Blood Lead Reference Value: Recommendation to LEPAC

May 14, 2021

Presented by Jill Ryer-Powder, Ph.D., MNSP, DABT

Chair BLRV Workgroup, Member LEPAC

Charge of Blood Lead Reference Value (BLRV) Workgroup

- CDC currently uses a BLRV of 5 micrograms per deciliter (ug/dL) to identify children with blood lead levels (BLLs) that are higher than most children, i.e., children in the highest 2.5% of blood lead levels
- The current BLRV is based on the 97.5th percentile of the National Health and Nutrition Examination Survey (NHANES) blood lead distribution in children ages 1-5 years using data from 2007-2008 and 2009-2010
- CDC is charged with assessing NHANES data every 4 years using the two most recent survey cycles of available data to determine if the blood lead reference value should be updated
- The BLRV Workgroup was charged to provide recommendations for establishing or re-establishing a BLRV for the CDC's National Center for Environmental Health (NCEH) via the Lead Exposure and Prevention Advisory Committee (LEPAC)

Members of the BLRV Workgroup

- Jill Ryer-Powder; Chair; LEPAC Member; Principal Health Scientist, Environmental Health Decisions
- Wallace Chambers; LEPAC Member; Deputy Director of Environmental Public Health, Cuyahoga County Board of Health
- Nathan Graber; LEPAC Member; Pediatrician, St. Peter's Health Partners
- Bruce Lanphear; Professor, Simon Fraser University
- Julianne Nassif; Director of Environmental Health, Association of Public Health Laboratories (APHL)

Members of the BLRV Workgroup (Continued)*

- Amanda Reddy; Executive Director, National Center for Healthy Housing (NCHH)
- Mark Werner; Director of Bureau of Environmental and Occupational Health, Wisconsin Department of Health Services
- Nsedu Obot Witherspoon; Executive Director, Children's Environmental Health Network (CEHN)

* Ginger Chew; Designated Federal Officer (DFO), Health Scientist, Division of Environmental Health Science and Practice, National Center for Environmental Health (NCEH)

Progress of the BLRV Workgroup

- Conducted virtual meetings since October 2020 that covered:
  - Purpose and charge of BLRV Workgroup
  - Decisions regarding the final product (i.e., report of recommendation)
  - Decision regarding recommendation
  - Document with recommendation and supporting information
- Completed report of recommendation
- Submitted draft report to LEPAC for review and approval (April 2021)

Overview of Recommendation Report

- Purpose of report
- Historical background
- Charge of the BLRV Workgroup
- Current status of the BLRV
- BLRV Workgroup Recommendations
- References

Purpose

- Define BLRV
- Provide information regarding how BLRV is being used by CDC and other entities
- Present current status of BLRV
- Present BLRV Workgroup's recommendations

Historical Background

- 1960s – CDC defined threshold for childhood lead poisoning ≥60 ug/dL
- 1967 – average childhood BLL in US ≥15 ug/dL and maximum acceptable threshold was 40 ug/dL
- 1991 – CDC reset the "level of concern" to ≥10 ug/dL for children under 6 years old; this level remained for 2 decades
- 2010 – CDC's Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommended establishing "reference value" (BLRV) as standard for children with "elevated blood lead levels"
  - Recommended BLRV be based on nationally representative sample of children (97.5th percentile of concentrations for US children aged 1-5 years)
  - BLRV should be reevaluated every 4 years from most recent NHANES survey

Historical Background (Continued)

- 2017 – National Center for Environmental Health (NCEH)/Agency for Toxic Substance and Disease Registry (ATSDR)/Board of Scientific Counselors (BSC) Lead Poisoning Prevention Subcommittee mad recommendation to lower BLRV from 5 ug/dL to 3.5 ug/dL
- Based on NHANES data showing decreased blood lead levels in US
- Recommendation in the form of a report submitted the CDC/NCEH
- CDC/NCEH responded to recommendation with a Federal Resister Notice (FRN) that was reviewed by the Office of Management and Budget (OMB)
- OMB expressed reservations about the rule-making and provided comments to CDC
- BLRV has yet to be revised and currently remains at 5 ug/dL

Acceptance of Certain ACCLPP Recommendations by CDC

- Discontinuation of term blood lead “level of concern”
- The use of a new reference value for the identification of children with elevated blood lead levels

The BLRV Workgroup

- Established in March 2020 under CDCs Lead Exposure and Prevention Advisory Committee (LEPAC)
- Workgroup composed of experts in toxicology, pediatric medicine, lead screening, lead exposure prevention, analytical chemistry, and public health surveillance
- Workgroup 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
- Workgroup reviewed scientific publications, consulted additional experts, reached consensus among workgroup members, and composed draft recommendation report
- The Workgroup met periodically and reported findings to the LEPAC

Objectives of BLRV Workgroup

- 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

Objectives of BLRV Workgroup (Continued)

- 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 BLRV

- Defined in 2012 in a report from ACLPP and a document from President's Task Force on Environmental Health Risks and Safety Risks to Children entitled "Federal Action Plan to Reduce Childhood Lead Exposures and Associated Health Impacts"
- Federal Action Plan document indicated that BLRV should serve 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 evaluated their effectiveness"
- BLRV is a statistic derived from the distribution of the concentration of lead in blood
- BLRV can characterize individual results as "elevated" or "not elevated"

The BLRV is Not:

- A clinical reference level defining an acceptable range of blood lead levels in children
- A health-based toxicity threshold
- A predictor of the health outcome for a particular person

The BLRV 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 and Use of BLRV

- Current value is 5 ug/dL, and based on NHANES data from 2007-2008 and 2009-2010
- 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
- CDC reports the number of children with blood lead levels greater than or equal to the BLRV on their website. The total number of children tested is posted along with the prevalence of children with EBLLs (i.e., ≥BLRV). These data are posted here

Current Value and Use of BLRV (Continued)

- The BLRV is used by health-care providers to trigger educational interventions and follow up testing
- Health care providers may initiate nutritional interventions, refer patients for developmental services, supply education, and potentially additional actions
- BLRV is used by some State Health Departments to guide case management and environmental/ home assessment. Information regarding use by State Health Departments is provided here

BLRV Workgroup Recommendations to LEPAC – Slide 1

- Adopt a revised BLRV of 3.5 ug/dL based on most recent NHANES cycles 2015-2018
- LEPAC reaffirm CDC's commitment to regularly evaluate 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 raise, the BLRV in the future
- BLRV should be used as a public health benchmark for all communities/jurisdictions, including high risk communities
- A BLRV of $\geq$3.5 ug/dL measured using a capillary sample should be followed by a confirmatory venous sample
- Emphasize use of materials (e.g., test tubes, needles, alcohol swabs, etc.) designated for collection of blood lead samples to decrease likelihood of contamination

BLRV Workgroup Recommendations to LEPAC – Slide 2

- Urge manufacturers of sampling/testing equipment to implement practices that minimize likelihood of contamination and increase sensitivity
- Manufacturers of specimen collection materials should offer trace metal free products (e.g., swabs, tubes, needles, syringes, etc.) that contribute no more than 0.2 µg/dL; CDC's DLS requires no more than 0.1 µg/dL
- Laboratories and clinician practices performing testing should pre-screen sampling and testing materials to reduce contamination from external sources
- Point of care manufacturers should improve the analytical technology to reliably measure lead at 1 µg/dL
- 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

BLRV Workgroup Recommendations to LEPAC – Slide 3

- Laboratories and clinician practices performing testing should participate in external quality assessment programs
- All positive POC measurements should be repeated using definitive test methods (e.g., 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
- CDC should carry out an 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

BLRV Workgroup Recommendations to LEPAC – Slide 4

- 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 (CLIAC), 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

BLRV Workgroup Recommendations to LEPAC – Slide 5

- 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

Guidance on How BLRV Should be Used

- Two purposes for BLRV:
  - Inform parents, caregivers, health care professionals, childcare professionals, K-12 schools that a child's exposure is higher than most other children in the US
  - Serve as a public health benchmark to determine which communities may have exposure to lead
- Guidance for use by:
  - Government agencies (e.g., CDC, EPA, FDA)
  - Non-government agencies
  - Other stakeholders (e.g., schools, healthcare providers)

Communication of BLRV to States and Other Stakeholders

- BLRV must be communicated in a coordinated and effective manner to health care professionals, public health departments, parents/caregivers, childcare professionals, K-12 schools
- Environmental health infrastructure, enhanced surveillance, primary/secondary prevention measures are important to identify
- Response to threats of lead exposure and associated adverse health outcomes require strategy for targeted outreach
- Necessary to engage with partners who work directly with each range of stakeholders to assist with outreach and uptake needs

Conclusions

- Workgroup's recommendation to adopt a revised BLRV or 3.5 ug/dL and implement a plan to address barriers associated with testing, communicating, and capacity of affected agencies and stakeholders 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,
  - Identifying lead-exposed children, and
  - Improving their health outcomes
- Recommendation of lowering BLRV has the potential for CDC and other federal agencies to play a key role in this effort - also take steps to address and mitigate potential challenges associated with testing, communicating and capacity constraints of current systems and technology

Discussion

For additional information, please contact:

Presented by Jill Ryer-Powder, Ph.D., MNSP, DABT

Chair BLRV Workgroup, Member LEPAC