as the "level of concern" in children for two decades [1-3].

In 2010, the CDC's Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) evaluated new approaches, terminology, and strategies for defining elevated blood-lead levels (EBLLs) among children. The ACCLPP recommended establishing a new "reference value", herein referred to as the blood lead reference value (BLRV), of 5 $\mu\text{g}/\text{dL}$ as the standard for identifying children with EBLLs [4]. They further recommended that the reference value should be based on a nationally representative sample of children, i.e., the 97.5th percentile of BLL concentrations for U.S. children aged 1 to 5 years [5]. The ACCLPP recommended that the BLRV should be reevaluated every four (4) years with data from the most recent childhood population-based blood lead surveys, extracted from the National Health and Nutritional Examination Survey (NHANES): (<https://wwwn.cdc.gov/nchs/nhanes/Default.aspx>).

In 2012, CDC leadership announced acceptance of the following recommendations established by the ACCLPP:

1. The discontinuation of the term blood lead "level of concern," to acknowledge that there is no safe level of lead exposure; and,
2. The use of a new reference value for the identification of children with EBLLs.

In 2017, the National Center for Environmental Health/Agency for Toxic Substance and Disease Registry (NCEH/ATSDR) Board of Scientific Counselors (BSC) Lead Poisoning Prevention Subcommittee made the recommendation to lower the BLRV from 5 $\mu\text{g}/\text{dL}$ to 3.5 $\mu\text{g}/\text{dL}$ based on NHANES data. This recommendation went to CDC/NCEH who responded to the report and drafted a Federal Register Notice (FRN) which was reviewed by the Office of Management and Budget (OMB). OMB expressed reservations about the rulemaking and

provided comments to the CDC. The BLRV has yet to be revised and currently remains at 5

Blood Lead Reference Value Workgroup

The Blood Lead Reference Value (BLRV) Workgroup (herein referred to as the Workgroup) was established in March of 2020 under the CDC's Lead Exposure and Prevention Advisory Committee (LEPAC). The Workgroup is composed of experts in the fields of toxicology, pediatrics, lead screening, lead exposure prevention, analytical chemistry, and public health surveillance.

The Workgroup is charged with providing scientific and programmatic expertise on public health policies, practices, and state-of-the-science to the LEPAC to assist CDC's NCEH/ATSDR efforts to identify and address childhood lead exposure nationwide. The Workgroup is specifically tasked with providing recommendations to NCEH/ATSDR through the LEPAC on the rationale for establishing CDC's BLRV and how to define, use, and update the BLRV. The Workgroup accomplishes these tasks by reviewing scientific publications, consulting additional experts, and reaching consensus among workgroup members. The Workgroup meets periodically and reports findings to the LEPAC. The objectives of the Workgroup include, but are not limited, to consideration of the following:

- Identify and evaluate challenges to effectively measuring BLLs
- Identify and evaluate feasibility of current measurement methods to reliably measure low BLLs and to distinguish between 3.5 µg/dL and 5 µg/dL
- Identify and evaluate concerns about unintended consequences of lowering the BLRV, such as diverting resources away from high-risk groups
- Identify the appropriate method to determine the BLRV, including consideration of incremental cost-benefits
- Propose how often the BLRV should be reviewed/updated
- Describe how changes in the 97.5th percentile of BLLs in NHANES may affect the BLRV
- Provide expert advice and guidance on how the BLRV should be used, including the role of federal agencies and states and what BLLs should trigger case management
- Provide guidance on the impact on lead programs, surveillance efforts, and case management including environmental investigations
- Understand the role of each state in their actions associated with the BLRV

Current Status of the BLRV

Defining the BLRV

The blood lead reference value was initially defined in the 2012 report from ACCLPP [4]. It is also defined in the document entitled "Federal Action Plan to Reduce Childhood Lead

Exposures and Associated Health Impacts,” a product of the President’s Task Force on Environmental Health Risks and Safety Risks to Children [6]. The Federal Action Plan indicated that the BLRV served as “a policy tool that helps identify the children in the upper end of the population blood lead distribution in order to target prevention efforts and evaluate their effectiveness.”

The BLRV is a statistic derived from the distribution of the concentration of lead in blood. Reference values, such as the BLRV, can be used to characterize individual results as “elevated” or “not elevated” in comparison to the distribution of levels of a particular chemical or trace element in a population. The BLRV is not a clinical reference level defining an acceptable range of blood lead levels in children, nor is it a health-based toxicity threshold, and it cannot be used to predict the health outcome for any particular person. Rather, it is intended to be used as a policy tool that helps identify the children in the upper end of the population blood lead distribution.

Current Value

The CDC website currently states that 5 µg/dL is the BLRV recommendation, and the value is based on NHANES data from 2007-2008 and 2009-2010 [5]. In the 2013/14-2015/16 NHANES cycles, 5 µg/dL was located between the 99 and 99.1 percentiles. There were two values (4.97 and 4.99) between 4.88 and 5.18. Therefore, 5 micrograms/deciliter is closer to 99.1 percentile.

Current Use of BLRV by CDC

As previously stated, CDC uses a blood lead reference value of 5 µg/dL to identify children with blood lead levels that are much higher than most children’s levels. This level is based on the U.S. population of children ages 1-5 years who are in the highest 2.5% of children when tested for lead in their blood [5]. The CDC provides guidance regarding follow-up and case management for children whose blood lead level is <5 µg/dL and 5-9 µg/dL [7].

The CDC also reports the number of children with blood lead levels greater than or equal the BLRV on their website. States and some cities (New York City and Washington DC), funded by the CDC, report the number of children tested and their BLLs quarterly (with a lag of 1 -2 quarters). The total number of children tested is posted along with the prevalence of children with EBLLs (i.e., ≥ BLRV). The data are posted here:

<https://www.cdc.gov/nceh/lead/data/surveillance-data.htm>

Current Uses by Other Entities

The BLRV is used by health-care providers to trigger educational interventions and follow up testing. Health care providers may also initiate nutritional interventions, refer patients for developmental services, supply education, and potentially additional actions.

The BLRV is also used by some State Health Departments to guide case management and environmental/ home assessment. Information regarding use by State Health Departments is provided at <https://nchh.org/resource-library/state-health-department-policies-for-children-with-elevated-blood-lead-levels.pdf>. As an example, children in Massachusetts, whose tests indicate

a lead level greater than 5 µg/dL must have a confirmatory test with a venous sample as soon as possible and not more than two months after the first test. In South Carolina, Management by the child's medical home, including health and nutrition education, lead risk discussions, developmental screening, and retesting begins at 5 µg/dL. These interventions are a policy goal, but not a strict mandate by CDC, other agencies, or health departments.

BLRV Workgroup Recommendations

BLRV and Basis

The Blood Lead Reference Value Workgroup recommends that the LEPAC adopt a revised BLRV of 3.5 µg/dL (based upon most recent NHANES cycles 2015-2018) [8]. The workgroup also recommends that the LEPAC reaffirm CDC's commitment to regularly analyzing NHANES data to identify the 97.5th percentile and adopt a policy that this analysis may be used to either maintain or lower, but never increase, the reference value in the future.

These recommendations are consistent with the use of a reference value that is not a threshold for toxicity, nor a fine line for determining when actionable steps should/ should not occur. In the past, experts were challenged with how to integrate the lack of a health effects threshold into the development of a public health action level. Using a BLRV replaced a potentially arbitrary approach, and this workgroup cautions against similarly inappropriate uses of this level. It is important to understand that the BLRV identifies children with a greater exposure to lead than most. The BLRV is not a level at which no health effects occur [5]. Lowering the level is anticipated to address the largest number of the most vulnerable children with limited resources. As such, the BLRV should be used as a public health benchmark. Regional and local variation in the distribution of childhood blood lead levels exist, however, this workgroup is recommending that even for the highest risk communities, 3.5 µg/dL should be used to trigger certain responses by health care providers and public health agencies. This will further guide the distribution of those limited resources to where they are needed most. Jurisdictions that currently manage the greatest burden of exposure should consider how to optimize their programmatic responses so that their efforts will continue to be effective without overwhelming current mechanisms for case management and environmental investigations. A commitment not to increase the reference value in the future, even in the event that the 97.5th percentile increases, will also create more stability for jurisdictions and reduce confusion for parents and providers.

An evaluation of proficiency test results by the NCEH DLS concluded that the current point of care and laboratory methods for measuring blood lead are sufficiently sensitive and precise at 3.5 µg/dL (see Attachment 1). DLS reported that the precision for measurements made at between 3.0 and 4.1 µg/dL are similar to estimates reported previously for 4.0 to 6.0 µg/dL (Attachment 1, slide #24). Specifically, precision ranged from 0.83-1.8 µg/dL for values 3.0 and 4.1 µg/dL (Attachment 1, slide #21). However, outliers were excluded ± 4 standard deviations (ICPMS (2.9%), GFAAS (2.5%), LeadCare II (37%) (Attachment 1, slides #27). DLS also

reported that the sensitivity ranged from 0.05 –1.06 µg/dL (ICPMS) to 0.8-1.5 µg/dL (GFAAS) to 3.3 µg/dL (Lead Care II) (Attachment 1, slide #12). CDC's voluntary Lead and Multi-Element Proficiency quality assurance program showed that 40% of samples were unable to quantify and reported a nondetectable result at a target blood lead value of 1.48 µg/dL compared with only 5.5% at a target BLL of 4.60 µg/dL [9]

The Workgroup acknowledges that not all POC sites and laboratories are currently set up to achieve the level of precision necessary to consistently measure blood lead levels in this range. It is also important to note that blood collection equipment with even minimal lead contamination, can potentially cause a large discrepancy between the actual blood lead level of the child and the concentration measured. Therefore, to improve the accuracy of lead measurements special attention must be paid towards using materials (vials, vacutainers, needles, alcohol swabs, etc.) designated for collection of blood lead samples [10].

Capillary specimens are known to have a higher likelihood of contamination during the collection process leading to concern that false positive results which would require additional phlebotomy for children with BLLs that are truly < 3.5 µg/dL. Researchers in Maine evaluated this issue with surveillance data using 10 µg/dL as a cutpoint and found 73% false positives [11]. Researchers in Minnesota used a lower cutpoint (5 µg/dL) and found that 60% of samples were false positives [12]. Therefore, a BLRV \geq 3.5 µg/dL for a capillary sample should be followed by a confirmatory venous sample.

To maintain and/or improve compliance with current screening recommendations, this Workgroup recommends the use of capillary blood lead screening with point of care (POC) instruments only when venipuncture samples tested by a definitive technology are impractical, unavailable or when use of venipuncture alone will negatively impact on lead exposure screening rates. Since tests on capillary samples collected in the office setting using POC instruments bias high and are prone to false-positive results, it is unlikely that a child with an elevated lead level will be missed using this method. The current limit of detection for the only POC instrument currently available for use in the United States, Lead Care II, is 3.3 µg/dL and some degree of error is expected. **Therefore, every detectable POC blood lead measurement should be confirmed with a properly collected venous lead sample sent to a laboratory with the ability to accurately measure a blood lead level of 3.5 µg/dL with a standard error of +/- 2 µg/dL .** In some jurisdictions, public health agencies depend on the data from blood lead screening programs, typically conducted by primary care providers and in settings such as WIC offices. Confirmatory venous lead levels improve the quality of these data. Subsequent follow up testing for children with confirmed BLLs \geq 3.5 µg/dL with venous blood lead samples, also improves the accuracy of the measurement to account for several factors including variation within individuals, contamination during collection and quality of analytic methods. Any actions taken in response to a BLL should take into account the limitations in the methods of collections and analysis.

The BLRV Workgroup recommends: 1) manufacturers of sampling and testing supplies

Sampling and Analysis

Sampling and analysis to measure the level of lead in the blood of children are important components of the recommendation to lower the BLRV. Clinical specimens of blood and urine for NHANES are collected using consistent practices including pre-screened materials in controlled environments to minimize the likelihood of contamination from exogenous sources. The specimens are then all tested at CDC's Division of Laboratory Sciences (DLS), a world-class facility that implements rigorous engineering and process controls to avoid laboratory contribution of lead to the specimens. Whole blood venipuncture specimens are analyzed for lead concentration using isotope dilution, inductively coupled plasma-mass spectrometry (ICP-MS). These highly controlled sampling and testing protocols result in DLS providing extremely precise and accurate measures of lead in clinical specimens. This level of rigor is not practical for routine pediatric lead testing as there are insufficient resources and capacity to meet testing demand. In practice, patient samples are obtained either by the finger stick technique (capillary) or venipuncture (venous) at well childcare visits or at public health specimen collection events. Collection materials may or may not be pre-screened. The collection protocols and environment in which these specimens are taken is highly variable.

Pediatric lead specimens are currently tested by three (3) analytical practices:

1. Lead Care II (<https://www.magellandx.com/leadcare-products/leadcare-ii/support/product-specifications/>) is a POC instrument approved for the measurement of lead in whole blood (capillary specimens only). The test, which is based on anodic stripping voltammetry (ASV), is Clinical Laboratory Improvement Amendments (CLIA) waived permitting its use in non-laboratory environments. It has a manufacturer derived reporting range of 3.3-65 µg/dL. This technology is prone to interferences from other electronegative constituents found in medical supplies.

Note: Sulfur compounds present in some vacutainer formulations (used in the collection of venous samples) interfere with ASV technology resulting in low or false negative lead concentrations, prompting U.S. Food and Drug Administration (FDA) to limit the use of the Lead Care II instrument to capillary specimens. The Becton, Dickinson and Company (BD) vacutainer tube recall is described here: <https://www.fda.gov/safety/recalls-market->

[withdrawals-safety-alerts/bd-updates-instructions-use-certain-bd-vacutainerr-blood-collection-tubes.](#)

2. Graphite Furnace Atomic Absorption Spectrometry (GFAAS) is a moderately priced, high throughput technology that reliably measures lead and other elements if appropriate quality management practices are implemented and practiced. GFAAS testing is conducted in fixed-site laboratories meeting the requirements for highly complex analyses, as defined by CLIA. Individual laboratories determine their detection and reporting limits, but with rigorous practices should achieve 1 µg/dL.
3. Inductively Coupled Plasma-Mass Spectrometry (ICPMS) when combined with isotope dilution internal standards, is the most specific and sensitive technique for measuring lead and other elements in clinical specimens. ICPMS is an expensive technology which requires highly skilled analysts to perform optimally. It is found in fixed site laboratories meeting CLIA requirements for highly complex analyses. Laboratories determine their detection and reporting limits but should measure well below 1 µg/dL for lead in whole blood.

Given the differences in sampling and testing, it is not currently feasible for all laboratories performing pediatric lead testing to reliably measure lead at the proposed BLRV of 3.5 µg/dL. The reference value being proposed should be considered a goal that may be achieved over time if manufacturing, specimen collection, testing quality practices, and POC technologies are enhanced to reduce contamination and afford greater analytical sensitivity. Specifically, the following changes are required to achieve the 3.5 µg/dL goal:

- Manufacturers of specimen collection materials should offer trace metal free products (e.g., swabs, tubes, needles, syringes) that contribute no more than 0.2 µg/dL; CDC's DLS requires no more than 0.1 µg/dL (See Attachment 1, slide #24).
- Point of care manufacturers should improve the analytical technology to reliably measure lead at 1 µg/dL.
- Laboratories and clinician practices performing testing should pre-screen sampling and testing materials to reduce contamination from external sources.
- Laboratories and clinician practices performing testing should implement rigorous quality management practices to minimize contamination and to improve laboratory precision and accuracy for measuring lead in whole blood.
- Laboratories and clinician practices performing testing should participate in external quality assessment programs.
- All positive POC measurements should be repeated using definitive test methods (GFAAS, ICP-MS) on a venipuncture specimen.
- If the BLL measurement is ≥ 3.5 µg/dL but < 5 µg/dL, children should not be enrolled into case management until local jurisdictions confirm that they have the laboratory capacity to accurately report results in this range. See [here](#) for confirmatory testing guidance.
- CDC should carry out additional study of laboratory proficiency and capacity accompanied by educational messaging for BLL measurements ≥ 3.5 µg/dL but < 5 µg/dL prior to implementation of the change in the BLRV and provision of interim guidance.
- Centers for Medicare and Medicaid Services (CMS) should adopt more stringent acceptance limits for lead proficiency testing recommended by the Clinical Laboratory Improvement Advisory Committee (CLIA), Association of Public Health Laboratories (APHL), and others.

- CDC should expand outreach to the clinical and public health communities to raise awareness of the potential for exogenous contamination and provide easily accessible, step-by-step training for appropriate specimen collection.
- CDC should provide clear guidance to state, local, territorial, and tribal health departments on how the BLRV should and should not be used.
- CDC should provide translational materials aimed at explaining sources of lead exposure, childhood lead testing, as well as the interpretation for parents and caregivers.
- CDC should increase financial and technical support to state, local, territorial, and tribal health departments and public health laboratories to enhance environmental health surveillance for childhood lead testing.
- CDC should facilitate the development of a comprehensive pediatric lead screening database.

A diagram that explains testing decision points is shown in Attachment 2. Note that this is an aspirational goal since this relies upon manufacturers offering and labeling products (e.g., swabs, tubes, needles, syringes) that contribute no more than 0.2 µg/dL. This determination should not depend upon clinicians knowing the trace metal content of the products if not labeled or certified as such,

Guidance on How BLRV Should Be Used

The CDC blood lead reference value is intended to serve a dual purpose. It should be used to inform parents, care givers, health care professionals, childcare professionals, and K-12 schools that a child's exposure is higher than most other children. This reference value should also serve as a public health benchmark to determine which communities are exposed to lead.

Effective efforts to prevent and respond to childhood lead poisoning require the collective work of many partners, including but not limited to a range of federal, state, territorial, and local agencies, as well as homeowners, landlords, and clinical providers. The proposed recommendation to reduce CDC's current blood lead reference value to 3.5 µg/dL would have significant implications for governmental agencies, non-governmental agencies, and stakeholders at all levels.

Department of Health and Human Services (DHHS)

Centers for Disease Control and Prevention (CDC)

- **Role:** CDC is a primary source for public health guidance related to lead poisoning, including establishing the blood lead reference value, defining best practices for preventing and addressing lead poisoning, and establishing cooperative agreements to fund state and local agencies to support lead poisoning prevention and response work throughout the nation.
- **Impact:** This change in the BLRV may result in an increase in the number of children diagnosed with lead poisoning in the United States. One anticipated response would be for CDC to review and augment its guidance on best practices to ensure that they support the goal of preventing and responding effectively to observed lead poisoning cases. As the blood lead levels continue to decrease, factors other than lead paint might drive some exposures, and CDC might need to give more guidance on these other sources of exposure. For example, this change in the BLRV may increase the

fraction of lead poisoning cases where drinking water is the primary identified source of exposure; CDC guidance may need to be reviewed and adjusted to reflect this. Areas with high prevalence could experience more acute needs for the advisory and financial resources for which they rely on the CDC. Many areas previously considered to have a low prevalence may see lead poisoning emerge for the first time as a priority requiring coordinated response and may also rely on CDC for guidance on how to effectively address the issue in their communities. Educating stakeholders on the definition of the BLRV, limitation of this approach, and most effective means of identifying and addressing human lead exposure remains a critical role of the CDC. Potentially, the CDC could call for more frequent blood lead testing of the individual children identified and a nutritional assessment to include testing for iron deficiency.

Center for Medicaid and Medicare Services (CMS)

- **Role:** CMS is the lead subagency within DHHS for ensuring that the benefits of Medicaid and Medicare programs are effectively delivered in the United States.
- **Impact:** A reduction in the BLRV would likely result in a significant increase in the incidence of lead poisoning among Medicaid-enrolled children across the nation. This would require additional financial resources for the following:
 - case management and environmental investigation services that are funded by CMS and its state governmental partners,
 - reimbursement for screening and follow up,
 - establishment of quality standards for providers, and
 - hazard abatement resources that are made available to some states through the Children’s Health Insurance Program (CHIP).

Food and Drug Administration (FDA)

- **Role:** FDA regulates the composition of foods, medications, and other consumer products, such as cosmetics, as well as equipment including POC testing devices used for blood lead screening.
- **Impact:** A reduction in the BLRV may result in an increase in the fraction of lead poisoning cases attributed to sources other than residential paint, which may lead to increased investigation and enforcement activity within FDA. The proposed BLRV is likely to result in action levels near the detection and quantitation limit for many POC lead screening devices currently on the market and may spur efforts to improve the sensitivity of POC screening devices going forward. The FDA should consider the BLRV in how they set limits and guidelines for the lead content of consumer products (food, dietary supplements, etc.) and medical devices.

U.S. Environmental Protection Agency (EPA)

- **Role:** EPA coordinates a range of efforts and programs aimed at controlling exposure to lead as an environmental contaminant. This includes regulating lead in drinking water systems, controlling exposures from air pollution and Superfund sites, and ensuring that renovations and abatements on lead-based paint are performed by trained and certified firms and individuals that follow specific work practices to reduce lead contamination.
- **Impact:** A reduction in the BLRV may lead to an increase in the fraction of new lead poisoning cases attributable to sources other than residential paint, such as drinking water and soil [13]. This may increase public and political interest in addressing the continued exposure hazard posed by lead pipes in the aging infrastructure of many public water systems as well as increased attention to other sources including soil.

Department of Housing and Urban Development (HUD)

- **Role:** HUD provides significant resources to address a range of hazards in owner-occupied and rental housing, including lead in residential paint. HUD also supports public housing efforts across the nation. HUD supports efforts by the CDC to consider the data from its [NHANES](#) and determine whether to reduce its blood lead reference value (BLRV) for children under age 6 from its current value of 5 µg/dL. The focus of HUD's comments is on the CDC's recommendations for action when such a case is identified, in particular, for children in HUD-assisted housing that may have lead-based paint, i.e., built before 1978 (Consumer Product Safety Commission, [16 CFR 1303.1\(b\)](#)). CDC presented the following discussion in the April 2019 Mini Rollout Plan for its rollout of its then-proposed public comment Federal Register notice related to updating of the BLRV for children under age 6:

“With the updated BLRV, children with higher lead exposures will continue to be eligible for the same targeted services as previously described. The primary difference between the current BLRV of 5 µg/dL and the proposed updated BLRV of 3.5 µg/dL is that children with a [blood-lead level] (BLL) between 3.5 and 5 µg/dL will now be recommended to receive routine assessment of nutritional and developmental milestones; environmental assessment of detailed history to identify potential of lead exposure; nutritional counseling related to calcium and iron intake and; follow-up BLL testing at recommended intervals based on the child's age.”

The “environmental assessment of detailed history” is not a physical assessment (environmental investigation) of the housing or other property the child frequents, but is a detailed history taken by the child's healthcare provider to identify potential sources of lead exposure.

- **Impact:** A reduction in the BLRV may lead to increased demand for HUD resources aimed at addressing lead hazards in homes and the community.

State, Local, and Territorial Public Health Agencies

- **Role:** State and local public health agencies work to identify and respond to cases of lead poisoning among children and establish and enforce policies by which follow-up activities such as nursing case management and investigation of properties for lead hazards are carried out at the state and local level. These agencies also have a leading role in collecting, compiling, analyzing and disseminating data on childhood lead poisoning and serve as primary sources of data on childhood lead poisoning for federal, state and local partners. In some jurisdiction, state and local public health agencies lead regulatory programs to ensure that lead abatement workers are properly trained and certified. Much of the funding for the work carried out by state and local health departments comes from federal agencies such as CDC, HUD and EPA.
- **Impact:** A reduction in the BLRV would result in an increase in the number of children with observed lead levels above the BLRV and concomitantly an increase in the number of children for whom provision of nursing services would be warranted as well as an increase in the number of property investigations that would naturally follow. This could result in an increased demand for property risk assessment and lead hazard abatement services to ensure that identified hazards related to poisoning cases are abated to ensure that current poisoning cases are resolved and that no future cases arise at such properties. This may require an increase in the federal funding that supports these efforts.

Early Learning Facilities and K-12 Schools

- **Role:** Early Learning Leaders are critical to the successful reduction of lead poisoning among the traditional six (6) weeks to five (5) year old infant/child population that they serve. Early Learning Leaders are early learning facility owners, facility directors, and providers that have to be educated on the implications of lead poisoning, how to prevent exposure, lead remediation best practices, and to encourage the families they serve to get their children tested. K-12 school nurses, administration, and staff also play a critical role in protecting children from lead and can serve as a useful resource to inform their families on updates to the BLRV. Schools also offer an important opportunity for reducing lead exposure routes within their facilities.
- **Impact:** The partnership of both early learning and K-12 schools is essential in efforts to reduce lead exposures and protect the most vulnerable of children. Education and developmental services are an important consideration in the management of lead exposed children. A reduction in the BLRV may lead to an increased demand for early learning facilities and K-12 schools to provide education and resources to staff and related families as more children are recognized as experiencing the deleterious effects of lead. In addition, the specific neurological impacts of lead poisoning upon children may increase the need for targeted educational support for impacted families and educators.

Healthcare Providers

- **Role:** Pediatric health care providers are responsible for the majority of lead exposure screening and clinical follow up. This includes confirmatory testing, developmental and nutritional screening, ongoing monitoring of BLLs, referrals, education, reporting to surveillance programs, coordination with public health agencies and treatment where indicated. All BLL test results need to be communicated to families in a timely and appropriate manner. This process continues until the lead exposed child has a blood lead levels below the BLRV and environmental investigations and subsequent responses are complete.
- **Impact:** Implementation of the adopted BLRV will increase the number of children referred for confirmatory and follow up blood lead testing. Additional time and resource will be allocated to communicating results and providing education to families with children on the meaning of their blood lead test results, potential impacts on the child and interventions to prevent further exposure and mitigate the potential impacts on health and development. Pediatric professional organizations will need to update guidance for pediatric health care providers on the implementation of the adopted BLRV in clinical practice that aligns with the recommendations to be developed by CDC. Pediatric health care providers will need to identify the laboratory resources available to their patients to enable implementation of the BLRV in their practice.

Communication of BLRV to States and Other Stakeholders

The BLRV must be communicated in a coordinated and effective way to health care professionals, public health departments, parents/caregivers, childcare professionals, and K-12 schools. Risk communication strategies must be improved upon and strong. Environmental health infrastructure, enhanced surveillance, and primary and secondary prevention measures to identify and respond to environmental threats to the public's health continue to be important aspects of childhood lead prevention that should also be a part of related awareness building and education. A strategy for targeted outreach to these key partners is required to ensure that all receive and understand the information. Engagement with partners who directly work with each range of groups is necessary to assist with the outreach and uptake needs.

CONCLUSION

The Workgroup recommends adopting a revised reference value of 3.5 µg/dL and implementing a plan to address barriers associated with testing, messaging, and capacity of affected agencies and stakeholders at the federal, state, and local levels. This recommendation is consistent with the 2018 *Federal Action Plan to Reduce Childhood Lead Exposure and Associated Health Impact's* goals of reducing children's exposure to lead sources and identifying lead-exposed children and improving their health outcomes [6]. That plan also outlines a vision that the

“United States will become a place where children, especially those in vulnerable communities, live, learn, and play protected from the harmful effects of lead exposure”. Many factors will contribute to our nation’s ability to realize that vision. The recommended lowering of the BLRV has the potential to play a key part if CDC and other federal agencies also take steps to address and mitigate potential challenges associated with testing, messaging, and capacity constraints of current systems. The Workgroup believes that this is both possible and imperative.

References

1. CDC. *Preventing Lead Poisoning in Young Children*. 1991 [cited 2021 March 19]; Available from: <https://wonder.cdc.gov/wonder/Prevguid/p0000029/p0000029.asp> .
2. CDC's Advisory Committee on Childhood Lead Poisoning Prevention. *Interpreting and Managing Blood Lead Levels <10 µg/dL in Children and Reducing Childhood Exposures to Lead*. 2007 [cited 2021 March 19]; Available from: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5608a1.htm> .
3. Schmidt, C. *America's Misguided War on Childhood Lead Exposures*. 2018 [cited 2021 March 19]; Available from: <https://undark.org/2018/03/21/lead-testing-child-blood-levels/> .
4. CDC's Advisory Committee on Childhood Lead Poisoning Prevention. *Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention*. 2012; Available from: https://www.cdc.gov/nceh/lead/docs/final_document_030712.pdf .
5. CDC. *Blood Lead Reference Value*. 2012; Available from: <https://www.cdc.gov/nceh/lead/data/blood-lead-reference-value.htm> .
6. President's Task Force on Environmental Health Risks and Safety Risks to Children. *Federal Action Plan to Reduce Childhood Lead Exposures and Associated Health Impacts*. 2018; Available from: https://www.epa.gov/sites/production/files/2018-12/documents/fedactionplan_lead_final.pdf .
7. CDC. *Recommended Actions Based on Blood Lead Level*. 2020 [cited 2021 March 19]; Available from: <https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm> .
8. CDC. *NHANES Questionnaires, Datasets, and Related Documentation*. 2020 [cited 2021 March 19]; Available from: <https://wwwn.cdc.gov/nchs/nhanes/Default.aspx> .
9. Caldwell, K.L., et al., *Measurement Challenges at Low Blood Lead Levels*. *Pediatrics*, 2017. 140(2).
10. Caldwell, K., et al., *LAMP: A CDC Program to Ensure the Quality of Blood-Lead Laboratory Measurements*. *J Public Health Manag Pract*, 2019. 25: p. S23-S30.
11. Anderson, M.K., et al., *Using state lead poisoning surveillance system data to assess false positive results of capillary testing*. *Matern Child Health J*, 2007. 11(6): p. 603-10.
12. Wang, A., et al., *Screening for Elevated Blood Lead Levels: False-Positive Rates of Tests on Capillary Samples, Minnesota, 2011-2017*. *J Public Health Manag Pract*, 2019. 25 Suppl 1, Lead Poisoning Prevention: p. S44-S50.
13. Mielke, H.W. and P.L. Reagan, *Soil is an important pathway of human lead exposure*. *Env Health Perspect*, 1998. 106: p. 217-229.