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## Exposure Investigation

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### Jasper and Newton Counties Missouri Lead Exposure Investigation

Oronogo-Duenweg Mining Belt Superfund Site  
Newton County Mine Tailings Superfund Site  
Jasper and Newton Counties, Missouri

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## Project Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) evaluates community exposures and makes recommendations to prevent harmful exposures to hazardous substances in the environment. ATSDR and partners will conduct a lead Exposure Investigation (EI) at the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund Sites in Jasper and Newton counties, Missouri respectively. EIs involve collecting and analyzing biologic tests and environmental contamination data to determine whether people have been exposed to hazardous substances.

The Oronogo-Duenweg Mining Belt (primarily in Jasper County) and Newton County Mine Tailings Site are contaminated with lead and other metals from historic lead mining, milling, and smelting [EPA 2004, 2010]. The U.S. Environmental Protection Agency (EPA) has been characterizing and cleaning up areas related to these sites since 1995.

This EI will test up to 225 children (less than [ $<$ ] 72 months) and 75 pregnant women or women of childbearing age (15-44 years) to determine blood lead levels (BLLs) in the community. The EI will also include environmental sampling, both inside and outside of households. The samples will be collected by state and federal partners and used to determine lead levels in the environment. The EI will use the results of the tests to better understand how environmental contamination may impact BLLs.

The EI has the following objectives:

1. Evaluate BLLs in Jasper and Newton County residents, who are children ( $<$ 72 months) and women who are pregnant or of childbearing age (15-44 years) that participate in the investigation.
2. Review environmental sampling data collected by state and federal partners. Samples will be taken from participating residents' indoor and outdoor environments including soil, drinking water from private wells at the tap, public water collected at the tap, household dust, and interior and exterior painted surfaces.
3. Administer a survey questionnaire to document demographic, behavioral, occupational, and educational information of participants. Parents/guardians will complete the survey for the child participants.
4. Evaluate lead levels in environmental samples and the association between environmental lead levels with BLLs.
5. Recommend ways to lower environmental exposures to lead.
6. Provide an opportunity for all participants and parents/guardians of child participants to discuss their blood lead findings with an ATSDR medical officer.

## Investigators and Collaborators

This EI is a collaborative project between ATSDR, Centers for Disease Control and Prevention (CDC) Division of Laboratory Sciences (DLS), EPA, Missouri Department of Health and Senior Services (MDHSS), Jasper County Health Department, Newton County Health Department, Joplin City Health Department, and the Mid-America Pediatric Environmental Health Specialty Unit (PEHSU). ATSDR will work collaboratively with all partners throughout this process and provide assistance as needed. The roles and responsibilities of each collaborative partner are listed below.

- **ATSDR:** ATSDR is responsible for designing the study protocol, recruiting participants, collecting blood, and reporting the study results.
- **CDC DLS:** CDC DLS is responsible for analyzing blood samples for lead.
- **EPA:** EPA is responsible for collecting, processing, and analyzing residential soils and drinking water from private residential wells. Samples will only be collected from participating households. The laboratory analysis will be performed by EPA Region 7's Science and Technology Center or contracted laboratories.
- **MDHSS:** MDHSS is responsible for collecting and analyzing household dust, measuring lead in interior and exterior painted surfaces, and analyzing drinking water from public water supplies. Laboratory analysis for dust wipe and public water samples will be performed by the Missouri State Public Health Laboratory (SPHL).
- **PEHSU:** PEHSU is responsible for assisting ATSDR with clinician education and involvement and developing action plans for case management of participants with BLLs exceeding the blood lead reference value (BLRV). The BLRV is used to identify children who have more lead in their blood than other children, described in detail below.
- **Local Public Health Authorities (LPHAs):** LPHAs are responsible for conducting case management for participants with EBLs.

## Introduction

### Background

The EI will measure lead in the blood of children (<72 months) and pregnant women or women of childbearing age (15-44 years) and lead contamination in and around households near the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites. The EI will evaluate the association between BLLs and environmental lead levels. The Oronogo-Duenweg Mining Belt and the Newton County Mine Tailings Superfund sites are listed on the EPA National Priorities List (NPL) and are part of the Tri-State Mining District (TSMD). The TSMD encompasses approximately 2,500 square miles of land in Kansas, Missouri, and Oklahoma.

The TSMD was one of the foremost lead-zinc mining areas of the world. Lead and zinc ores were actively mined, milled, and smelted for over 100 years. Historic mining activities generated millions of tons of waste (described in Appendix A) that contaminated soil, groundwater, and sediments with lead and other metals.

ATSDR released a Preliminary Public Health Assessment for the Oronogo-Duenweg Mining Belt in 1990 and a Public Health Assessment for the Newton County Mine Tailings Site in 2006. Public Health Assessments evaluate hazardous waste sites to determine whether people could be harmed by coming into contact with site-related substances. Both assessments concluded that the sites posed a public health concern due to human exposure to metals via ingestion and inhalation of contaminated groundwater, soil, sediment, and air [ATSDR 1990, 2006].

In 1991, ATSDR, in partnership with the Missouri Department of Health (MDOH) now known as the MDHSS, initiated a lead and cadmium exposure study to determine if residents living in the Jasper County Superfund site area had blood lead and urine cadmium levels higher than residents living in a comparison area. The final report, published in 1995, found that BLLs were significantly higher in the exposed group. Urine cadmium levels did not significantly differ between the control and study populations. Environmental exposure to the area soil was the most important factor influencing the distribution of BLLs [ATSDR 1995].

EPA implemented major interventions in response to the 1995 report. By June 2000, they had remediated 2,288 residential yards. In 2000, ATSDR and MDOH conducted a follow-up lead exposure study to determine whether the interventions had been effective in reducing the mean BLLs of children residing in the area. The final follow-up study report, published in 2002, found that educational and environmental interventions were effective in reducing mean BLLs [ATSDR 2002]. The findings and conclusions of these studies are described in Appendix A.

The CDC has updated recommendations on children's BLLs over time as science and understanding of the health impacts of lead have evolved. Until 2012, children were identified as having a blood lead "level of concern" if the blood lead test result was greater than or equal to ( $\geq$ )10 micrograms per deciliter ( $\mu\text{g}/\text{dL}$ ). CDC no longer uses the term "level of concern" and instead uses a BLRV to identify children who have more lead in their blood than most children. In 2012, CDC began using a BLRV of 5  $\mu\text{g}/\text{dL}$  and in 2021 lowered the BLRV to 3.5  $\mu\text{g}/\text{dL}$  (described further in the next section) [CDC 2021b].

Given CDC's changes to the BLRV, in October 2021, EPA asked for ATSDR's assistance in conducting a blood lead assessment for the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites [EPA 2017, EPA 2019]. There are concerns that historic residential soil clean up levels may not remain sufficiently protective.

ATSDR is a non-regulatory federal public health agency and does not develop or advise environmental cleanup levels. ATSDR is conducting this EI in partnership with EPA, MDHSS, Jasper County Health Department, Newton County Health Department, Joplin City Health Department, and PEHSU to measure and compare BLLs and environmental levels for participating women and children residing within the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings sites.



## Health Impacts and Exposures to Lead in the Environment

Lead is a naturally occurring element in the earth's crust and is present in environmental media including air, water, and soil. A major source of lead in the environment has historically been from anthropogenic emissions from the combustion of leaded gasoline. Other anthropogenic sources include the mining, milling, and smelting of lead ores. Lead is found in many products such as old water pipes and their soldered connections, storage batteries, fishing sinkers, ammunition, imported children's toys, some pottery produced in Mexico, some homeopathic or herbal remedies, and consumer products (e.g., contaminated food, make up, jewelry, and leaded crystal) [ATSDR 2020]. Lead-based paint used in pre-1978 housing and associated lead contaminated dust are often the most widespread and dangerous sources of lead for young children [CDC 2009].

No safe level of lead has been identified that is free from deleterious health effects in children [CDC 2012, 2021c]. If an adult has been exposed to lead or has had high levels of lead in their blood in their past, the lead in their blood or lead stored in their bones can be harmful during pregnancy. As a result, BLLs should be kept as low as possible.

The CDC BLRV of 3.5 µg/dL is based on the U.S. population of children ages 1 to 5 years who are in the highest 2.5% of BLLs based on the 2015-2016 and 2017-2018 National Health and Nutrition Examination Survey (NHANES) cycles [CDC 2021a, 2021b, 2021c]. In the U.S., screening adults for lead exposure is almost exclusively done in the context of workplace exposures, and the National Institute for Occupational Safety and Health (NIOSH), a nonregulatory body, recommends that BLLs in adults should be < 5 µg/dL [NIOSH 2021]. All BLLs measured in the state of MO are reportable to MDHSS for all age groups, regardless of the reported lead level [MDHSS 2018].

Lead exposure can adversely affect all humans; however, lead exposure is most harmful to children, infants, and developing fetuses. Lead exposure and the associated health effects in infants and children are well documented. The adverse effects include damage to the brain and nervous system, slowed growth and development, learning and behavior problems, and hearing and speech problems. These can lead to lower intelligence quotient (IQ), decreased ability to pay attention, and underperformance in school. Lead exposure in children is often difficult to see and most children have no obvious immediate symptoms [CDC, 2021c].

Epidemiologic cohort studies suggest that prenatal lead exposure is inversely related to fetal growth and neurodevelopment, even with maternal BLLs < 10 µg/dL and independent of the effects of postnatal lead exposure. The exact mechanisms by which low-level lead exposure, whether incurred prenatally or postnatally, may adversely affect child development remains uncertain [CDC 2010]. Lead in the blood during pregnancy can increase risk for miscarriage; cause the baby to be born prematurely; and damage the baby's brain, kidneys, and nervous system.

In general, people can be exposed to lead through

- The inhalation of dust contaminated with lead (inhaled lead has greater bioavailability than ingested lead),
- The ingestion of drinking water containing lead,
- The ingestion of contaminated dust or soil (hand-to-mouth activities in young children),
- The ingestion or inhalation from occupational exposure (e.g., miners, mechanics, transportation workers, welders, etc.), and
- The intentional ingestion of solids containing lead such as soil (pica behavior).

Certain traits put people at higher risk for lead exposure [Brink et al. 2013]. Some characteristics (e.g., age, race, sex, socioeconomic status) contribute to experiencing disproportionate impacts. Young children are at highest risk because of their hand-to-mouth behavior which increases the likelihood of exposure to lead in the environment.

In addition to the risks posed by living in historic mining impacted areas in the Oronogo-Duenweg Mining Belt and Newton County Mine Tailing sites, other major risk factors for higher lead levels within our study population are living in housing built before 1978 and lower socioeconomic status. As part of the EI, ATSDR will administer a questionnaire with questions related to these risk factors. The answers will be used to inform results.

### **Justification for the EI**

EIs developed by ATSDR employ focused biologic and environmental sampling to determine whether people are or have been exposed to contaminants at specific locations (e.g., where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation).

ATSDR uses EIs to fill a data gap that is essential for evaluating community exposure pathways and determining if a health hazard is present. The EI team conducts point-of-human-contact sampling (environmental and/or biological) focused on areas where exposures are expected to be high.

The EI team evaluated the following four questions to determine whether an EI is appropriate to fill a data gap for the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites.

#### **1. Can an exposed population be identified?**

Yes. EPA has conducted extensive soil sampling and found high levels of lead throughout the impacted areas within both Jasper and Newton Counties. Sensitive populations could be at risk for exposure to harmful levels of lead in this community, specifically children < 72 months (i.e., younger than 6 years old) and women who are pregnant or of child-bearing age.

#### **2. Does a data gap exist that affects the ability to determine if a health hazard exists?**

Yes. Communities near the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings sites have been shown to have historic exposure to lead. While extensive response actions have been taken to reduce exposure, lead contamination remains present in soils at varying levels and some areas have yet to be investigated. It is unknown how historic and ongoing exposure to lead may be associated with BLLs.

**3. Can an exposure investigation be designed that will address this data gap?**

Yes. The EI will focus on participants across both sites where contamination from historic mining activities is highest. EPA environmental sampling data and site investigation information will be used to identify areas where lead contamination is known or suspected to be present. Blood lead results will be compared to BLRVs and interpreted using levels of lead found in the households of participants. Samples will be taken from soil, drinking water, house dust, and interior and exterior paint.

**4. How will the EI results impact the public health decision(s) for the site?**

The results of the EI will allow ATSDR to measure and compare BLLs and environmental levels and to provide recommendations on how to reduce exposure. The results may lead to an increase in education about exposure and prevention and recommendations for remedial or removal actions. The results may also help inform future clean-up work.

**Objectives of the EI**

ATSDR will examine BLLs, review environmental sampling data, and examine the relationship between BLLs and environmental sources of lead. Sampling protocols are explained in detail in Appendix E.

The EI has the following objectives and associated methods:

1. Evaluate BLLs for Jasper and Newton counties' residents who are < 72 months, women who are pregnant, or women of childbearing age (15-44 years) that participate in the investigation.
  - Minor siblings > 72 months may also have their BLLs evaluated for participating families at the parent/guardian's request.
  - Recommend case management for child participants with BLLs  $\geq 3.5$   $\mu\text{g}/\text{dL}$  and adult participants with BLLs  $\geq 5$   $\mu\text{g}/\text{dL}$  [CDC 2021b].
    - Recommend follow-up evaluation and retesting with a Primary Care Provider (PCP), obstetrician-gynecologist (OB/GYN), pediatrician, or health department.

- Recommend screening for developmental and behavioral issues in children. Refer children with developmental and behavioral issues, as needed.
  - Provide information on nutrition that may help to decrease the absorption of lead into the body [CDC 2002].
2. Review environmental sampling data collected by state and federal partners from participating residents' indoor and outdoor environments.
  3. Administer a questionnaire to document demographic, behavioral, occupational, and educational information of participants. Parent/guardians will complete the survey for child participants.
  4. Evaluate lead levels in environmental samples and the association between environmental lead levels and BLLs.
  5. Recommend ways to lower environmental exposures to lead.
  6. Provide the opportunity for all participants and parents/guardians of child participants to discuss their blood lead findings with an ATSDR medical officer.

## EI Design

The goal of the EI is to implement sample collection in the summer/fall of 2022 when contact with soil, and therefore, exposure to lead, is expected to be high due to increased outdoor activity by residents in the preceding months with good weather. Blood lead testing will occur first. Environmental samples will be collected from participants' households within 90 days of blood collection. Sampling protocols are detailed in Appendix E.

According to the U.S. Census Bureau, the population of Jasper County Missouri is 121,328, 6.6% (approximately 8,000) are children under the age of 5 [CB 2021]. The population of Newton County Missouri is 58,236, 6.1% (approximately 3,550) are children under the age of 5 [CB 2021]. Females aged 15-44 account for 21% (approximately 25,500) of the Jasper County population and 25% (approximately 14,500) of the Newton County population.

Participants for the EI will be recruited from the areas within the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund sites' boundaries (Appendix B). The EI will seek participants who reside in areas where soil lead contamination is highest or suspected to be present. ATSDR will use site investigations and historic site sampling data provided by EPA Region 7 to identify these areas.

Children < 72 months, pregnant women, and women of childbearing age will be eligible for inclusion. ATSDR will also evaluate BLLs for minor siblings of participants ≥ 72 months, if requested by a parent or guardian, as a public health service to the community. However, their results will not be evaluated as part of the EI.

## Population of Focus and Sample Size Determination

Children (< 72 months), pregnant women, and women of childbearing age (15-44 years) living in historic, lead mining impacted areas in Jasper or Newton Counties around the Oronogo-Duenweg Mining Belt and the Newton County Mine Tailings sites are eligible to participate.

Sufficient resources are available to enroll up to 300 participants. The goal is to enroll 225 children < 72 months and 75 women who are pregnant or of childbearing age. If ATSDR participation goals are met, ATSDR will inform other interested participants of local blood lead testing resources.

The proposed sample sizes were based on community demographics, budgetary constraints, and vulnerable populations. Sample size calculations further support the proposed sample sizes based on reasonable assumption.

## **Recruitment**

Residents within the boundaries of the Oronogo-Duenweg Mining Belt and Newton County Mine Tailings Superfund Site and designated areas are eligible to participate (see Sitewide Mining Areas of Interest in Appendix B).

Recruitment priority will be given to area residents where lead contamination is highest or suspected; however, participation will not be limited when contamination presence or absence is unknown. EPA environmental sampling data and site investigation information will be used to identify areas where lead contamination is known or suspected to be present [EPA 2021c, 2021d, 2021e].

ATSDR will take a hierarchical approach to recruitment by first prioritizing areas where lead contamination is highest. If necessary, ATSDR will expand recruitment to include areas within the site boundaries where environmental sampling is planned or where contamination is possible based on proximity to historic mining sites of interest.

1. ATSDR will create a mailing list for the residents in Jasper and Newton Counties where lead contamination is known to be present or where environmental investigations are pending. Contact information will be provided for participants to make appointments for testing.
2. Fact sheets, fliers, and postcards providing information on testing will be prepared by ATSDR and provided to LPHAs, distributed to eligible participants, and printed in local news publications and online outlets.
3. Digital recruitment material will be developed, and targeted social media advertising will be purchased. Click and impression advertisements will be purchased through Facebook and Instagram. Advertisements will target women with children, women who are pregnant, women of childbearing age, men with children, and grandparents.
4. ATSDR will develop a webpage to display information about the EI, eligibility criteria, and enrollment information.
5. ATSDR will focus on daycares, preschools, and elementary schools in the area to request partnership to recruit from client families.
6. ATSDR will recruit through established or newly created in-person connections with the community. Recruitment will occur through local events or public information sessions aimed at community groups, religious organizations, or other influential community members including elected officials.

7. ATSDR will work with LPHAs and local media outlets to broadcast recruitment information via radio or local news channels.
8. ATSDR will work with MDHSS, LPHAs, and the PEHSU to provide recruitment information and material to area PCPs, pediatricians, clinicians, and other area healthcare providers.
9. A \$20 token of appreciation in the form of a cash gift card will be provided to each eligible participant. Participants will receive the gift card at the time of blood draw.
10. Recruitment efforts will stop once the participation goal of 225 children <72 months and 75 pregnant women or women of childbearing age (15-44 years) has been met.

### **Consent and Parental Permission Forms**

Participants of the blood lead testing will be provided with a Consent/Parental Permission form (Appendix D) as appropriate prior to sample collection. Participants will read and sign the forms while ATSDR personnel are present. ATSDR, MDHSS, and EPA personnel will be available to answer any questions participants may have about the EI. Participants will be provided with a copy of the forms for their records.

The Consent/Parental Permission form and all other EI documents used to communicate with participants have been evaluated for reading level using Flesh-Kincaid Grade Level tool in Microsoft Word. The reading level goal is 8<sup>th</sup> grade or below. Appendix D includes copies of the forms.

### **Questionnaire**

Participants will be asked questions regarding demographics, household attributes, soil exposure, and daily activities (Appendix E). The responses will be used in the evaluation of the blood results. Prior to use, the questionnaire will be approved through the Office of Management and Budget (OMB) using the existing OMB generic package for EIs (OMB number 0923-0048, expires 04/2022). The protocol, including the questionnaire, will be submitted to OMB as a Generic Information Collection (GenIC) package for the site.

### **Blood Sample Collection**

Venous draw blood lead sampling is the most reliable method for measuring recent and ongoing exposure to lead. Blood will be collected by a certified phlebotomist using appropriate blood drawing protocols. Blood lead results cannot identify a specific source of exposure. Results reflect lead exposure from all potential sources.

A phlebotomist will collect 3 milliliters (mL) of blood from a vein of each participant who provides consent using 3mL ethylenediamine tetra-acetic acid (EDTA) coated pre-screened evacuated tubes provided by the DLS laboratory.

The blood samples will be maintained at an appropriate refrigerator temperature (2-8° C) after collection. Samples will be shipped on ice packs by overnight delivery to DLS. The DLS will analyze blood samples for lead concentration using DLS method 3040.1-04916.8-02 in whole

blood by Inductively Coupled Plasma Mass Spectrometry (ICP-MS). Reference NHANES method 2019-2020: [Cadmium, Lead, Manganese, Mercury, and Selenium - Blood \(cdc.gov\)](https://www.cdc.gov/nchs/data/ntds/ntds_2019-2020.pdf).

EI personnel will adhere to the Health and Safety Plan provided in Appendix F when handling and shipping blood samples.

1. Blood collection day/s.
  - There will be two blood collection events. There will be one event at a central location for each county, to reduce travel burden on participants.
  - Eligible participants will complete:
    - a consent/parental permission form and questionnaire for ATSDR,
    - a property access form for EPA, and
    - a property access form for MDHSS.
  - A venous blood sample will be obtained from each participant.
  - MDHSS will provide participants using municipal drinking water with a sample container and instructions for sample collection. Residents will use the instructions to collect a sample on the day MDHSS samples their indoor/outdoor environment to ensure a first-draw sample. Sampling instructions are described in Appendix F. Residents using private drinking water wells will work directly with EPA to arrange sample collection.
  - Blood samples will be submitted to DLS for analysis.
2. ATSDR will provide EPA and MDHSS with the addresses and consent forms for participants where environmental samples will be collected.

## Environmental Sampling

1. MDHSS will perform interior dust, interior and exterior paint, and public drinking water sampling within 90 days of blood collection.
  - MDHSS will collect up to 10 interior dust wipe samples per household:
    - a blank,
    - a floor inside the primary entryway used most by the household,
    - a floor and windowsill in the primary living area,
    - a floor and windowsill in the child's bedroom/sleeping area,
    - a floor and windowsill in the kitchen, and
    - a floor and windowsill in the interior play area.
  - Dust samples will be sent to the Missouri SPHL.
  - MDHSS will collect XRF readings inside the home from child's bedroom, kitchen, and main play area with up to 9 readings per room to include the most accessible:
    - interior window area on sash,
    - outer window area on sill,
    - interior door,
    - interior door jamb,

- floor (unless carpeted),
  - baseboard,
  - radiator (if present), and
  - cabinets or shelves.
  - MDHSS will collect XRF readings outside the home from side walls, windows, doors, and porches with up to 10 possible readings to include:
    - Two sides of the home. From each side, readings will include a
      - side wall,
      - window sash,
      - window trough,
      - door, and
      - door jamb.
    - Main porch. The porch reading will include the
      - floor,
      - banister, and
      - column.
  - MDHSS will provide general health education information on exposure reduction and prevention if XRF screening results indicate the presence of lead-based paint.
  - MDHSS will send resident-collected first-draw water sample for residences on public water drinking supply to SPHL for analysis.
2. EPA will perform exterior soil and private well drinking water sampling.
- Collect composite soil samples from the top 0-2 inches to represent:
    - General yard non-play area within 100 feet of structure walls (36 increments)
    - Drip zone soils within three feet of structure walls (9 increments)
    - Play area if present (9 increments)
    - Garden area if present (9 increments)
  - Collect drinking water samples from kitchen tap for homes with private wells.
  - EPA will process and analyze collected soil using XRF at the regional office and send 10% of soil samples to the Science and Technology Center (STC) Region 7 Laboratory for laboratory analysis.
  - EPA will send water samples to the STC or contracted laboratory for analysis.

### **Laboratory Analysis**

ATSDR staff will ship the venous blood samples via FedEx overnight express mail to CDC DLS in Atlanta for analysis. The laboratory will follow their standard procedures for analyzing blood for lead. The analysis results from DLS will be transmitted to the ATSDR Principal Investigator (PI) in an electronic spreadsheet format. No personal identifiers will be provided to the laboratory.



Appropriate data quality assurance and quality control (QA/QC) will be performed by the DLS and will meet accuracy and precision standards [Caudill et al. 2008]. After all the blood samples are analyzed, the results will be provided to the ATSDR PI for interpretation. Results in the final report will be grouped to correspond to those found in the updated NHANES tables [CDC 2021d].

Laboratory analysis for dust wipe and public water samples will be performed by the Missouri SPHL. The laboratory analysis for soil and private drinking water samples will be performed by EPA Region 7's STC or contracted laboratories.

### **Data Analysis**

Data analysis will be performed using R, SPSS, SAS, and/or Prism software. Descriptive analyses will be provided and presented via distinctive and clear figures along with descriptions in text. These will include the various BLLs and environmental data, broken down by age, sex, status on known lead exposures, comparison to NHANES, etc. Various comparison approaches may be used, depending on what comparisons are being made. Simple one-tailed t-tests will be used to determine if there are differences between two populations. Populations will be defined based on the various observations and data collected (e.g., environmental data, age, gender, etc.). More rigorous ANOVA, Pearson's R, and regression analyses will be used to further describe and interpret observations.

### **Description of Risks and Benefits**

**Benefits:** Participants and/or parents and legal guardians will be informed if they have recent and ongoing exposure to lead. Lead testing and test interpretation is free. If ATSDR finds levels of lead in blood above the BLRVs, we will contact the participants and provide recommendations to reduce exposure. Each eligible participant will receive a \$20 cash gift card for their participation.

An additional benefit for participants and local health care providers will be increased awareness of potential health effects associated with lead exposure.

**Risk:** We anticipate the risks to be very low. Participants may feel a sharp sting from the needle used to draw blood. Sometimes a bruise or small blood clot can occur where the blood is taken. These bruises or clots usually go away on their own. Participants may feel lightheaded for a short time. Rarely, fainting may occur. Although it is rare, infection could develop as a result of the puncture through the skin, or the needle could irritate or injure a nerve. This irritation may cause temporary numbness or pain in part of the arm. If participants have a history of anemia, a bleeding disorder, or are taking blood thinning medication, we recommend that they talk to their doctor before joining this study.

**Other Considerations:** Homeowners may be required to disclose the results of their environmental sampling if they sell their home. Participants may be inconvenienced during the environmental sampling because EPA and MDHSS will need to access their home.

Environmental sampling should take about two hours total to complete, one hour each for EPA and MDHSS.

### **Protection of Confidentiality**

ATSDR has a Privacy Impact Assessment associated with our Generic EI Office of Management and Budget (OMB) package. Participants' confidentiality and personal information will be protected by ATSDR to the fullest extent possible by law.

Individual test results will not be made available to the public. Confidential information and/or electronically captured data will be kept in locked cabinets and/or password protected computers and devices. Electronically captured data will protect privacy through the creation and use of a unique identifier. Personally identifiable information will be connected to a unique identifier to be maintained and protected by ATSDR. At the conclusion of the EI, ATSDR will prepare and publish a report summarizing the findings, but will not reveal personal identifiers (e.g., names or addresses). Reports produced after the EI implementation will not identify specific individuals or residences.

All blood samples that are sent to the laboratory for analysis will be labeled with a unique identifying number. De-identified results from the laboratory will be entered into an electronic database and sent to the ATSDR PI. Using a key, the PI will link laboratory and questionnaire data and maintain a complete de-identified dataset used for analysis.

### **Feasibility and Limitations**

ATSDR staff have experience in this type of investigation and have previously worked on lead exposure investigations. ATSDR is well positioned to address lead issues and to respond to community concerns that may be voiced during this EI.

#### **Potential limitations include**

1. We may not know the source of a participant's exposure.
2. Participants' blood lead concentrations cannot be used to predict the future occurrence of disease nor be attributed as the cause of current or past health problems. Though the health effects associated with lead exposure are well documented, there are numerous factors that can contribute to the development of disease.
3. The number of participants recruited may not give ATSDR a complete understanding of the extent of exposure attributable to historic lead mining, milling, and smelting.
4. The results of this EI will be applicable only to the individuals tested in these specific communities and cannot be generalized to other populations.

## **Handling Unexpected or Adverse Events**

There is a small chance of unexpected or adverse events occurring during this EI. The most likely adverse event is a participant feeling lightheaded or fainting during blood collection. The EI Medical Officer and the phlebotomist collecting blood are trained in responding to such situations. If any adverse event should occur, the PI will notify local emergency services and ATSDR in Atlanta.

## **Dissemination, Notification, and Report of Findings**

ATSDR, MDHSS, and EPA will communicate results and coordinate necessary response actions with participants and partners. The biological and environmental data will be evaluated to better understand how environmental contamination may be associated with BLLs.

Participants will be informed of their test results by letter. The letters will be mailed via the U.S. Postal Service. Letters will be addressed to adult participants and parents or guardians. A \$20 cash gift card will be included in the letters for each eligible participant. Sample letters that will be used to inform participants of their results are included in Appendix H.

A final report will be written and made available by ATSDR to participants online. A public availability session will take place in the area after the report is released. Representatives from ATSDR will be available to answer questions the community may have.

## **Projected EI Timeline**

### Weeks 1 to 6:

- Initiate recruitment activities.
- Schedule phlebotomists based on the total number and schedules of participants.
- Contact local media requesting announcements of ATSDR's recruitment process.
- Mail recruitment fact sheet and invitation to residents' households.
- Provide recruitment materials to local government offices and businesses that work with children < 72 months and pregnant women or women of childbearing age (e.g., daycare centers, preschools, elementary schools, and area healthcare providers). The invitation will include ATSDR contact information to allow prospective participants to ask questions about the EI and make appointments for data and sample collection.

### Weeks 7 to 12:

- Continue local recruitment efforts, including the use of social media, in-person events, and print and broadcast media.
- Continue scheduling testing appointments.

### Weeks 13 to 14:

- Collect blood samples in a central location within each county.
- Call or text participants the day before their appointment as a reminder.
- Register every participant upon arrival to the data and sample collection location.

- Provide the Consent/Parental Permission and access forms to participants to read and sign.
- Explain the data and sample collection process. All potential participants have the right to refuse participation without penalty.
- Administer one questionnaire per person. Adults complete the questionnaire for each child.
- Collect blood samples after the Consent/Parental Permission forms and questionnaire are completed.
- Provide MDHSS-supplied water sample bottle and instructions to residents on public water systems to ensure a first draw sample can be collected.
- Schedule environmental sampling with EPA and MDHSS if possible.
- Send the blood samples to CDC DLS for analysis.

Weeks 15 to 21:

- Analyze blood samples at CDC DLS.

Weeks 15 to 28:

- Conduct environmental sampling within 90 days of blood testing.

Weeks 15 to 36:

- Begin to analyze BLLs, questionnaire, and environmental data upon receipt from partner agencies.
- Notify participants of individual test results, interpretations, and recommendations via a letter. Sample letters are included in Appendix H.
- Provide or coordinate follow-up for children, pregnant women, and women of childbearing age with BLLs above the applicable reference values.
- Follow-up with a personal phone call from the ATSDR Medical Officer or PI to participants and parents or guardians to discuss any questions or concerns.

Weeks 25 to 64:

- Complete evaluation of BLL data in relation to the environmental data and questionnaire information.
- Complete writing the report for publication.
- Submit the report for review and release.
- Release the report on the ATSDR website.
- Meet with local community to discuss results.

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