Final

Date
March 4, 2020

SECOND BUTTE RMAP MEDICAL MONITORING STUDY (PHASE 2) REPORT

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FINAL

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STATEMENT FROM THE BUTTE MEDICAL MONITORING STUDY WORKING GROUP

What is this study about?

The Butte Superfund program addresses human health risks from exposure to historic mining contamination in the Butte Priority soils Operable Unit (BPSOU) in two ways:

- Capping more than 600 acres of mine waste dumps that cover the hill, often right in residential areas.
- Directly targeting people’s homes, yards and attics for cleanup if they pose an unacceptable risk.

That part, called the Residential Metals Abatement Program (RMAP), uses a systematic sampling approach to find properties contaminated with arsenic, lead or mercury. More than 1,350 yard and attic cleanups were completed by the end of 2018; most triggered by lead, some triggered by arsenic, and none triggered by mercury. Two prior arsenic biomonitoring studies conducted in Butte and a recent study in Anaconda have not found any evidence of elevated arsenic exposure due to arsenic in soil, so lead continues of be the focus of this study.

The RMAP also includes blood lead testing for young children, primarily through the Women, Infants and Children program administered by the Health Department. Blood lead testing is a reliable way to identify children with elevated lead exposures from any source. When a child’s blood tests high for lead the RMAP prioritizes that home for immediate action if the yard or attic lead is elevated. RMAP also investigates and helps fix other potential lead sources. For example, Butte has a very high proportion of older homes that are expected to have lead-based paint.

In 2006, the U.S. Environmental Protection Agency (EPA) required that the children’s blood lead dataset, collected as part of the RMAP, be used to study lead exposure to assess effectiveness of the RMAP. The current study is the second of six that must be conducted every five years.

Medical Monitoring Study Timeline

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
✓	✓				
→→2014	→→2019	→→2024	→→2029	→→2034	→→ 2039

Who conducted this study?

The medical monitoring study was funded by Atlantic Richfield and conducted by Ramboll, consultants to Atlantic Richfield. The study was overseen by a working group consisting of community partners and representatives of:

- U.S. Environmental Protection Agency (EPA)
- Montana State Department of Environmental Quality (MDEQ)
- Butte-Silver Bow Health Department (BSBHD)
- Citizens’ Technical Environmental Committee (CTEC)
- Montana Department of Public Health and Human Services (MDPHHS).

Why the focus on children?

Although the blood lead testing program has not excluded adults, it focuses on children. They are the most sensitive population. The EPA recognizes that there is no safe level of lead, and it is particularly detrimental to developing brains of small children. Small children also have the highest exposures due to how they play.

What did we learn about lead exposures in Butte?

Most importantly, blood lead levels have decreased both nationally and in Butte since 2002, but the rate of decrease is leveling out according to the most recent data (both nationally and in Butte). The Phase 1 study showed that the average Butte blood lead levels were not higher than expected in a comparable community without the historical mining influence, but some parts of Butte still had more children with elevated blood lead levels than expected. Higher rates of elevated blood lead levels in Uptown vs. the Flats were found to persist in the Phase 2 study. Higher rates of elevated blood lead levels are also found in the warmer months when children are more likely to contact soil while playing outside.

Higher rates of elevated blood lead levels cannot be attributed solely to mine waste. The most prevalent remaining risk factor for lead exposure in Butte children is living in an older home with lead paint. More than 80% of Butte houses were built before 1960. The American Academy of Pediatrics recommends targeted blood lead screening for young children in communities where more than 25% of the houses were built before 1960. Screening is also recommended for pregnant women in communities with a lead source.

The Phase 2 study also identified a limitation in the reliability of the elevated blood lead measurements from the LeadCare II equipment used by the Health Department. This equipment is reliable for an initial assessment, but elevated levels should be confirmed by another kind of test. Often the confirmation test will show the blood lead was not elevated. The Health Department does not have the resources to conduct the confirmation test and patients seldom got the test from their physician. This means we don’t have a precise measure of the rate of elevated blood lead levels in Butte.

What can we expect next?

The Working Group has made a series of recommendations for EPA to consider for RMAP operations, future studies, and public outreach and communication:

- Additional staff for the Health Department blood lead program to support on-site confirmation testing for elevated blood leads,
- Greater outreach to parents, pediatricians and expectant mothers to increase blood lead screening,
- Additional analyses of existing RMAP environmental data in the Phase 3 report,
- Continuing periodic updates by MDPHHS of cancer incidence and mortality in Butte,
- Improved public outreach and communication about Superfund-related health issues.

Working Group also recommends it be maintained as an active group, meeting at least several times per year to facilitate implementation of the recommendations and to plan for the next study.

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ACRONYMS AND ABBREVIATIONS

AR	Atlantic Richfield Company
ATSDR	Agency for Toxic Substances and Disease Registry
BINWOE	binary weight of evidence
BLL	blood lead level
BPSOU	Butte Priority Soils Operable Unit
BSBHD	Butte-Silver Bow Health Department
CDC	Centers for Disease Control and Prevention
COC	contaminant of concern
CTEC	Citizens' Technical Environmental Committee
GSD	geometric standard deviation
HHRA	human health risk assessment
HI	hazard index
HQ	hazard quotient
IEUBK	integrated exposure uptake biokinetic
LAO	Lower Area One
LCL	lower confidence limit
LOD	limit of detection
MCTR	Montana Central Tumor Registry
MDEQ	Montana State Department of Environmental Quality
MDPHHS	Montana Department of Public Health and Human Services
mg/kg-day	milligram(s) per kilogram per day
µg/dL	microgram(s) per deciliter
µg/g	microgram(s) per gram
µg/L	microgram(s) per liter
$\mu g/m^3$	microgram(s) per cubic meter
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
OR	odds ratio
ppm	part(s) per million
PRC	Professional Research Consultants
PRG	preliminary remediation goal

RBA	relative bioavailability adjustment
RfD	reference dose
RMAP	Residential Metals Abatement Program
RME	reasonable maximum exposure
ROD	record of decision
RR	rate ratio or relative risk
SCEM	site conceptual exposure model
SIR	standardized incidence rate
TCEQ	Texas Commission on Environmental Quality
UCL	upper confidence limit
URF	unit risk factor
USEPA	U.S. Environmental Protection Agency
UV	ultraviolet
WIC	Women, Infants, and Children

GLOSSARY OF TERMS

Additivity: When the effect of a mixture can be estimated from the sum of the exposure levels (weighted for potency in dose or concentration additivity) or the probabilities of effect (response additivity) of the individual components.

Age-adjusted rate: A rate that has been calculated to control for the effect of age, which allows comparison of rates across populations (e.g., Montana compared with the United States). An age-adjusted rate is a weighted average of the age-specific rates.

Analytical detection limit: The threshold below which values cannot be reliably measured.

Analytical method sensitivity: The extent to which the analytical method can reliably measure smaller concentrations.

Antagonistic: A mixture exhibiting an effect less than that estimated by assuming additivity.

Biomonitoring: A method of assessing individuals' exposures to chemical(s) by measuring quantities of the chemical or its breakdown products in biological specimens such as blood or urine samples.

Capillary sample: Blood sample obtained by collecting blood from a finger or heel stick.

Categorical variables: Qualitative variables representing grouped data. Examples may include race, income status, or sex (Yale 2013a).

Cohort: Individuals with a commonality that comprise a group (Merriam Webster 2013a).

Confidence interval: An approximate range, estimated from the sample data, within which the unknown parameter is likely to fall (Yale 2013b).

Confidence limit: Either of the two numbers that specify the endpoints of the confidence interval.

Correlation: A relationship existing between variables where changes occur together.

Crude rate: A rate is said to be crude if the measure has not been adjusted for any factor, such as age.

Dependent variable: The response variable that changes based on the independent variable(s).

Epidemiology: The study of the distribution and determinants of disease in a population. Epidemiology is the science of public health. In Latin, epidemiology means "-ology" study of, "epi-" upon, "demi-" the people.

Exposure: The contact of people with chemicals.

Exposure medium: The contaminated environmental medium to which an individual is exposed, such as soil, water, sediment, and air.

Exposure odds ratio: A measure of an association between exposure and disease in epidemiological studies.

Exposure pathway: The path a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or a population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, an exposure route, and a receptor. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of inter-media transfer) also are included.

Exposure route: The mechanism by which a contaminant comes in contact with a person (e.g., by ingestion, inhalation, dermal contact).

Federal poverty level: The income level by family size used by the U.S. federal government to determine poverty status.

Geometric mean: A measure of central tendency that is typically used when the underlying data are lognormally distributed. The geometric mean is the equivalent of the nth root of the product of n sample values (Merriam Webster 2013b).

Geometric standard deviation: A factor that describes the variation or spread of the values within a distribution, which is typically paired with a geometric mean and is usually reported for a lognormal distribution.

Histogram: A graph that represents the frequency distribution of data.

Independent variable: A variable that is used as a predictor or explanatory variable to describe a dependent variable. Independent variables are generally measured or recorded variables.

Incidence: The occurrence of new cases of disease among a population at risk of disease over a period of time. Incidence is often reported as a number or rate.

Lognormal distribution: In probability theory and statistics, the lognormal distribution is the probability distribution function of random variables whose logarithms are normally distributed.

Mean: The average value of a set of numbers.

Media: Specific environmental components—air, water, soil—that are the subject of regulatory concern and activities.

Median: The middle value in an ordered set of numbers.

Mortality: Death due to a particular cause among a population over a period of time. Mortality is often reported as a number or a rate.

Multivariable statistical model: Model that contains more than one independent variable and examines each variable’s influence on the dependent variable (e.g., blood lead level) after adjusting for the other variables in the model.

Non-detect: A number below the lowest value that can be reliably measured.

Normal (Gaussian) distribution: A distribution in which probability density function of random observations is symmetric around the mean and forms a bell-shaped curve.

Percentile: A value below which a specified percentage of observations within a population of data fall (e.g., 95^{th} percentile).

Poverty-income ratio: The total family income divided by the federal poverty threshold specific to family size, year, and state of residence.

Precision: A measure of the closeness of agreement among individual measurements.

Prevalence: The existing cases of a disease at a particular point in time or over a period of time. Prevalence is often reported as a number or a percentage.

P value: Expression of the level of statistical significance of a statistical result and the likelihood it is not a product of chance (IWH 2005).

Rate: A measure of the number of events that occur in a defined population with respect to time. A rate may or may not be a proportion. Example: a / (a+b), where a is the number of people experiencing an event during a certain time period and (a+b) is the total number at risk of the event during that same time period.

Rate ratio: Also defined as relative risk; a measure of an association between exposure and disease in epidemiological studies.

Ratio: The comparison of any two numbers in which the two numbers are separate and distinct quantities. Example: a/b, where both a and b refer to the frequency of some event or occurrence.

Sensitivity analysis: Assesses the influence of factors or assumptions, such as missing data or method of analysis, on the study conclusions (Thabane et al. 2013).

Statistically significant: When observed differences between groups are determined not to be attributable to chance (IWH 2005).

Statistical power: The probability that a statistical test will reject the null hypothesis when the null hypothesis is false (IWH 2005).

Synergistic: A mixture exhibiting an effect that is greater than that estimated by assuming additivity.

Univariate model: Model that contains only one independent variable and examines that variable's influence on the dependent variable (e.g., blood lead level).

Venous sample: Blood sample obtained from the vein via venipuncture.

Weighting factor: Estimated value that modifies the influence of a record on the overall fit of the parameters of a model to the data.

EXECUTIVE SUMMARY

This report of the Second Butte RMAP Medical Monitoring study (Phase 2) presents the results of the second of six public health studies examining the effectiveness of the Residential Metals Abatement Program (RMAP) for the Butte Priority Soils Operable Unit (BPSOU) Superfund site that will be conducted over a 30 year period. The health studies are overseen by a working group representing the U.S. Environmental Protection Agency (EPA), Montana State Department of Environmental Quality (MDEQ), the Butte-Silver Bow Health Department (BSBHD), Atlantic Richfield, the Citizens' Technical Environmental Committee (CTEC), and the Montana Department of Public Health and Human Services (MDPHHS).

This Phase 2 report presents an update of trends in blood lead levels (BLLs) in Butte children, as well as summaries of other exposure studies conducted in Butte. It also presents summaries of disease rate studies in Butte, including an updated study of cancer incidence and mortality conducted by the MDPHHS. In response to public comments and questions, the report presents information about the soil cleanup levels for lead, arsenic and mercury in BPSOU, as well as the EPA human health risk assessments supporting the cleanup levels.

Blood Lead Study

This medical monitoring study focused on blood lead data collected from Butte children from 2012 through 2017 and evaluated trends over this time period, by Butte neighborhood, and as compared to areas outside of Butte. These trends were compared with those observed in the first study which examined BLLs from 2003 through 2010.

Lead exposures and average BLLs have declined dramatically among U.S. children since the 1970s because many lead uses in products such as gasoline and lead paint have been discontinued and because of ongoing efforts to control exposures to the multitude of lead sources. These continually declining BLLs make it difficult to distinguish changes in BLLs in Butte that are attributable to the RMAP as compared to control of other sources.

This study focused on elevated BLLs, i.e., those above 5 micrograms lead per deciliter blood (µg/dL), a reference level developed by the Centers for Disease Control (CDC) in 2012 based on the highest 2.5% of child BLLs in the U.S. The percentage of Butte children with BLLs above 5 µg/dL has dropped dramatically over the time period evaluated in the first two health studies, with the rate of decline slowing as levels approach those found in children across the U.S. In Butte, this percentage decreased from 33 percent in 2003 to 5 percent in 2017.

Children living in neighborhoods in Uptown were found to have higher rates of elevated BLLs than children living in the Flats. Although there are more old homes (built before 1940 and likely to have lead paint) in Uptown, elevated BLLs were more frequent in children living in Uptown even after accounting for house age. The rate of elevated BLLs is also higher in the warmer months when children are more likely to contact soil while playing outside, especially in Uptown.

The percent of Butte children with elevated BLLs is still higher than the average reported in a national survey of BLLs. There are several possible reasons for this difference. One reason could be continuing exposures to lead in soil that hasn't yet been cleaned up or to lead paint in homes not yet abated. Another reason could be related to the method used to collect blood samples in Butte. The national survey used samples collected by venipuncture. The Butte samples are collected by a finger stick. The venous samples usually provide a more reliable indication of elevated BLLs. For example, in Michigan, which has a state-wide blood lead surveillance program with samples collected by finger stick, 3.4% of the children had elevated BLLs in 2015. Only half of those children were confirmed to have elevated BLLs when tested by venipuncture.

The percent of elevated BLLs in Butte is also lower than the percent in many U.S. counties (often those with a high percentage of older housing). Looking again to Michigan, in 2015 the three counties with the highest percent of elevated BLLs had rates of 10.1%, 6.5% and 6.2%. And finally, the percent of elevated BLLs are higher among low income children such as those tested in Butte. The national survey is representative of children at all income levels, whereas the Butte data are mostly from children whose families have income low enough to qualify for the Women, Infants and Children (WIC) program. For example, in Michigan, the rate of elevated BLLs statewide was 3.4%, but among children enrolled in Medicaid, the rate was 4.2%, more than 20% higher.

Conclusions: Rates of elevated BLLs (i.e., those above 5 µg/dL) in Butte children have declined dramatically since 2002 but have been declining much more slowly since 2011. While the RMAP likely has contributed to these declines the magnitude of impact cannot be quantified. Furthermore, there is no reliable reference population to determine if the rates of elevated BLLs in Butte are higher than would be expected in a similar community without the historical mining influences found in Butte.

Studies of Cancer and Other Diseases

Five studies of disease occurrence in Butte were identified, beginning with a study of skin cancer published in 1992, and followed by three studies of cancer incidence for the Butte population compared with state and/or national data in 2002, 2012 and 2018. The 2012 and 2018 studies also considered cancer mortality rates. The fifth study examined mortality rates of a broad range of diseases. The two most recent studies are briefly described here. In addition, self-reported rates of common diseases and risk-related behaviors (e.g., smoking) for Butte are compared with rates in the rest of Montana and in the U.S. in the periodic community health needs assessments conducted by BSBHD (most recently in 2017).

In 2018, the Montana Department of Public Health and Human Services (MDPHHS) updated the 2012 Silver Bow County cancer mortality and incidence analysis extending the analysis through 2016. This study relied on the Montana Central Tumor Registry. Age-adjusted incidence rates for all cancers combined were statistically the same as rates for other Montana residents from 2002 through 2016. The rate of new breast, bladder, kidney, liver, colorectal, and lung and bronchus cancer cases were statistically the same in Silver Bow County and the rest of Montana from 2007-2016. The rate of new prostate cancer cases in men in Silver Bow County has been declining and was significantly lower from 2007-2016 compared with the rest of Montana. Mortality results were more variable than results for incidence, which is a more reliable measure of the effects of environmental exposure on disease rates.

A recent study of disease mortality rates was published by Davis et al. (2019) who used mortality data obtained from the CDC WONDER site to examine the hypothesis that elevated exposures to metals in Deer Lodge and Silver Bow counties might be associated with certain diseases. Deer Lodge and Silver Bow were reported to have overall higher mortality compared to the rest of Montana from 2000 to 2015 for cancers and cerebrovascular and cardiovascular conditions, with decreasing mortality over the time period studied. However, no exposure data were linked to the cases to support the assertion that different mortality rates were associated with metal exposures, and no analysis of remediation timelines was presented to support the hypothesis that reduced rates were associated with remediation.

Conclusions: None of the Butte disease rate studies included individual level exposure data or occupational history, and all are hypothesis generating studies (i.e., surveillance or ecological studies) primarily used to suggest future studies that should be done. None of these studies can be linked to causes of observed elevated incidence or mortality. Studies of disease incidence are valuable for use in identifying areas of focus for future studies.

Recommendations

Based on the Phase 2 study, the Working Group has provided recommendations in four categories: RMAP operations, future exposure/biomonitoring studies, future epidemiology/disease studies, and public outreach and communication. One general recommendation is that the Working Group be maintained as an active group, meeting at least several times per year to facilitate implementation of the recommendations and to plan for the next study.

RMAP operations: Phase 1 recommendations for RMAP outreach activities have been implemented. Two new recommendations include:

- Assessment of landlord participation rates in RMAP and of the effectiveness of outreach to landlords.
- Establishment of a position within the BSBHD for an environmental health clinician specializing in pediatrics. It is recommended that this person conduct additional outreach to local physicians and clinics to increase screening and data availability for young children and pregnant women consistent with clinical recommendations for communities with lead risk factors (such as older housing with lead-based paint in Butte).

Future exposure/biomonitoring studies: Recommendations for future exposure/biomonitoring studies and RMAP operations include the following:

- Continued focus on lead biomonitoring,
- Increased tracking and refined follow-up for individuals with elevated BLLs,
- Increased outreach to local pediatricians and clinics to augment the available blood lead data.

The two prior arsenic biomonitoring studies conducted in Butte and a recent study in Anaconda have not found any evidence of elevated arsenic exposure due to arsenic in soil; therefore, another arsenic exposure study in Butte is not likely to yield useful information about soil remediation effectiveness. Based on the recent study in Anaconda, regular access to un-remediated attics could be a source of exposure. Additional community engagement is needed to address expressed concerns about arsenic exposure.

Future epidemiology/disease studies: Periodic updates by MDPHHS of cancer incidence and mortality in Butte-Silver Bow versus Montana and the U.S. should continue. Hypothesis-generating studies that have been conducted so far do not support concerns about elevated cancer rates in Butte. Rates of diseases other than cancer are difficult to study because there are no registries that reliably document incidence. The findings of the community health needs assessments should be reviewed to determine if they provide indications of possible environmental exposures related to Superfund or other sources within the community. Neurological diseases, and especially multiple sclerosis are a continuing community concern; however, the CDC has stated that a study of this disease is not feasible or needed. The literature should continue to be monitored for developments that might provide insights other diseases of concern to the community.

Public outreach and communication: Many misperceptions about the extent of remediation and potential for ongoing exposures were identified in a 2018 survey of community risk perceptions. Few people reported relying on EPA public meetings for information about Superfund-related remediation and health issues, relying instead on local news media, family and friends, and social media. EPA and responsible parties should supplement public meetings and flyers with regular communications via local news and social media due to a health risk perception gap between BPSOU residents and the regulatory agencies. Methods should also be developed to more proactively engage members of the public.

1. INTRODUCTION

This report presents the second in a series of public health studies for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana. The first Superfund study report, titled Butte Priority Soils Operable Unit Public Medical Monitoring Study, Phase 1, was issued in July of 2014 (ENVIRON 2014b). This study focuses on updated analyses of blood lead data compiled as part of a Residential Metals Abatement Program (RMAP) administered by Butte-Silver Bow County. The RMAP is one component of a massive remediation program that has been underway in the Superfund site for decades. The goal of the medical monitoring studies is to support an evaluation of the effectiveness of ongoing remediation and residential metals abatement efforts, and to yield recommendations regarding whether future changes are needed to these efforts.

In addition to updating the blood lead analyses, this report includes summaries of the human health risk assessments (HHRAs) conducted by the U.S. Environmental Protection Agency (USEPA), reviews of the toxicity of the key metals evaluated in the risk assessments, and descriptions of the soil cleanup levels guiding the remediation efforts. Prior exposure and health studies conducted in Butte are also described. An updated study of cancer incidence and mortality conducted by the Montana Department of Public Health and Human Services (MDPHHS) is included among these studies.

1.1 Scope of Study: RMAP Requirements and Limitations

The BPSOU cleanup efforts for arsenic, lead, and mercury have been underway for more than 30 years. The Atlantic Richfield Company (AR) has conducted much of the cleanup outside of residential areas, and the Butte-Silver Bow Health Department (BSBHD) has been leading residential yard and home metals abatement efforts via the RMAP. The RMAP includes a biomonitoring program in which thousands of blood lead samples have been collected from Butte children for at least 15 years.[1] Using the available blood lead data to assess exposures in Butte is desirable because blood lead levels (BLLs) provide a direct and relatively stable measure of all sources of lead exposures a child may have, including lead exposures from soil, dust, water, air, food, paint, and consumer products. Furthermore, BLLs are measured each year in thousands of U.S. children, making it possible to compare Butte levels with BLLs for children outside of Butte and assess if RMAP and other Superfund remediation actions have effectively reduced exposure to historic mining related contamination. The Phase 1 study evaluated over 3,000 blood lead results collected from 2003 through 2010. The Phase 2 study updates the analysis with over 3,000 blood lead results collected from 2012 through 2017.

The RMAP is governed by a plan that is periodically updated. The RMAP Plan specifies that studies will be conducted every 5 years for 30 years to evaluate the biomonitoring data collected under the RMAP to assess the methods used, and to identify trends in exposures and any insights regarding the effectiveness of the RMAP. The Phase 1 study followed the medical monitoring study requirements in the 2010 RMAP plan (Butte Silver Bow County and Atlantic Richfield Company 2010). In January 2017 a final revised RMAP Plan was issued (Butte Silver Bow County and Atlantic Richfield Company 2017). The 2017 plan was not approved by USEPA and is undergoing further revision and will be released once the BPSOU Unilateral Administrative Order

[1] Biomonitoring for arsenic and mercury has also been available under this program since 2010 but only when arsenic and mercury concentrations in soil or accessible dust have been high enough to warrant such testing. Because the environmental concentrations were seldom high enough to offer such testing, there are no arsenic and mercury biomonitoring data that could be used to support an exposure study.

is finalized, which is expected by early 2020. The language from the 2017 RMAP plan as quoted below provides a clear description of the goals of the biomonitoring part of the study.

> Butte-Silver Bow will periodically evaluate medical monitoring (i.e., "biomonitoring") data approaches and data compiled under the Program every 5 years for a period of 30 years. The first of these studies was completed and approved by EPA in 2014. Five additional periodic evaluations will be conducted over the next 25 years. Reports documenting these periodic evaluations will respect the privacy of the participants and will be available to the public, the EPA, Montana Department of Environmental Quality (DEQ), and potentially responsible parties for the BPSOU. While the Program has focused on arsenic, lead, and mercury, lead has proven to be the primary metal triggering abatements and is the only metal routinely included in biomonitoring. Thus, periodic evaluations will focus on lead. While not a focus, any applicable data for arsenic and mercury will also be reviewed. Similarly, periodic evaluations will focus on effected and sensitive populations as defined by the Program. Data gathered through the Program's routine activities, as well as the results of prior periodic evaluations, will be considered in each periodic evaluation.
>
> The purpose of conducting periodic evaluation of biomonitoring data compiled in conjunction with the Program is two-fold. First, because the state of the science related to collection and interpretation of biomonitoring data continues to evolve, it is necessary to periodically evaluate the medical monitoring approaches used in the Program to ensure that the biomonitoring data can continue to be used to support the Program's mitigation of potentially harmful exposures of BPSOU residents to sources of lead, arsenic, and mercury contamination. Second, examination of the complete biomonitoring database every five years can provide valuable information with regard to exposure trends over time and in comparison to reference populations over the same time periods. Information and analysis supporting both purposes can inform potential improvements to routine activities as needed to ensure the Program's continued effectiveness.

As noted above, in addition to the study of BLLs, this medical monitoring study includes an updated study of cancer incidence and mortality conducted by the MDPHHS, as well as reviews of all identified studies (both historical and recent) that examine metal exposures and possible association of metal exposures with disease rates in Butte.

1.2 Study Planning and Public Engagement

As was the case for the first study, the conduct of the Phase 2 study was overseen by the Butte Medical Monitoring Study Working Group (the "working group") representing USEPA, Montana State Department of Environmental Quality (MDEQ), the BSBHD, AR, the Citizens' Technical Environmental Committee (CTEC), and MDPHHS. Members are listed below.

USEPA – Nikia Greene, Dr. Charlie Partridge, Christopher Wardell

BSBHD – Karen Sullivan, Eric Hassler, Brandon Warner, Julia Crain

AR – Josh Bryson

AR Technical Consultants – Ramboll (Dr. Rosalind Schoof, Cynthia Van Landingham)

MDPHHS – Laura Williamson, Dr. Matthew Ferguson, Heather Zimmerman

CTEC Representatives – Joe Griffin, Dr. Bill Macgregor, Dr. Steve Ackerlund

Community Partners – Dr. Seth Cornell, Dr. John Ray, Dr. Dave Hutchins

MDEQ – Daryl Reed

Agency for Toxic Substances and Disease Registry (ATSDR) – Dr. Michelle Watters (only for initial planning phase)

The working group held three in person meetings (in July 2018, March 2019 and September 2019) and a series of teleconferences to plan the study and review the findings. Also, three public meetings soliciting input for the study were held in July 2018, October 2018 and March 2019. As a result of public input, additional topics identified by residents have been added to this report with the goal of responding to public concerns and interests that are relevant to Superfund actions to protect human health. These topics include an explanation of the health risk assessment process, the results of prior BPSOU health risk assessments, the basis for soil cleanup levels, and assessment of the current protectiveness of these levels. Separate from the Phase 2 study, a risk perception study was conducted by Montana Tech researchers to survey Butte residents' perceptions of environmental health and Superfund activities. Preliminary results of this study are presented in Section 2, and other thoughts about public engagement are discussed in the conclusions and recommendations section.

1.3 Phase 2 Study Scope and Report Organization

The Phase 2 study scope reflects both the RMAP Plan and input received from Butte citizens at public meetings and from community stakeholders. The primary study elements are described below according to the organization of this report:

Butte Superfund History and Community Characteristics – The history of Superfund remediation in Butte is briefly summarized with a focus on BPSOU and residential areas. Other community characteristics and information about health status that are important determinants of public health are then described, followed by a description of a recent survey of perceptions of environmental health issues in Butte.

Review of Risk Assessments and Cleanup Levels – Prior HHRAs conducted within and near the BPSOU are summarized; also described are the derivation of cleanup levels and the periodic review of cleanup levels during the reviews of the BPSOU record of decision (ROD) conducted every 5 years.

Review of Past Exposure/Biomonitoring Studies – Current biomonitoring sampling procedures, analytical methods, and concentration benchmarks, and assessment of the need for any potential updates/improvements. Prior BPSOU exposure studies (including the Phase 1 study) are summarized.

Review of Disease Prevalence and Rate Studies – Prior studies of disease prevalence in Butte are summarized, including results of an updated MDPHHS analysis of morbidity and mortality statistics for the Butte population compared with state and national data. Additional relevant published literature is also described.

Phase 2 Blood Lead Data Analysis –Blood lead data from 2012 through 2017 and summary statistics are compiled, and a plan is presented for data analysis. Exposure trends over time, by Butte neighborhood, and (to the extent supported by available data) in comparison to a defined reference population are evaluated.

Key Findings and Recommendations – A final section presents key findings related to epidemiological and exposure studies, as well as recommendations of any areas where changes to activities conducted via the RMAP may be useful. Recommendations for public outreach are also provided.

2. SUPERFUND HISTORY AND BUTTE COMMUNITY CHARACTERISTICS

While Superfund is one potential health concern in Butte, health studies must consider other factors that are important determinants of public health such as age demographics, socioeconomics, access to health care, and behavioral factors like smoking and exercise. In this section we briefly summarize the history of Superfund remediation in Butte, describe location and demographic factors that may influence disease rates, provide background on community health concerns and disease prevalence rates, and summarize findings of a recent study on community risk perceptions related to Superfund.

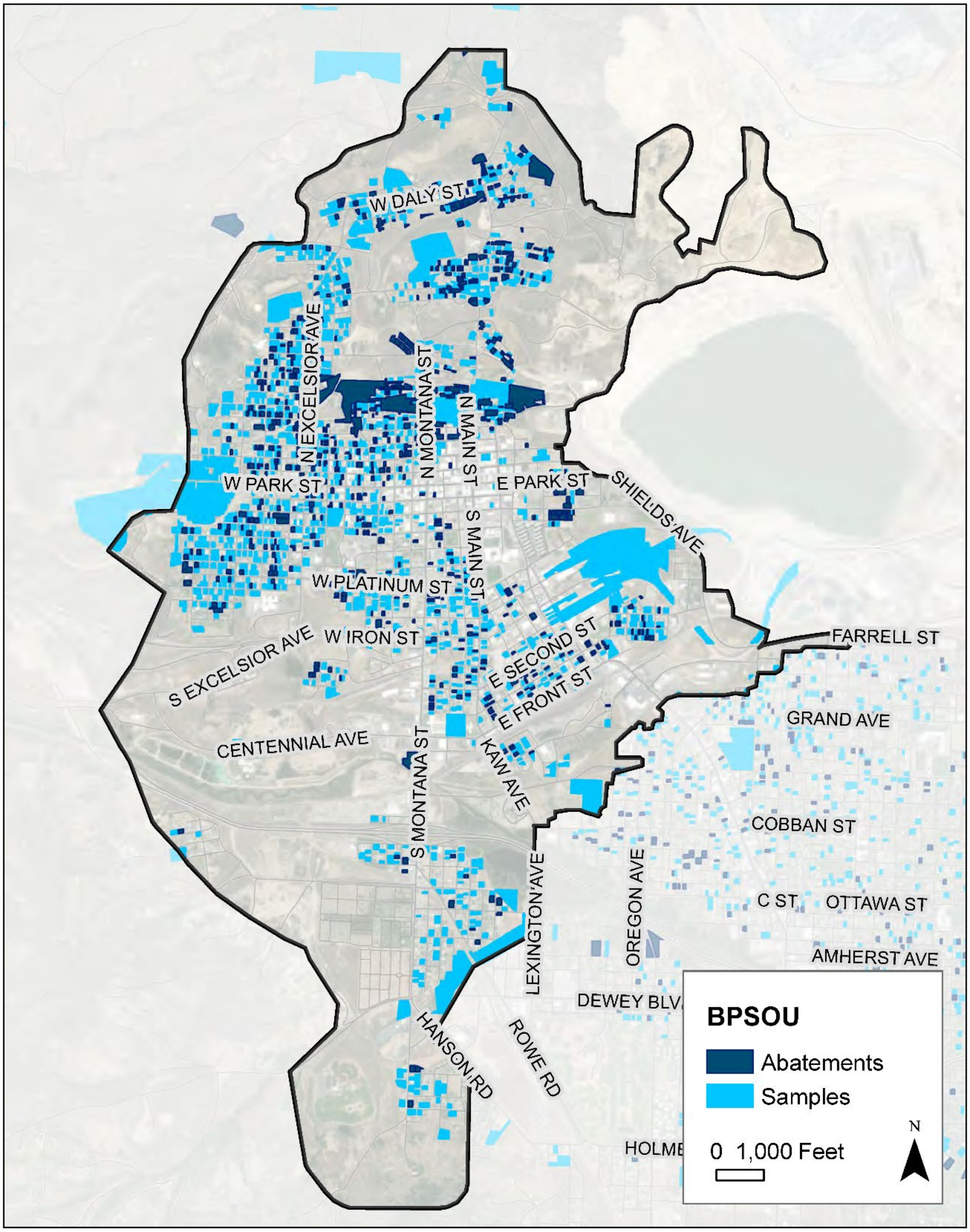
2.1 Superfund in Butte

According to USEPA's website (https://cumulis.epa.gov/supercpad/SiteProfiles/index.cfm?fuseaction=second.Cleanup&id=0800416#bkground), since the late 1800s extensive surface and underground mining activity resulted in wastes dumped into areas in and around Butte, as well as into streams and wetlands near mining operations, and smelters and mills produced aerial emissions of metals. These activities contaminated soil, groundwater and surface water. In 1982, USEPA proposed the Silver Bow Creek be added to the National Priority List and it was listed as a Superfund site in 1983. The Butte Area was added to the Silver Bow Creek site in 1987. From 1987 to 1999 thousands of samples were collected, mostly from waste dumps. Capping of waste dumps began in 1988, and while the program continues, most of the larger waste dumps having greater exposure potential were capped before 2000. Altogether millions of cubic yards of mine waste and contaminated soil have been remediated in Butte-Silver Bow County over the past 35 years.

In residential areas, the RMAP, which began in 1994, is now more than half complete within BPSOU (see Figure 1), having sampled 3,408 residential parcels and abated 1,351 properties and attics as of 2018 (BSBHD 2019). The RMAP boundaries have expanded over time to include the "Adjacent Area", and other areas and hundreds of properties have been sampled and abated in these areas (Figure 2). Currently the boundary is being expanded to include parts of the Westside Soils Operable Unit. The Phase 2 study continues to focus on the area within BPSOU.

The Butte-Silver Bow Superfund Operations & Maintenance Department is developing a searchable database that will enable the public to access data for specific parcels, i.e., if those parcels have been sampled or remediated.

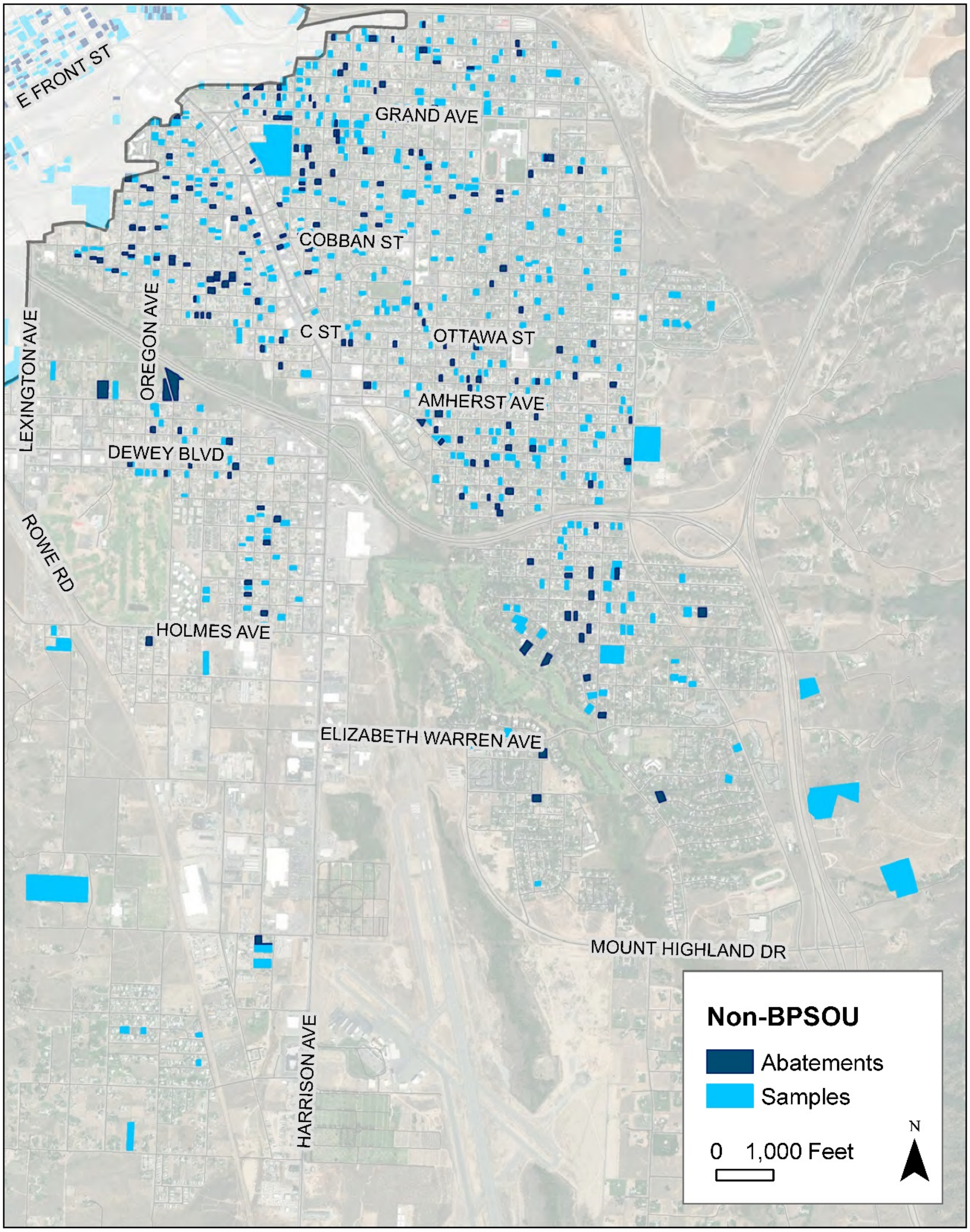
Figure 1: BPSOU Properties Sampled and Abated by RMAP Through 2018



\\GIS-Serv11\Disk3\Butte\Planning\Reclamation\Maps_2019\RMAP_templates.mxd

Service Layer Credits: Source: Esri, DigitalGlobe, GeoEye, Earthstar Geographics, CNES/Airbus DS, USDA, USGS, AeroGRID, IGN, and the GIS User Community

Figure 2: Properties outside BPSOU Sampled and Abated by RMAP Through 2018



\\GIS-Serv11\Disk3\Butte\Planning\Reclamation\Maps_2019\RMAP_templates.mxd

Service Layer Credits: Source: Esri, DigitalGlobe, GeoEye, Earthstar Geographics, CNES/Airbus DS, USDA, USGS, AeroGRID, IGN, and the GIS User Community

BSBHD maintains a database of residential metals sampling and abatement information as part of the RMAP. The RMAP database includes details of sampling for indoor dust, outdoor soil and paint, as well as indoor and outdoor abatements that have taken place since February 1992 throughout the RMAP area. A new, comprehensive RMAP database is currently under construction. BSBHD also publishes "Annual Construction Completion" reports that summarize RMAP activities conducted each year and/or planned for subsequent years.

Historically, the vast majority of the RMAP activities occurred in Uptown[2], which is geographically closer to historic mining and ongoing mining associated with Montana Resources operations. Naturally-occurring mineralization is also more prevalent in Uptown than in the Flats, as well as an increased prevalence of older housing. A proportionally greater increase in sampling events occurred in the Flats, from pre-2003 (35 events) to 2003 through 2010 (147 events). The increased intensity of RMAP activities in neighborhoods further from Uptown likely reflects early prioritization of RMAP outreach toward residents of Uptown where more of the oldest homes in Butte are located and in closer proximity to mining-related exposure sources. This trend is expected to have continued after 2010.

It is important to note that the available data do not allow for comparison of the effect of remediation on blood-lead levels on a resident-specific level, only on a community level. This is because where a single property is associated with both blood lead data and RMAP data, the two types of information may or may not be related to each other. This is because blood lead records that were collected in conjunction with RMAP activities were not documented as such. Similarly, individuals who participated in blood lead testing through the Women, Infants, and Children (WIC) program and were encouraged to participate in the RMAP were also not tracked. Additionally, pre- and post-abatement blood lead testing is not tracked as such in the records provided by BSBHD..

The Phase 1 medical monitoring study found that prior to 2003 a greater proportion of sampling events resulted in abatements for both Uptown and the Flats (38% and 43%, respectively) as compared with the later period of 2003 to 2010 (29% and 22%, respectively). As the program initially prioritized properties that had the highest potential for exposures and most sensitive populations, finding a higher rate of abatements prior to 2003 was not unexpected.

Despite a much greater sampling intensity in Uptown than in the Flats prior to 2003 and the increased rate of sampling in the Flats relative to Uptown during the period from 2003 to 2010, there is little difference between Uptown and the Flats in terms of the proportion of abatements to sampling events within each time period. This suggests that while lead exposure potential has been characterized at more properties within Uptown than the Flats, the frequency of results that trigger abatements in both areas is similar; however, the triggers for abatement were different in the Flats as compared with Uptown. An analysis in the Phase 1 study determined that the proportion of paint to yard abatements was higher in the Flats than in Uptown. In the Flats almost all the abatements were for lead paint with very few for soil lead, while in Uptown approximately half the abatements were for soil lead and half for lead paint.

2.2 Community Description

Butte-Silver Bow is a city-county located in southwestern Montana, just west of the Continental Divide, at an elevation of more than 5,500 feet. The estimated 2018 population of Butte-Silver Bow is just under 35,000 in

[2] As described later, the two primary BPSOU areas considered in this study are Uptown and the Flats.

(https://www.census.gov/quickfacts/fact/table/silverbowcountymontana,MT/PST045218, accessed 9/17/19), and Butte is one of only seven Montana cities with a population greater than 10,000. The county covers 518 square miles and in 2010 had a population of 47.6 per square mile compared with an average of 6.8 per square mile in all of Montana. As of 2013 only 6 of the 56 counties in Montana had an urbanization level classification similar to that of Butte-Silver Bow County (i.e., micropolitan or having at least one city with a population greater than 10,000) (Ingram and Franco 2014). Another five Montana counties were classified as small metro areas (i.e., having a metropolitan statistical area with a population of less than 250,000). The remainder were nonmetropolitan, with no city of at least 10,000.

The estimated Butte-Silver Bow population increase from 2010 to July 2018 is 2.3% versus an increase of 7.4% for all of Montana. While the population has been slowly growing in recent decades, it has declined since 1980. Butte-Silver Bow County's population is slightly older than that of the rest of Montana and the U.S., with an estimated 19.1% 65 or older in July 2018 versus 18.7% in all of Montana. The average age in Butte has been increasing ever since 1950, likely contributing to ongoing increases in death rates as the population ages (BSBHD and St. James 2011). Butte-Silver Bow also has a higher percentage of the population living in poverty compared with Montana as a whole (16.3% for Butte-Silver Bow vs. 12.5% for all of Montana according to the census estimate for July 2018).

Insights into Butte-Silver Bow County health status and public concerns about environmental health are available from studies described in the following sections. These studies provide background for assisting with the interpretation of studies specifically focused on the Superfund response, which are addressed in the remaining sections of this document.

2.2.1 Community Health Needs Assessments

Since 2006, the BSBHD has conducted a series of community health needs assessments to help inform local public health policy and priorities. The assessments are intended to serve as tools for determining ways to improve residents' health, reduce health disparities, and increase accessibility to preventive services through prevention programming and collaborative initiatives. These assessments serve as a foundation for community health improvement plans to help direct important public resources to areas of greatest need.

Recently, assessments examining health status, behaviors, and needs of residents have been conducted every 3 years (BSBDH and St. James 2011, PRC 2014, 2017). The two most recent surveys have employed a consistent methodology to collect quantitative and qualitative data via surveys of representative community members. The participants were residents 18 and older from the "Primary Service Area," including ZIP codes 59701, 59702, 59727, 59743, 59748, and 59750 (which include some parts of Jefferson and Beaverhead counties). These areas were chosen by looking at recent patients of St. James Healthcare. The 400 participants' responses were collected by telephone interviews. Professional Research Consultants (PRC) used random-selection of telephone responses to try to accurately represent the population served by St. James Healthcare. Demographics of the respondents were also considered in order to apply weighting variables when the responses were analyzed to assure that the distribution of survey respondents in terms of age and other factors matched the target population. From these responses, PRC (2017) created the following priority list of health issues based on respondents' ratings of the scope and severity of the issue in the community and on the perceived ability of the hospital to positively impact the issue:

1. Substance abuse

2. Mental health
3. Nutrition, physical activity, and weight
4. Injury and violence
5. Tobacco use
6. Cancer
7. Access to healthcare services
8. Potentially disabling conditions

The priority health list from the 2017 study includes mostly the same issues identified in 2014, but it includes only the 8 top issues in comparison to the 11 health issues listed in 2014. The four highest priority issues were the same, although their order varied. In 2014, the additional three priority health issues were diabetes, heart disease and stroke and respiratory disease.

The study area self-reported prevalence (not age-adjusted) for these issues was compared with the prevalence in the rest of Montana and the U.S. Note that these self-reported prevalence rates are not confirmed by medical records. The national prevalence rates presented for comparison were collected by PRC using the same survey methodology. The results for Montana are from the Behavioral Risk Factor Surveillance System Prevalence and Trends Data published online by the Centers for Disease Control and Prevention (CDC). The results for diseases that can be affected by environmental factors (and therefore could be relevant for this Superfund medical monitoring study) are summarized here:

- **Cancer**. Skin cancer prevalence (5.3%) was lower than the prevalence in all of Montana and the U.S. (both 7.7%; only the difference with Montana was significant). The prevalence for other cancers (not including skin cancer) was 7.4%, similar to the rates for Montana and the U.S. (7.9% and 7.7%, respectively). A key study finding relative to cancers was much lower rates of having had a recent mammogram or pap smear in the study area compared with either Montana or the U.S. There was better news about colorectal screening, which while still lower than U.S. rates had climbed to be comparable to Montana rates. In 2014, the rate of colorectal screening in the study area had been much lower (53% in 2014 vs. 63.8% in 2017).
- **Cardiovascular disease**. Although a little higher in the study area, both heart disease and stroke rates were similar to the U.S. rates and had not changed much since 2014. The prevalence of high blood pressure in the study area was similar to U.S. rates and had declined significantly since 2014 (down to 34.6% from 44.7%). Rates of high cholesterol were similar to U.S. rates and significantly lower than in 2014. The rates of having at least one cardiovascular risk factor (including being overweight, smoking, being inactive, having high blood pressure or high cholesterol) were comparable to U.S. rates (83.8% in the study area vs. 83.0% in the U.S.) and had declined significantly since 2014, when they were 89.8%.
- **Respiratory disease**. Asthma rates in the study area (12.2%) were higher than those in Montana (8.9%) or the U.S. (9.5%), but a significant difference was found only as compared with Montana. This represents an increase from 2014 when the rate was 10.9%. The chronic obstructive pulmonary disease rate in the study area (12.9%) was also significantly higher than the Montana rate (5.7%). The U.S. rate of 9.5% was not significantly lower.

- **Diabetes**. The rate of diabetes in the study area (10.3%) was significantly lower than the U.S. rate (14.5%) and not significantly different than the Montana rate (7.9%).
- **Smoking**. Smoking rates are a risk factor for many diseases. The 2017 rate in the study area (12.4%) demonstrated a marked decline from 2014 (20.9%). The 2017 study area rate is significantly less than the Montana rate of 18.9% and is also less (but not significantly) than the U.S. rate of 14.0%. For exposure to environmental tobacco smoke (i.e., having a member of the household who smokes at home), the 2017 study area rate was 9.1%, similar to the U.S. rate of 10.2%. This was a marked decline from the 2014 rate of 16.0%.

Other disease examined in 2017 included Alzheimer's and kidney disease, neither of which had rates that differed significantly from U.S. rates. For each health issue studied, the survey participants were asked to rate the issue as a major problem, a moderate problem, a minor problem or no problem at all. For those reporting an issue as major, the reasons why are summarized in the report. Environmental factors were noted only for cancer and respiratory disease, and most of those comments related to current air quality concerns (i.e., they were not Superfund related).

2.2.2 Environmental Health Perceptions (Nagisetty et al. 2019)

As the current medical monitoring study working group began its initial planning for the 5-year review of the RMAP's effectiveness, the group's members spent considerable time and effort discussing the scope of its mandate. During these discussions, two themes emerged: biomonitoring (essentially, analysis of the BLL data), and broader community health concerns that some members of the group (the CTEC and public participants) felt needed to be accounted for as potentially related to Superfund. The latter theme emerged in the form of repeated citations of community members' adverse health experiences, and their concerns that those health issues were potentially related to environmental exposures.

In partnership with a team of researchers from Montana Tech, the CTEC sought and secured funding from the National Institutes of Health (NIH) to explore the nature and extent of these community concerns. Recipients of USEPA technical assistance grants (TAGs), like the CTEC, are not allowed to use those grant funds to conduct original research, yet the working group's Superfund mandate didn't provide the flexibility to respond to this second theme. Thus, the NIH grant provided a much-needed way to gain information about specific environmental health concerns that had not been addressed by the previous cycles of community health needs assessments sponsored by BSBHD and St. James Healthcare.

The NIH funding authorized a pilot study of the Superfund-related environmental health risk perceptions of a randomized sample of Butte residents between late summer of 2018 and late spring of 2019. The central hypothesis the study sought to test was that a substantial gap exists between the documented achievements of Superfund cleanup and the public's perceptions of how well those achievements protect the community's health and well-being. The outcome objectives are to inform public risk communication needs in Butte and at complex Superfund sites more generally.

The study's preliminary stages comprised a review of 30 years of publicly available Superfund records, including RODs and other decision documents, as well as media accounts of USEPA-public interactions, and this review provided a strong preliminary confirmation of the suspected perception gap.

The survey portion of the research effort provided a combination of quantitative results to validate the existence of the perception gap and qualitatively derived insights into the sources and nature of the gap. Out of 550 surveys mailed to the random sample of Butte residents, 163 were completed and returned, for an overall response rate of 29.6%. A demographic comparison was conducted to assess the demographic representativeness between the 163 mail-in survey respondents and the Butte, Montana population, as determined via census results, as well as the Butte-Silver Bow community health needs assessment survey results.

In testing the representativeness of the surveys returned, one interesting anomaly emerged among the various demographic categories: age. While other categories of respondents (sex, ethnicity, etc.) closely approximated the census data for the community, more than twice as many respondents were older than age 65 than there should have been given the city's population distribution. This feature possibly influenced results in unknown ways.

The survey queried general perceptions of health in the community (e.g., water, soil, air, etc.) and then placed those explicit perceptions in the context of mine waste. The survey asked about the effectiveness of various remedial actions, about residents' knowledge and understanding of those remedial actions, and about the agencies and organizations conducting the remedial actions. The final section of the survey collected demographic information of respondents.

2.2.2.1 Results

Although a disconnect between community perceptions and environmental protections documented by responsible agencies was confirmed by the literature review of previous reports and articles, the survey results showed the scope and magnitude of such a disconnect to be more pronounced than expected. Despite the substantial efforts that USEPA and other responsible entities have invested in informing the community about the Superfund remedial work, the study showed that those efforts have left Butte's residents ill-informed or misinformed in many cases.

Perhaps the first and most pronounced disconnect was the widespread perception that drinking water in Butte is contaminated by mine waste—most frequently, a perception that Butte drinking water may be somehow contaminated by the Berkeley Pit. The obvious disconnect here is that some of the most well-publicized investments made since Superfund remedial work began in the 1980s have been replacements and improvements in Butte's water supply.

An equally pronounced disconnect revealed by the survey was that a majority of responders (62.7%) perceive that cancer incidence rates in Butte are greater than averages for the United States, and this perception contradicts clearly articulated and widely publicized official statistics. The fact that more than a third of respondents (34.8%) perceive that the lead levels in Butte children are greater than published national averages of children's BLLs also contradicts the Phase 1 medical monitoring study results, which concluded that as of the 2009-2010 study period, average BLLs in Butte's children were not higher than expected for a comparable community without the historical mining influence.

The previous example points to another serious disconnect: lack of connection in the environmental health perceptions between remedial activities and the improved health outcomes those activities were designed to achieve. In general, the responders are quite familiar with the majority of the remedial construction activities that have taken place or are currently underway. Perceptions were positive for USEPA efforts to protect human health, including the RMAP and inclusion of community input in shaping decisions and actions. Yet, although responders have positive perceptions about completed and ongoing remedial activities, perceptions for associated health outcomes are negative. For example, periodic health studies conclude that the RMAP has been very effective in reducing children's BLLs, but responders, while indicating positive perceptions of the RMAP, perceive that Butte children suffer from a higher BLL burden than children elsewhere in the state and nation.

The contrast in overall versus mine waste-specific environmental health perceptions was clearly evident among the responders. Perceptions were more negative for all mine-waste-specific questions than the corresponding overall health-quality questions. Superfund's presence in Butte since the 1980s may itself be a declaration of the health hazards of mining waste, so this response might not be very surprising, and perhaps similar disconnects should be expected in all Superfund communities. However, the strong association between overall and Superfund-specific environmental health perceptions suggests that if Superfund-specific perceptions can be improved through better engagement and communication of objective environmental health benefits, then perhaps the overall environmental health perceptions of the community may improve as well. This potential disconnect warrants further investigation.

The survey's findings about where people get information about Superfund-related remediation and health issues should give pause to those planning community involvement efforts. The least-used source of information was USEPA public meetings— and this source is typically the one most relied upon by the agency. USEPA reports (including everything from decision documents to fact sheets) receive considerably more attention from responders, but are not the medium through which the majority are receiving their information. The three most widely cited sources of information revealed in the survey were, in order, local news media (93.8%), family and friends (44.1%), and social media (25.7%).

2.2.2.2 Implications for Health Risk Communication

Extrapolating what this study suggests for other Superfund sites was one of the secondary objectives of the original research plan. Several recommendations stand out:

- Community environmental health perceptions need to be integrated as a separate research project during initial remedial design activities for a site.
- Effective communication processes need to be put in place to anticipate the potential for the growth of a perception disconnect in the local community.
- Demographics at every site will differ to some degree, and communication channels favored by different sectors of the affected population at a given site need to be selected and deployed on a regular basis. Informational pieces directly authored by local Superfund staff have been rare, leaving most content to either community Op-Ed commenters or staff at the particular media outlet. Regularly scheduled reports written for the public and submitted to such media outlets, as well as regular interview situations with radio, TV, and social media, will help ensure that a full cross-section of residents are engaged.
- Wherever remedial activities aim to reduce health risks faced by local residents, reports and presentations about those activities need to emphasize how remedial actions are designed to improve health outcomes. Technical complexities in such reports and presentations need to be subordinated to ensure that the main purpose of the work—health protection—is recognized and understood by everyone.

The NIH-funded pilot study confirmed the existence of the health risk perception gap between BPSOU residents and the regulatory agencies, and it provided insights into some of its characteristics. Future work is needed to understand more clearly the extent to which the gap is primarily the result of residents' misunderstanding, or lack of engagement with Superfund issues, or, on the other hand, the extent to which the gap results from responsible officials not paying sufficient attention to residents' experiences and perceptions of adverse health impacts. The RMAP offers the ideal structural venue to address this sort of future work.

3. REVIEW OF RISK ASSESSMENTS AND ACTION LEVELS

USEPA policy is to use risk assessments to predict potential risks for people expected to be most highly exposed and most susceptible to adverse health effects. Risk assessments are preferred over other assessment options like epidemiology studies because it can predict potential adverse health effects before they occur, and a risk assessment can be performed in communities where population size, available health data, and many other complicating factors can limit the power of epidemiology studies to detect adverse effects. USEPA then sets cleanup goals, termed action levels, for contaminated media such as soil that are expected to protect sensitive members of the population. For the BPSOU, USEPA completed risk assessments for multiple chemicals in soil and dust and determined that the primary chemicals of concern were lead, arsenic and mercury.

In this section the methods for assessing health risks and deriving action levels are described. The approaches used for identifying chemicals of interest in the risk assessments and for considering mixtures of chemicals are also described. Summaries of the health risk assessments and action levels for the BPSOU are provided, followed by summaries of the reevaluation of the action levels in the 5-year reviews.

3.1 Health Risk Assessment Methods

An HHRA is a quantitative evaluation of the risk posed to human health by the actual or potential presence or release of chemicals in the environment. Thus, a risk assessment predicts the likelihood of health effects in a population but does not directly measure the occurrence of health effects. Therefore, a risk assessment is very different from an epidemiology study, which reports the incidence of specific health effects, or a biomonitoring study, which reports the concentrations of chemicals in people’s bodies.

The HHRA process as defined by USEPA (1989) contains four major steps. The first step is to characterize the site and the chemicals associated with the site. This step encompasses many activities, including a review of sources that release chemicals to the environment, the identification of the chemicals released, an evaluation of the available data, and an assessment of how people in the community might contact the chemicals. The result of this step is the creation of an exposure pathway model that describes how and where people might come into contact with the chemicals associated with the site.

The second step is to evaluate the potential exposure of people to the chemicals being evaluated. This portion of the risk assessment process, which is referred to as the exposure assessment, examines in detail how people may come into contact with the chemicals. As part of this step, potential doses or intakes of chemicals from air, dust, soil, water, or other media are quantified.

The third step is the toxicological evaluation. The toxicological evaluation, which is referred to as the toxicity assessment, looks at the potential toxicity of the chemicals being evaluated and identifies doses that may cause toxicity and doses that are not expected to cause health effects. Toxicity values are developed to be protective of both cancer and noncancer effects.

The fourth step is the risk characterization. The risk characterization combines the results of the exposure assessment and the toxicity assessment to describe potential risks to human health associated with exposures to site-related chemicals. The doses of chemicals to which people may be exposed are compared with the toxicity values to determine the adverse risk of health effects. This step provides results that can be used to help decide if actions need to be taken to reduce chemical exposures at the site.

Baseline HHRAs have two primary goals. The first goal is to evaluate current and potential future human health risks from the site and to characterize the ways in which people are exposed to site-related chemicals. The second goal is to support the development of risk-based action levels.

3.1.1 Exposure Pathways

An exposure pathway describes the way in which a person may come into contact with a source material. For example, at mining sites, source materials often include waste rock and tailings deposits. An exposure pathway that connects these source materials to people is called a "complete exposure pathway." An exposure pathway that does not connect these source materials to people is referred to as an "incomplete pathway." Exposures to people occur only if there is a complete exposure pathway. With a complete exposure pathway, the potential for health effects needs to be evaluated, but if the pathway is incomplete, there is no exposure and no risk.

An exposure pathway that is not complete does not pose a health risk

To be a complete exposure pathway, five exposure pathway elements must be present as described further below.

- **Source Material** – This is the original material (e.g., mine waste or tailings) that contains chemicals of potential concern and can be released to the environment.
- **Exposure Medium** – An exposure medium is an environmental component such as soil, house dust, water, or air where contaminants from the source have moved.
- **Exposure Point** – A location where people may come in contact with exposure media is referred to as the "exposure point." Risk assessors are usually most interested in the concentration of a chemical at the exposure point (the "exposure point concentration"), which may be different than the concentration in the source material.
- **Exposure Route** – Exposure route describes how a person can get materials from the exposure medium into his or her body (e.g., eating, drinking, breathing, or absorbing through the skin). The significance of exposure to a chemical usually differs depending on whether a person ingests, breathes, or just touches that medium. For example, skin contact with metals in soil is usually less worrisome than ingesting them.
- **People** – This is the population of individuals who may be exposed if all the other exposure pathway elements are present. When exposure pathways are discussed, people are sometimes referred to as the "receptor population," and the focus of analysis is on people who may be more susceptible or vulnerable to a given exposure.

If any one of these five exposure elements is missing, the exposure pathway is not complete. Health effects are possible only if an exposure pathway is complete. Therefore, exposure studies and risk assessments focus on complete exposure pathways because if the pathway is incomplete, there is no exposure and no risk.

3.1.2 Metals Included in Risk Assessments

Typically, a limited number of contaminants pose the primary health risk at a site, while other chemicals detected at a site may not pose significant health risks or may not contribute significantly to the overall site risk (USEPA 1989). In these cases, the procedures to evaluate frequency of detection, essential nutrient information, and a concentration-toxicity screen may be used to reduce further the number of chemicals of potential concern in each medium evaluated as part of the risk assessment. The USEPA guidelines (1989) therefore recommend focusing on a group of contaminants of concern (COCs) based on inherent toxicity, site concentration, and behavior of the contaminants in the environment. The following sections provide an overview of key risk assessment issues for lead, arsenic, and mercury, the primary BPSOU COCs for soil.

The Third Five-Year Review Report for Silver Bow Creek/Butte Area Superfund Site (USEPA 2010) indicated the following regarding the initial screening of metals:

> When the initial screening study for BPSOU soils was conducted in 1987, 23 metals and arsenic were analyzed in soil samples. These metals and arsenic were further evaluated in the site risk assessments. Based on the information obtained in the contaminant screening and risk assessments, concerning risk pathways and soil contamination relationships, EPA developed the list of COCs for the site. EPA risk assessors reviewed these actions as part of the five-year review process, and determined that the screening and risk assessments, as well as the current action levels remained valid and are protective of human health and the environment.

As described in Section 2.2, COCs for the BPSOU HHRAs were refined in a preliminary baseline risk assessment in 1991. At that time, soil arsenic, cadmium, lead, and mercury were considered. Cadmium was not found to be present at concentrations sufficient to warrant further quantification of risks, while arsenic, lead, and mercury were further evaluated. Additional metals have been identified as COCs in other Butte operable units for groundwater and surface water. Table 1 summarizes the COCs identified for each exposure medium. The Fourth Five-Year Review Report for Silver Bow Creek/Butte Area Superfund Site (USEPA 2016a) considered and reconfirmed the COCs in different Butte exposure media.

Table 1. COCs by Exposure Medium

COC	Solid Media	Groundwater	Surface Water
Aluminum			X
Arsenic	X	X	X
Cadmium		X	X
Copper		X	X
Iron			X
Lead	X	X	X
Mercury	X	X	X
Silver			X
Zinc		X	X

Notes:
For humans, primary exposure pathways at the site include the following:
- Ingestion of surface soils (for residents, commercial workers, and railroad workers)
- Ingestion of interior dust (for residents and commercial workers)
- Dermal exposure to surface water (for recreational visitors)
- Ingestion of surface water (for recreational visitors)
- Ingestion of alluvial groundwater was calculated, although there are currently no exposures.

3.1.2.1 Lead Toxicity and Risk Assessment

In this section an overview is provided of lead toxicity, risk assessment methods for lead, and the bioavailability and mineralogical forms of lead present in Butte soils.

Lead Toxicity. Lead exposures result in a wide range of adverse effects, including effects on the nervous system, cardiovascular system, immune function, heme synthesis and red blood cell function, and reproductive and developmental function. Tens of thousands of studies of lead toxicity have been reported. This literature has been evaluated in recent regulatory reviews (NTP 2012, USEPA 2013, NHMRC 2015, ATSDR 2019c). The scientific understanding of lead toxicity is based on toxicity studies in animals and human epidemiology studies or clinical poisoning reports. Many toxicity and epidemiology studies have limitations with regard to the strength of associations between a chemical and observed adverse health effects, as well as in the precision and reliability of their ability to predict doses of a chemical that may cause health effects. Consequently, when public health or regulatory authorities conduct dose-response assessments to predict the dose of a chemical that may cause adverse health effects or a discernible risk of adverse health effects, a weight-of-evidence analysis is typically undertaken. This analysis considers all available studies for a chemical and evaluates the quality of the studies and the reproducibility of their findings before drawing conclusions about the effects associated with the chemical and the doses at which those effects may occur.

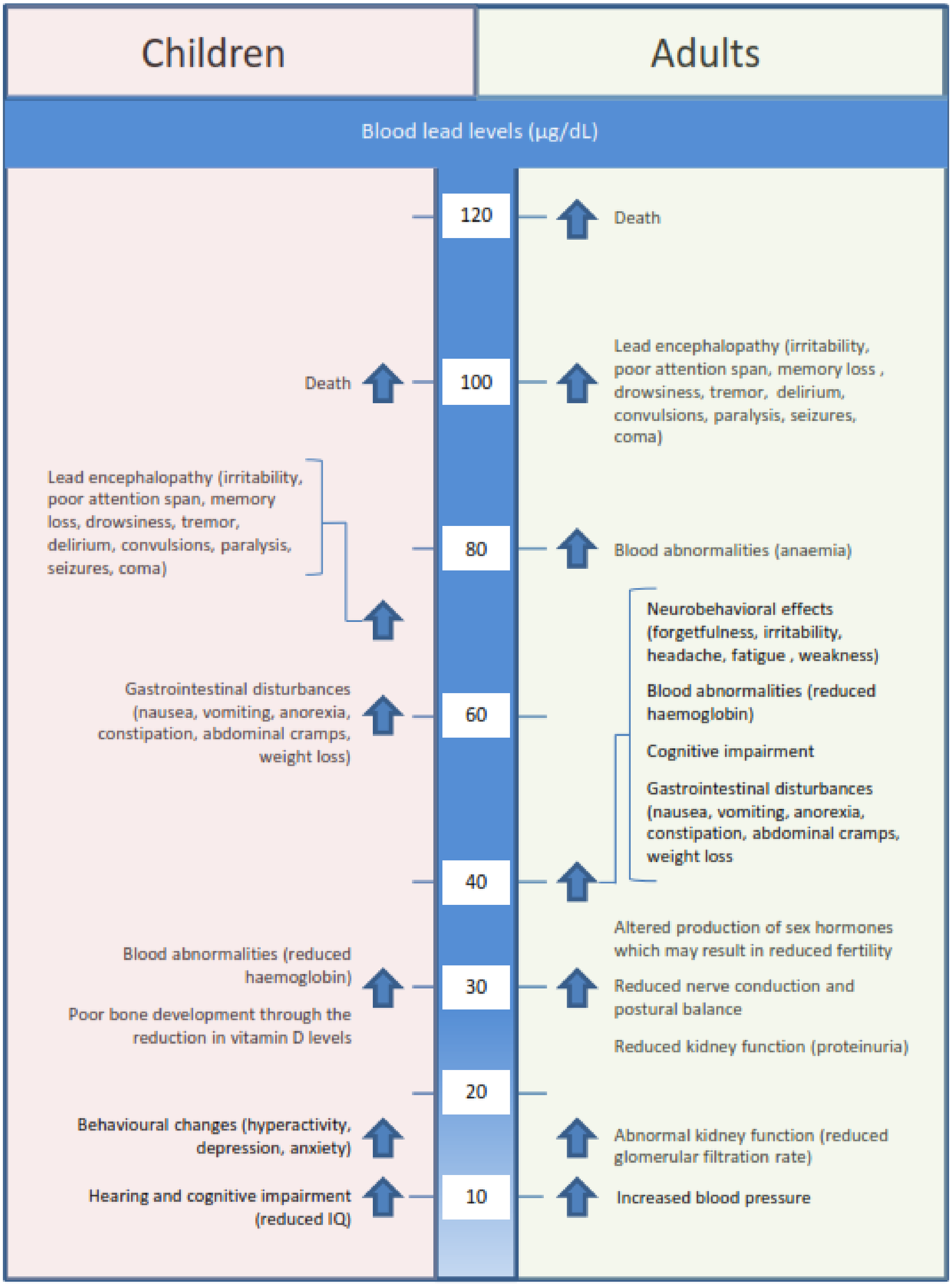
As shown in Figure 3, diverse adverse effects have been associated with lead exposures with BLLs of 10 µg/dL or higher, and a more limited set of adverse effects is associated with BLLs in the range of 5 to 10 micrograms per deciliter (µg/dL). A "no-effect" level has not been established for lead exposures (ACCLPP 2012, CDC 2012, NTP 2012, USEPA 2013).

Young children are the population of greatest concern because they are expected to have higher lead absorption rates and higher exposure per unit body weight than adults. Children are also more susceptible to the effects of lead (USEPA 2006a, NTP 2012). In the adult population, women of child-bearing age are of greatest concern, given the potential for adverse effects on the fetus resulting from elevated maternal BLLs.

Most of our understanding of the adverse effects occurring at low lead exposure levels is based on epidemiology studies. ATSDR (2007c) defines epidemiology as "the investigation of factors that determine the frequency and distribution of disease or other health-related conditions within a defined human population during a specified period." In other words, these are not controlled exposure studies in which a known amount of lead is administered to individuals and individual clinical outcomes are monitored. That leaves researchers reliant on studies in which people have experienced inadvertent exposure from existing lead sources. Such population-based studies present significant complexities in interpreting the connection between observed BLLs and adverse effects, because of a multitude of factors that contribute to variation in BLLs (NHMRC 2015, Wilson and Wilson 2016).

Further complicating interpretation of the studies, none of the effects ascribed to low level lead exposure are uniquely associated with lead. Other factors may cause the same effects, and there is wide variation among individuals in sensitivity to the lead and other factors. Furthermore, as described above, at low levels of lead exposure the association of BLLs with lead exposure sources covaries with many factors that may obscure the dose-response relationship for lead. For example, BLLs covary with age, gender, race, socioeconomic levels, mother's IQ and education, and season.

Figure 3. Health Effects of BLLs 10 µg/dL and Higher (From: NHMRC 2015)



Lead Risk Assessment. Assessment of lead exposure and risk is assessed based on BLLs. USEPA has used a target BLL (10 µg/dL) for evaluating risk management decisions. This target was based on the CDC's prior recommendation of 10 µg/dL as a blood lead "level of concern" when based on a confirmed venous blood draw. Based on the CDC level of concern, USEPA specified a risk management goal that the probability of any exposed child or pregnant female having a BLL above 10 µg/dL should not be greater than 5%. In accord with this approach, HHRA health risks from lead have been judged to be acceptable if the probability of a blood lead value exceeding the target BLL (10 µg/dL) did not exceed 5% based on toxicokinetic models used to predict a distribution of BLLs in an exposed population. The integrated exposure uptake biokinetic (IEUBK) model, is used to evaluate lead exposures for children and the adult lead model is used to evaluate lead exposures for adults. These probability estimates are based on all sources of the potentially exposed population's lead exposure, including both site-related exposures and baseline (non-site-related) exposures.

In 2012, CDC withdrew the blood lead "level of concern" concept for lead and derived a population reference level of 5 µg/dL, stating that "this new level is based on the US population of children ages 1-5 years who are in the highest 2.5 percent of children when tested for lead in their blood." Conceptually, the 2012 CDC reference level is not the same as the target BLL on which USEPA bases evaluation of lead risks, and USEPA has not yet determined if or how the 2012 CDC reference level may be used in risk management for lead sites in the future.

USEPA is reviewing its approach to addressing lead-contaminated soil at Superfund sites in light of more recent scientific information (USEPA 2016a), including the CDC's 2012 recommendation that children with BLLs above 5 µg/dL be referred to a health professional for medical monitoring. The CDC recommendation pertains to a child's exposure to all lead sources (e.g., paint, consumer products, soil, etc.) and serves as a national goal. USEPA is focused on limiting site-related lead exposure. Superfund remediation of the most highly lead-contaminated soil, combined with activities to address other lead sources, has proven to be an effective part of an overall strategy for reducing BLLs in children.

Butte Soil Lead Bioavailability. When lead is ingested from a solid exposure medium, such as soil, only a fraction of the lead ingested is absorbed into the blood stream. Bioavailability is a term that refers to the fraction of a chemical that is biologically available and absorbed by the body. Bioavailability is usually presented as a percentage and can be expressed either on an absolute basis (absolute bioavailability [ABA]) or a relative basis (relative bioavailability [RBA]) (USEPA 2007). RBA is determined as the ratio of the bioavailability of a chemical in one exposure context to that in another exposure context (e.g., the ratio of the bioavailability of lead in soil to the bioavailability of lead in water).

The bioavailability of lead in Butte soil and mine waste has been characterized in three kinds of studies. Studies of multiple Butte soil samples tested in rats, swine, and in vitro models all support USEPA's assumptions that Butte soil lead has very limited bioavailability compared with that of most other sites. The results discussed below are to be compared with the IEUBK model default assumption that the ABA of soil lead is 30%, while the ABA of lead in water and diet is assumed to be 50%. Based on these assumptions, the default soil lead RBA is 60% (i.e., comparing soil lead ABA with ABA of lead in water or diet).[3]

[3] RBA soil (60%) = ABAsoil (30%) / ABAwater,diet (50%)

The first Butte soil lead bioavailability study was a rat study (Freeman et al. 1992). In this study, young rats were given meal-form rat chow containing 0.2%, 0.5%, 2%, or 5% test soil with lead concentrations of either 810 or 3,908 parts per million (ppm) lead. The soils were described as "mine waste soils that were composites of soils collected from residential areas in Butte, Montana during November 1989." A control group was given feed mixed with lead acetate. Results were similar for both test soils. The reported mean soil lead RBA from this study was 20% based on blood data, 9% based on bone data, and 8% based on liver data. USEPA (1993) relied on this study and a subsequent study that included an intravenous test group (Freeman et al. 1994) as the basis for the 12% soil lead ABA assumption used in the IEUBK model for the 1994 HHRA and to develop the 1,200-ppm residential soil lead action level.

Subsequently, USEPA evaluated the bioavailability of Butte soil lead in a study in juvenile swine (Casteel et al. 1998). The test soil with 8,530 ppm of lead was described as a soil composite collected from waste rock dumps in the BPSOU. This study yielded RBA estimates of 19% for blood, 10% for bone, 13% for liver, and 15% for kidney, with a combined estimate of 14% (Casteel et al. 2006). The RBA estimates for blood and bone are very similar to estimates from the earlier rat study. As shown in footnote 3 above, the ABA of lead is about half the RBA for soil, so the RBA estimate of 14% indicates that Butte soil lead ABA is 7%. USEPA relied on this study as the basis for the soil lead ABA estimate in the Walkerville HHRA, but it increased the estimate from 7% to 10%.

Concurrent with the rat studies during the early 1990s, an in vitro method was developed to estimate the RBA of lead in soil and mine waste materials (referred to as in vitro bioaccessibility or IVBA). The first study examined four samples collected from mine waste/waste rock sites, which yielded lead bioaccessibility estimates of less than 6% (Ruby et al. 1993). During the IVBA method validation program, two of these mine waste samples, i.e., two of the Butte composite samples used in the rat study, and a Butte soil sample used in the swine study, were tested using a refined in vitro method. The resulting lead IVBA estimates for these three samples were 22.5%, 9.3%, and 19%, respectively (Ruby et al. 1999). A USEPA team conducted additional method refinements (Drexler and Brattin 2007), and in 2007 USEPA issued guidance on approved methods for assessing soil lead bioavailability using either the swine model or the in vitro method. The USEPA technical support document (USEPA 2007) for this guidance includes additional in vitro results for the Butte soil sample previously tested in swine, with an average IVBA of 22.3%, which is a lead RBA of about 16% (or a lead ABA of about 8%).

Taken together, these studies provide strong and consistent evidence that, regardless of lead concentration, Butte soil lead ABA is about 10% or less (i.e., less than one-third the typical value, as represented by the IEUBK default value of 30%). In contrast, in vitro data for soils collected from the Anaconda Smelter Superfund Site suggest that lead bioavailability is not reduced compared with the default assumption, and was somewhat higher (i.e., 34.5% for Anaconda vs. 30% default, Integral 2009), accounting for the lower lead action level in Anaconda.

The bioavailability of lead in Butte indoor dust is also expected to be lower than the IEUBK default value; however, because no site-specific bioavailability data for dust were available the default value was used by USEPA in the HHRA. Similarly, USEPA assumed the default value in assessing attic dust.

Butte Soil Lead Mineralogy. Multiple evaluations of soil lead mineralogy have included detailed characterization of the chemical forms of lead present in Butte soils (Davis et al. 1991, 1992, 1993, Ruby et al. 1993, Casteel 1998, USEPA 2007). Most of these analyses were conducted by Dr. John Drexler at the University of Colorado, using an electron microprobe. The Butte ore is primarily galena (lead sulfide), which has low water solubility and is poorly absorbed. Over time, ore in waste dumps and mixed with soil has weathered to form anglesite (lead sulfate) and other lead minerals that have low to moderate solubility.

Mineralogical analysis was conducted for the two soil samples used in the rat study (Freeman et al. 1992). For the lower-concentration soil (810 mg/kg lead), the predominant phases were manganese lead oxides, anglesite, and lead phosphates. Galena and iron-lead oxides were also present. The predominant phases in the higher-concentration soil (3,908 mg/kg lead) were anglesite and galena, with lead phosphates and iron-lead oxides also present. For the swine study, mineralogical analyses of the test soil showed the primary lead forms present (in decreasing order of prevalence) included anglesite, iron-lead sulfate, manganese lead oxide, galena, and lead phosphate (Casteel et al. 1998, 2006).

Lead bioavailability in Butte soils is further limited by the encapsulation of lead-bearing grains within larger particles (Davis et al. 1991, 1992, 1993, Ruby et al. 1993). Ruby et al. (1993) report on mineralogy of a large number of Butte samples with a wide range of lead concentrations, including 5 mine waste samples, 26 play area soils, 2 garden soils, and 9 soils collected around house perimeters. While there was substantial variation in the mineralogy across samples, the predominant lead phases in most of the soil samples were lead phosphate, manganese lead oxides, and iron-lead sulfates. The predominance of phases with limited solubility in these samples supports the use of the bioavailability study results from a smaller number of samples.

3.1.2.2 Arsenic Toxicity and Risk Assessment

For chemicals other than lead, toxicity values for carcinogenic (cancer) and noncarcinogenic (non-cancer) health effects have been developed for many chemicals by government agencies, including USEPA, ATSDR, and some state agencies. These toxicity values are numerical expressions of chemical dose and response, and they vary based on factors such as route of exposure (e.g., oral, inhalation, or dermal) and duration of exposure (e.g., acute, chronic). In HHRAs, estimated exposure doses are compared with the toxicity values to determine risks. Risks are quantified separately for carcinogenic (cancer) and noncarcinogenic (non-cancer) effects.

Arsenic exists in multiple oxidation states and in a number of inorganic and organic forms. The inorganic forms are the most toxic. Inorganic forms of arsenic include trivalent arsenic (As[III]), also called arsenite (the form found in arsenic trioxide), and pentavalent arsenic (As[V]), also called arsenate. Organic forms of arsenic include trivalent monomethylarsinous acid (MMA[III]), pentavalent monomethylarsinic acid (MMA[V]), dimethylarsinous acid (DMA[III]), and dimethylarsinic acid (DMA[V]). Arsenocholine, arsenobetaine, and arseno-sugars are organic forms commonly found in seafood.

The scientific literature on arsenic toxicity is voluminous and constantly expanding. A summary of arsenic toxicity is provided in the ATSDR ToxGuide (ATSDR 2007a). In 2016, the ATSDR issued an addendum to its 2007 arsenic toxicological profile that provides updates on studies of arsenic in humans and on information that advances the understanding of arsenic-induced toxicity (ATSDR 2016). Arsenic is classified by USEPA as a human carcinogen. Skin and internal organ cancer rates have been higher in populations exposed to high levels of arsenic in drinking water.

Cancer risks are described by using the slope of the dose-response curve at low doses, known as the slope factor. The units of the slope factor are dimensions of risk of cancer per unit dose. The oral slope factor for arsenic is 1.5 risk per milligrams per kilogram per day $(mg/kg\text{-}day)^{-1}$ (USEPA 1998). USEPA (1998) has determined that sufficient data exist to show that lung cancer mortality has been increased with arsenic inhalation. The inhalation unit risk factor (IUR) for arsenic is 0.0043 risk per microgram per cubic meter $(\mu g/m^3)^{-1}$, based on lung cancer in humans who have had occupational exposure.

Arsenic exposures can also cause noncancer effects. Early epidemiology studies identified skin as the most sensitive noncancer endpoint of long-term oral arsenic exposure. Hyperkeratinization[4] of the skin, formation of multiple hyperkeratinized corns or warts, and hyperpigmentation of the skin with interspersed spots of hypopigmentation are the most common types of lesions associated with oral arsenic exposure. The majority of studies demonstrate that these effects manifest at levels of approximately 0.002 to 0.2 mg/kg-day (ATSDR 2007b). The noncancer oral reference dose (RfD) for arsenic is 0.0003 mg/kg-day (USEPA 1998).

The USEPA arsenic toxicity values have not changed since the last update to the Integrated Risk Information System (referred to as IRIS) in 1998. USEPA is in the process of conducting an updated toxicity assessment for arsenic, but revised toxicity values are not anticipated to be released in the near future.

Recent research has demonstrated the plausibility of a nonlinear dose-response relationship for ingested arsenic that supports a threshold for arsenic carcinogenicity (Cohen et al. 2013, Gentry et al. 2014a, 2014b, Tsuji et al. 2019). These studies provide evidence for a mode of action involving cytotoxicity and regeneration based on human, animal, and mechanistic studies. Tsuji et al. (2019) conclude the likely threshold for arsenic in drinking water is 100 micrograms per liter (µg/L), well above the current drinking water standard. This threshold is high enough that most exposures to arsenic in diet, soil, and other environmental media should pose no carcinogenic risk when drinking water concentrations are not elevated (Schoof 2019).

Since common mechanisms are expected for inhaled and ingested arsenic, a threshold is also expected for inhaled arsenic (Lewis et al. 2015). There is also updated epidemiology data for smelter workers (including the Anaconda cohort) that has been used by the Texas Commission on Environmental Quality (TCEQ) to update the dose-response assessment for inhaled arsenic (Erraguntla et al. 2012). TCEQ used data from the Tacoma, Anaconda, and Ronnskar cohorts to derive an updated inhalation IUR of 1.5E-04 per $\mu g/m^3$.

Exposure to high arsenic concentrations in drinking water has also been associated with many other adverse health effects. ATSDR (2016) provides an updated review of the literature and identifies additional outcomes related to increased drinking water arsenic exposure. These include cardiovascular effects, such as arrhythmia, increased blood pressure, and atherosclerosis; effects on the endocrine system, such as diabetes mellitus; impairment of neurological function in adults; disturbances in immune responses; ocular effects; pulmonary disease; and developmental effects. USEPA is expected to consider all of these endpoints in determining critical endpoints for the updated dose-response analysis that is currently being developed.

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[4] Hyperkeratinization is a disorder of cells lining hair follicles. Cells generally sough off from the lining over time. However, in hyperkeratinization, the dead skin cells do not leave the follicle due to an excess of keratin, which is the type of protein that makes up hair, skin, and nails.

Soil Arsenic Forms and Bioavailability. The predominant forms of inorganic arsenic in soil are arsenite and arsenate compounds. The solubility of inorganic arsenic compounds in water varies widely. Sodium arsenate and arsenic trioxide are highly water soluble; less soluble forms include sulfide minerals, complex oxides, and arsenic present in iron, manganese, and phosphate mineral species. Ionic forms of inorganic arsenic may adsorb to soil constituents. The presence of less soluble mineral phases and ionic forms that are strongly adsorbed to soil particles or coprecipitated with other elements in soil is thought to contribute to the reduced bioavailability of arsenic in soil.

When present in a water-soluble form, inorganic arsenic is well absorbed through the oral route; studies in humans demonstrate that greater than 95% of arsenic in this form may be absorbed (ATSDR 2007b). Oral bioavailability of inorganic arsenic is reduced when the chemical is ingested as soil or dust because of the decreased solubility of the media and the presence of secondary reaction products. Organic arsenic is also less bioavailable than inorganic arsenic (ATSDR 2016). Less soluble forms of arsenic are reported to be one-half to one-tenth as bioavailable as the more soluble forms of arsenic (Roberts et al. 2007). Bioaccessibility, or the solubility of arsenic in the gastrointestinal tract, accounts for the variations in bioavailability measured in soils and other less soluble media. Physical and chemical factors of arsenic-bearing particles, such as morphology, arsenic mineralogy, and whether arsenic is on the surface or deeply embedded in the particle, affect the ability of the gastrointestinal tract to dissolve arsenic and ultimately its bioavailability (ATSDR 2016). Dermal absorption of arsenic is low compared with absorption from other routes of exposure (ATSDR 2007b), and dermal absorption from soil is negligible (ATSDR 2016, Lowney et al. 2007).

USEPA (2012) reviews studies of the relative bioavailability of soil arsenic and provides guidance for applying a default relative bioavailability adjustment (RBA) of 60% to adjust exposure assessments to correct for reduced bioavailability of arsenic in soil. USEPA (2012) also states a preference for use of site-specific data such as is available for Anaconda and Butte. Freeman et al. (1995) measured arsenic bioavailability in soil and dust from Anaconda using cynomolgus monkeys. Arsenic present in Anaconda residential soils and dust exhibited relatively low absorption into the body compared with water-soluble arsenic. Based on this study, in the HHRA for Anaconda (CDM 1996), USEPA used arsenic relative bioavailability estimates of 18.3% for soil and 25.8% for dust to derive soil arsenic action levels for Anaconda. Because soil arsenic in Anaconda is mostly from oxidized fine particulate emitted from the stack, the RBA for arsenic in Anaconda soil is expected to be higher than the RBA for arsenic in Butte soil which is impacted mostly by mining wastes that contain less soluble arsenic than arsenic in smelter emissions. Thus, these arsenic RBA values for soil and dust were also used in the HHRA for Butte (CDM 1997).

3.1.2.3 Mercury Toxicity and Risk Assessment

Mercury usually is present in soils as inorganic mercury, either as elemental mercury (Hg^0) or as one of two nonelemental ionic forms: mercurous (Hg^{+1}) or mercuric (Hg^{+2}) (ATSDR 1999). Elemental mercury has been sporadically encountered in Walkerville soil, while inorganic mercury has not generally been present at concentrations high enough to pose health risks.

For elemental mercury, inhalation is the primary exposure pathway because ingested elemental mercury is very poorly absorbed. The inhalation reference concentration for elemental mercury is 0.3 µg/m^3 (USEPA 1995b). The reference concentration is based on occupational studies in which workers developed hand tremor, increases in memory disturbance, and slight subjective and objective evidence of autonomic dysfunction. USEPA has not derived an oral RfD for elemental mercury because of its lack or oral absorption.

USEPA assesses inorganic mercury based on toxicity studies of mercuric chloride, a highly water soluble form of mercury not typically present in soil. The oral RfD for mercuric chloride is 0.0003 mg/kg-day based on autoimmune effects observed in feeding studies of rats (USEPA 1995a). The less soluble inorganic mercury forms found in soil are much less well absorbed and exhibit negligible toxicity.

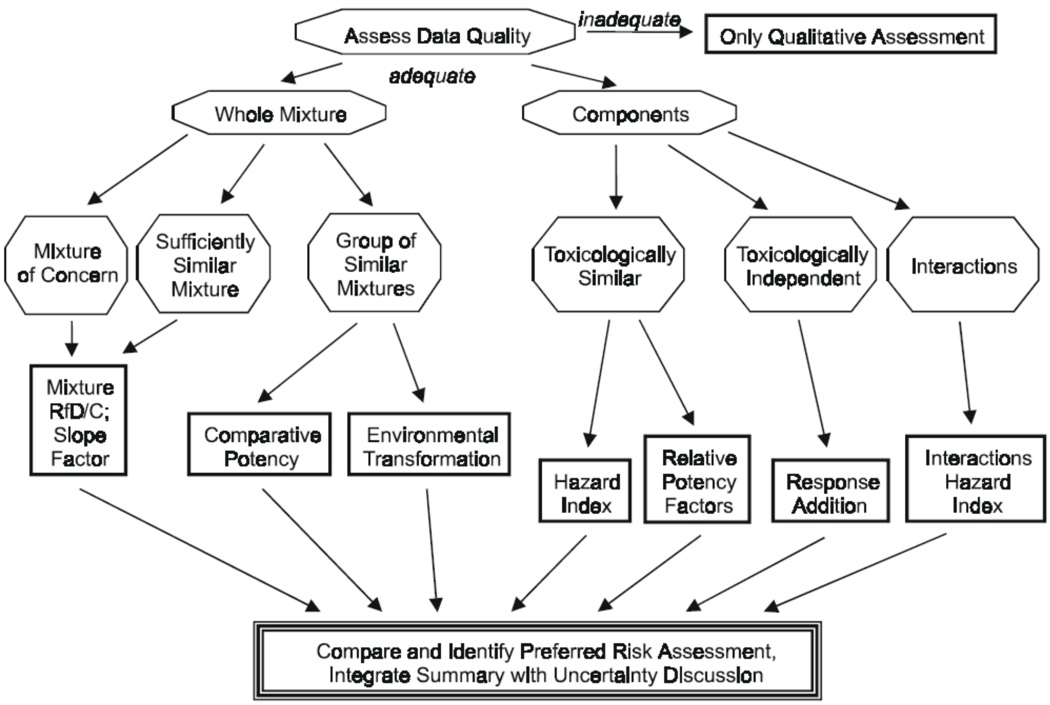
Soil mercury at mining sites is most often in the form of cinnabar, which is mercuric sulfide, or other forms that are much less water soluble than mercuric chloride. Although no regulatory or published oral toxicity values are available for mercuric sulfide, numerous studies in rodents document its limited oral absorption, which is estimated to be 1% to 4% that of mercuric chloride (Yeoh et al. 1986, Liu et al. 2008, Lu et al. 2010, 2011a, 2011b, Shi et al. 2011). Multiple in vitro studies have also demonstrated low RBA (the mean from 2% to 5% and maximum at 11%) for inorganic mercury in aged soils (Safruk et al. 2015, Rodrigues et al. 2014, Welfringer and Zagury 2009). Because of the limited occurrence of mercury in Butte soil, no site-specific soil bioavailability studies have been conducted and the Walkerville HHRA assumed an RBA of 100%, which is likely to overestimate potential exposures from mercury in soil (USEPA 2003).

3.1.3 Consideration of Mixtures

Mixture risk assessment has been part of the Superfund risk assessment process since the enactment of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) in 1980. Specific guidance for considering mixtures is included in the Risk Assessment Guidance for Superfund (RAGS) issued by USEPA in 1989. This guidance includes a default approach stipulating application of dose addition or independent action, where appropriate. For the first time, this guidance implemented component-based approaches for assessing the effects of multiple chemicals. It made a distinction between carcinogens and noncarcinogens. For carcinogenic substances, component risks are added, following the principles of independent action. For noncancer endpoints, RAGs also pioneered the quantitative evaluation of exposures via multiple pathways by using the hazard quotient (HQ) concept. When exposures include multiple chemicals, the doses of mixture components are scaled and added, in an application of the dose addition concept, termed the hazard index (HI).

A key question about mixtures is whether the effects of multiple chemicals will be additive, or whether some chemicals could interact in a way that causes greater than additive effects (termed "synergistic effects") or causes less than additive effects (termed "antagonistic effects"). The USEPA (2000) Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures outlines an approach examines this issue in risk assessment of chemical mixtures, following the steps from a traditional HHRA. This guidance describes several approaches that can be used depending on the available data, type of mixture, type of assessment, known toxic effects, and nature of exposure. The approaches to take are dependent on the available data (Figure 4).

Figure 4. Assessment Approaches for Mixture Assessments (USEPA 2000)



A key consideration is whether toxicity data are available for the whole mixture or for only component chemicals in the mixture. There are a few mixtures that have sufficient toxicity data to determine the dose-response for the whole mixture. Examples include the polychlorinated biphenyl mixtures called Aroclors, and mixtures of petroleum hydrocarbons. In most cases, such whole mixture data will not be available, and the assessment must proceed following the component approach. Dose- or response-additive models are recommended for this approach, as many studies have shown that dose addition of components can reasonably predict the toxicity of mixtures (USEPA 2000).

If the components are toxicologically similar, a relative potency factor method may be used. An example of this approach is the addition of relative potency factors derived for specific polycyclic aromatic hydrocarbons and for polychlorinated biphenyl congeners to derive toxic equivalent concentrations for use in risk characterization.

If the components are assumed to be toxicologically independent (i.e., the components in the mixture are assumed to have no influence on the toxicity of each other), the response addition method is used. Response addition is when the responses of the different chemicals that cause a different type of toxicity are combined.

In 2004, ATSDR issued a series of reports assessing the potential for interactions among mixtures of chemicals, including one evaluating various combinations of arsenic, cadmium, chromium, and lead (ATSDR 2004). These reports provided reviews of studies that had examined mixtures of the selected metals, as well as mechanistic and toxicokinetic information to make predictions about the potential for interactions to occur, both synergistic and antagonistic. ATSDR (2004) studied both binary and trinary mixtures of the metals and found that binary studies were sufficient for predictions of additivity. ATSDR (2004) assessed the data on interactions in a systematic approach to assign a binary weight-of-evidence (BINWOE) score. The BINWOE scores provide information on the direction of the interaction, mechanistic understanding, toxicological significance, and the confidence in the conclusion. For example, a BINWOE score of ">IIIB" (+0.23) indicates there is greater than additive interaction (>), inadequate or ambiguous mechanistic data to understand the interaction (III), and the interaction has been inferred or demonstrated for similar chemicals (B). The final weighting factor (+0.23) is based on a scale with minimum of 0.05 and maximum of 1.0.

ATSDR's Framework for Assessing Health Impacts of Multiple Chemicals and Other Stressors (Updated) (ATSDR 2018) recommends a three-tiered approach, similar to the approach outlined by USEPA (2000), to assess health impacts from multiple chemicals. Tier 1 is consistent with USEPA's (1989) Superfund risk assessment guidance, which directs that HQs less than 0.1 or cancer risk estimates less than 10^{-6} for single chemicals are not expected to pose adverse human health effects either individually or in combination with other agents. For HQs greater than or equal to 0.1 or cancer risk estimates greater than or equal to 10^{-6}, Tier 2 analysis for preliminary multiple chemical evaluation is performed. For noncancer effects for multiple chemicals, the HI is used, which is the sum of HQs for all the known chemicals of concern. For carcinogens combined cancer risk estimates were used, which are the sum of risks for all the known carcinogens of concern. Tier 3 analyses for refined multiple chemical evaluations are performed if the preliminary HIs are greater than or equal to 1 or the combined cancer risk estimates are greater than or equal to 10^{-6} from Tier 2 analysis.

Tier 3 evaluations are also performed if there are high concerns for additive or interactive actions or if additional data show evidence of health effects from combined exposure to the chemicals. Tier 3 evaluations include evaluating the possible greater- or less-than-additive joint actions, assessing joint actions through a weight-of-evidence approach, determining dose dependency based on pharmacokinetic models, applying HIs and combined cancer risk estimates based on common toxicity targets or common modes of action, applying exposure estimates to calculate HIs and combined cancer risk estimates, and developing HIs and combined cancer risk estimates for more susceptible subpopulations.

Weight of evidence for lead and arsenic interactions. Lead and arsenic interactions have been tested in a limited number of animal studies. ATSDR (2004) compiled data from animal and human studies, as well as mechanistic data, and offered assessments of the potential for interactions greater than or less than additivity, as summarized in Table 2. Among the three of four endpoint categories with sufficient information to make predictions about additivity, there was some evidence that neurological effects could be greater than additive, while both renal and hematological effects were predicted to be less than additive. Evidence of the potential for interactions is very limited, especially with regard to the dose-response for any potential interactions. Thus, there is not sufficient information to assess interaction potential quantitatively in risk assessments.

Table 2. Summary of Endpoint-Specific Additivity for Lead and Arsenic (ATSDR 2004)

	Lead on Arsenic	Arsenic on Lead	Direction of Interaction
Endpoint	**BINWOE Determinations[a]**		
Neurological	>IIIB (+0.23)	>IIB (+0.5)	Lead on arsenic: Greater than additive based on effects of combined exposure on reading and spelling in children (Moon et al. 1985). Additional corroborating information is not available, and mechanistic data are unclear. Arsenic on lead: Greater than additive based on a study of maladaptive classroom behavior in children (Marlowe et al. 1985). Supporting data are lacking, and mechanistic information is not clear.
Renal	<IIIB (-0.23)	<IIIB (-0.23)	Lead on arsenic and arsenic on lead: Less than additive based on the apparent protective effect of either element against the renal effects of the other in a chronic oral study in rats (Fairhall and Miller 1941). Mechanistic data do not offer clear support.
Cardiovascular	? (0)	? (0)	Lead on arsenic and arsenic on lead: The direction cannot be predicted due to a lack of mechanistic understanding and pertinent toxicological data.
Hematological	<IIIB (-0.23)	<IIIB (-0.23)	Lead on arsenic: Less than additive based on the apparent protection by co-exposure to lead against arsenic-induced decreases in hematocrit and hemoglobin in an intermediate dietary study in rats (Mahaffey and Fowler 1977, Mahaffey et al. 1981) and hemosiderosis (reflecting red cell destruction) in a chronic dietary study in rats (Fairhall and Miller 1941). Arsenic on lead: Less than additive based on the apparent protection by co-exposure to arsenic against lead-induced decreases in hematopoiesis in a chronic dietary study in rats (Fairhall and Miller 1941). The mechanistic data do not clearly support these conclusions.

[a]Notes:

Direction of Interaction:
? = Cannot be determined
< = Less than additive
= = Additive
> = Greater than additive

Mechanistic Understanding:
II = Intermediate understanding of mechanism
III = Ambiguous understanding of mechanism

Toxicological Significance:
A = Clear significance
B = Medium to low confidence
C = Low confidence

Sources:

Fairhall LT, Miller JW. 1941. Public Health Rep 56:1610–1625.
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3.2 BPSOU Health Risk Assessments

Four primary HHRAs have been conducted in the BPSOU, in 1991, 1994, 1997, and 2003. A preliminary baseline risk assessment of the BPSOU was conducted in 1991 (CDM 1991b), after a USEPA 1990 time-critical removal action. The 1991 remedial investigation/feasibility study and risk assessment focused on "environmental impacts due to contaminated soils in Butte (i.e., storm runoff impacts on Silver Bow Creek), future land use consideration, and evaluation of the effectiveness of past removal and reclamation activities." The assessment relied on extensive data and analyses conducted within the Butte Soils Screening Study (CDM 1988), which reported concentrations for arsenic, cadmium, lead, and mercury in over 700 soil samples. Not all of these data were used in the assessment because many locations had already been remediated or were scheduled for remediation. Mercury was not further evaluated in the BPSOU because elevated concentrations were identified primarily within the Walkerville area and were subsequently remediated (USEPA 2006b). Consequently, the 1991 HHRA identified arsenic, cadmium, and lead as the metals of potential concern. The risk assessment results indicated that cadmium in soils was unlikely to result in adverse health effects (i.e., all HQs and HIs for cadmium were less than 1.0).

Based on the finding of elevated risks for lead and arsenic, an HHRA focused on lead was conducted in 1994 (CDM 1994), followed by an HHRA focused on arsenic in 1997 (CDM 1997). In 2003, a supplemental HHRA was conducted for Walkerville to evaluate mercury exposure as well as potential exposures to arsenic, lead, and mercury in outdoor soil and indoor dust (USEPA 2003). These risk assessments were the basis for the residential action levels for these metals.

The BPSOU Baseline Risk Assessment for Lead (CDM 1994) evaluated residential exposures to lead, specifically for child residents (0-6 years in age). Lead sources identified included waste rock dumps, railroad beds, mine tailings, smelter emissions, and other mine-related materials. The routes of exposure identified for child residents include soil ingestion, dust ingestion, ingestion of lead-based paint from soil and dust (which is included in the soil and dust ingestion), dust inhalation, ingestion of food and water, and fetal lead intake from the mother. The IEUBK model was used to derive individual risk results for 147 residences. Lead risks were presented as "total risk", which included all source media (i.e., soil, dust, water, air, and diet), and as "adjusted risk", which included only exposures from lead in soil. Based on the total risk estimates, this assessment showed 50% of the homes evaluated had an estimated probability greater than 5% for a child having a blood lead level of 10 ug/dl. Based on the adjusted risks, 26% of the homes evaluated had an estimated probability greater than 5% for a child having a BLL of 10 ug/dl due to yard soil lead concentrations. Action levels for lead in soil based on this HHRA are described in the next section.

The BPSOU baseline HHRA for arsenic (CDM 1997) outlines the exposure pathways for arsenic. A site conceptual exposure model (SCEM) was prepared to evaluate the potential exposure pathways for arsenic. The SCEM identified residents, commercial workers, recreational users, and railroad workers as the receptors most likely to be exposed to arsenic. Each receptor has its own exposure pathways. For residents, adults and children aged 0 to 6, the SCEM identified ingestion of surface soils, ingestion of interior dust, and inhalation of fugitive dust as exposure pathways. For adult commercial workers, ingestion of surface soils, ingestion of interior dust, and inhalation of fugitive dust were identified. For adult railroad workers, ingestion of surface soils and inhalation of fugitive dust were identified. For recreational users, the exposure scenario evaluated adolescent individuals inner tubing in site creeks, and ingestion of surface water, dermal absorption of chemicals in surface water, and inhalation of fugitive dust were identified as the exposure pathways. The reasonable maximum exposure (RME) risk estimates did not identify any risk estimates or HIs above levels generally considered acceptable by regulatory agencies when exposure point concentrations were based on average concentrations across neighborhoods. However, because arsenic levels in soil are not evenly distributed in the BPSOU, USEPA determined removal action was necessary to address individual residential areas and commercially zoned areas to address potential arsenic "hot spots" (USEPA 1999). RME parameters were used to derive action levels for arsenic in soil as described in the next section.

The Walkerville HHRA (USEPA 2003) was a supplemental HHRA conducted to evaluate residential exposures to lead, arsenic, and mercury in soil, indoor dust, and indoor air. Exposure pathways considered included: ingestion of outdoor soil and indoor dust (basement soil, living area dust, and attic dust); inhalation of airborne dust from soil and indoor dust; and inhalation of indoor air vapor (mercury only). The assessment concluded that lead exposures for children had the potential to result in greater than 5% probability of exceeding a BLL of 10 ug/dl at 89 Walkerville residences. Lead exposures for adults did not result in unacceptable risks. With the exception of three houses that had high levels of mercury in outdoor soil or indoor air, estimated risks from arsenic and mercury were within levels generally considered acceptable by regulatory agencies.

Other HHRAs have been conducted in other areas of Butte, including Timber Butte (2006b), Montana Pole (USEPA 2006b, 2019), and Lower Area One (LAO) (CDM 1991a). These additional sites are briefly described here but are less relevant to assessing the effectiveness of remediation for the BPSOU. The Timber Butte site is adjacent to the BPSOU boundary and was the site of a time-critical emergency removal action in 1989, which included excavation of approximately 40,000 cubic yards of soil (USEPA 2006b).

The Montana Pole and Treating Plant NPL site, a 40-acre site situated north and south of Intestate 90 at the southwestern end of BPSOU, is a former wood-treating facility contaminated with pentachlorophenol, dioxins, and other organic compounds used in wood treatment. MDEQ is the lead agency, and the HHRA for Montana Pole and Treating Plant was summarized in the MDEQ (1993) ROD. Theoretical risks were highest for groundwater if used as drinking water, with risk estimates greater than $1x10^{-2}$ attributed to pentachlorophenol and dioxins; however, the groundwater is not used as a drinking water source and the groundwater plume is being effectively contained onsite (MDEQ/USEPA 2017). Elevated theoretical risks were also identified for consumption of homegrown vegetables and direct contact with soil (assuming future residential use) associated with pentachlorophenol and dioxins, but soil is being remediated and deed restrictions will prevent future residential development. While there is some overlap between Montana Pole and the BPSOU, these sites are studied and remediated separately and distinctly. The Montana Pole site is managed by MDEQ. The fourth 5-year review was completed in 2017, and work is ongoing (MDEQ 2019).

LAO, located in the western portion of the BPSOU Silver Bow Creek floodplain, includes the area where the Colorado Tailings and Butte Reduction Works were located. The final preliminary baseline risk assessment for LAO, completed in 1991, evaluated human health and ecological risks associated with inorganic contaminants in groundwater and surface water (arsenic, cadmium, chromium, lead, and zinc) (CDM 1991a). Risk estimates were conducted for current and future hypothetical scenarios, including occupational, recreational (swimming, innertubing), trespassing, and residential scenarios. Human health risks related to exposure to COCs in surface water were determined to be "low and negligible". A hypothetical scenario in which residents consumed groundwater for 70 years resulted in unacceptable risks for arsenic, cadmium, lead, and zinc. (USEPA 2006b). LAO was the subject of a 1991 emergency removal action (USEPA

2006b). The primary concern has been impacts of contaminated groundwater to Silver Bow Creek. Phase I removal and floodplain reconstruction work was completed in 1998, a Phase II removal was completed in 2000, and Phase III was deferred until the final remedial action (USEPA 2006b).

3.3 BPSOU Soil Action Levels

BPSOU soil action levels for lead, arsenic, and mercury were derived based on site-specific data and health protective assumptions in 1993, 1997, and 2003, respectively. The 2006 ROD for BPSOU (USEPA 2006b) confirmed the action levels, as summarized in Table 3, and identified a selected remedy. Subsequent analyses in the 5-year ROD reviews conducted in 2010 and 2016 each also maintained these action levels (USEPA 2010, 2016a). The basis for the arsenic, lead and mercury action levels is briefly described below, followed by a summary of the reviews.

Table 3. Soil, Dust, and Vapor Action Levels in 2006 ROD for BPSOU

Contaminant of Concern	Exposure Scenario	Concentration
Lead	Residential	1,200 mg/kg
	Non-Residential	2,300 mg/kg
Arsenic	Residential	250 mg/kg
	Commercial	500 mg/kg
	Recreational	1,000 mg/kg
Mercury	Residential	147 mg/kg
	Residential (vapor)	0.43 ug/m^3

Lead: The BPSOU soil action levels (also called preliminary remediation goals [PRGs]) were derived by USEPA using applicable USEPA guidance. USEPA applied the IEUBK Lead Model 0.61 with the assumptions from the 1994 baseline risk assessment and the site-specific bioavailability data demonstrating 10% absorption of lead from soil and dust from studies in monkeys and swine. A site-specific soil dust regression of 0.24 was applied based on paired data from the environmental health lead study (BSBHD/UC 1992), and the geometric standard deviation (GSD) of 1.68 was also applied in the modeling. Remaining exposure assumptions were default variables (USEPA 1993). USEPA derived a residential action level of 1,200 mg/kg (rounded up from 1,175 mg/kg) (USEPA 1993) and a action level of 2,300 mg/kg for non-residential soils (USEPA 2006b). These action levels were identified as needed to maintain a BLL of 10 µg/dL or less for at least 95% of the children between the ages of 0 and 6 years, which was within the USEPA-targeted risk range at that time.

Arsenic: The RME estimates from the CDM (1997) baseline risk assessment for arsenic were used by USEPA as the basis for soil action levels (PRGs). Site-specific inputs were used for arsenic in soil and house dust, and the bioavailability values of 18% and 25% were used for soil and indoor dust, respectively, based on data from studies in monkeys. Bioavailability data from Anaconda were used because data were not available for Butte soils. Soil action levels (PRGs) were calculated representing cancer risks of 1 in 10,000, 1 in 100,000, and 1 in 1,000,000. Under the RME scenario, the selected action level (PRG) of 250 mg/kg represents a 1 in 19,040 cancer risk, which is within the USEPA-targeted risk range (USEPA 2006b).

Mercury: USEPA used the RME exposure assumptions from the Walkerville HHRA to determine an indoor residential action level for mercury vapor of 0.43 micrograms per cubic meter (μg/m^3) and an action level of 147 mg/kg for mercury in residential soil (USEPA 2003).

Comments on action levels are addressed in the USEPA (2006b) responsiveness summary. Responses highlighted the extensive site-specific data used in the characterization and risk assessment, and indicated that many health-protective assumptions were applied and that risks were well understood. USEPA (2006b) summarized a main response regarding the protectiveness of the action levels, stating: "EPA's action levels are conservative, safe, and consistent with the law and EPA guidance." USEPA states in another response: "EPA uses conservative approaches in all of its risk assessments, and the risk assessments were done in accordance with the NCP and EPA by experienced EPA risk assessors. EPA is confident that its risk assessment and resulting action levels and triggers are fully protective of human health."

The Third Five-Year Review Report for Silver Bow Creek/Butte Area Superfund Site (USEPA 2010) reevaluated action levels for lead, arsenic, and mercury and stated that "EPA believes that the use of the three contaminants of concern for solid media – arsenic, lead, and mercury – and their respective action levels will ensure that human health is protected at the BPSOU." Cleanup levels for arsenic, lead, and mercury were unchanged from those shown in Table 3 above. USEPA (2010) also noted that comments had been addressed regarding concerns about manganese in soil. Specifically, when soil concentrations were compared to an appropriate risk-based screening level for manganese, no areas were identified that exceeded the screening level. Similarly, the USEPA (2011) explanation of significant differences to the 2006 BPSOU ROD noted modifications in aspects of the means and timing of remediation, but it made no changes in the action levels. The Fourth Five-Year Review Report for Silver Bow Creek/Butte Area Superfund Site (USEPA 2016a) reevaluated action levels for lead, arsenic, and mercury and again confirmed the same action levels.

4. REVIEW OF PAST EXPOSURE/BIOMONITORING STUDIES

As described in the prior section, health risk assessment is used to predict exposures to chemicals and the associated health risks. For the primary COCs at the BPSOU (lead, arsenic, and mercury), it is possible to measure recent exposures directly by analyzing the concentrations of these metals in biological samples collected from people. For all of these metals, there are multiple common sources of exposures that are not related to mining affected soils in the BPSOU. Inorganic arsenic, the form relevant for the BPSOU, is present at low levels in most foods and in higher concentrations in a subset of foods including rice and some seaweeds. Arsenical pesticides (including lead arsenate) have also been used widely across the U.S. in agricultural areas and in suburban lawns. In some communities (but not Butte), naturally elevated concentrations in drinking water are a significant source of arsenic exposure. For lead there are many, varied sources of exposure in homes and the community, including imported spices, costume jewelry, ceramic dishes, painted toys, vinyl blinds, brass drinking water fixtures, and lead pipes (lead pipes are not known to be present in Butte). Lead exposures can also occur in firing ranges, in the making of lead fishing sinkers or leaded glass, or in recycling lead batteries. Mercury also has multiple sources of exposure, including metal fillings in teeth, mercury released from broken thermometers, and mercury in fish.

Because of these pervasive sources, the results of biological sampling for an individual do not provide evidence of exposure from one specific source. For that reason, the use of biological testing as an adjunct to exposure assessment is usually done in the context of a more comprehensive community biomonitoring study. Biomonitoring studies may employ multiple biomarkers that vary based on the behavior of the chemical being studied. Common biomarkers include hair, urine, nails, and blood. Urine and blood are the most common matrices that are collected. Hair and nails have been studied as potential indicators of longer-term exposure (Wolowiec et al. 2013, Davis et al. 2014), but standardizing sample preparation procedures has been challenging, especially washing to remove external contamination and mineralization methods.

Since 1990, a series of biomonitoring studies have been conducted in Butte. In this section, biomonitoring methods for lead, arsenic, and mercury are reviewed, and reference concentrations are summarized; descriptions of studies conducted in Butte follow.

4.1 Biomonitoring Methods and Reference Levels for Lead, Arsenic, and Mercury

The primary biomonitoring option for lead is whole blood, while urine is used for arsenic and elemental/inorganic mercury. Urinary concentrations are typically presented both in µg/L of urine and in micrograms per gram (µg/g) of creatinine, a measure that allows correction for variation in hydration state. Hair and nails may be alternate methods for assessing lead and arsenic exposure, but they have had more limited use because of the need to process the samples rigorously to remove external contamination and because of the lack of reliable reference values. Bone-seeking elements such as lead may also be measured in bone, which provides an indication of long-term body burden.

National biomonitoring data for these three metals are summarized in the Fourth National Report on Human Exposure to Environmental Chemicals (CDC 2019). Every 2 years, nationally representative samples of urine and blood are collected from thousands of participants in the

National Health and Nutrition Examination Survey (NHANES). The CDC (2019) presents updated tables (through 2016) of descriptive statistics for a large number of chemicals, including arsenic, lead, and mercury. The applicable data are discussed in the following sections.

4.1.1 Lead

The most widely used method for evaluating lead exposure is measurement of lead in whole blood (CDC 2005, ATSDR 2007c). The elimination half-life of blood lead is about 30 days, making lead concentration in blood useful in assessing a few months of exposure history. Urinary lead concentration is sometimes reported, but it has limited usefulness for assessing exposure due to variable results and lack of historical datasets. The CDC (2019) is now including urinary lead as well as blood lead in the national biomonitoring program.

Nationwide, BLLs have declined markedly over the past 40 years (Table 4). Much of the decrease in BLLs can be attributed to the ban of leaded gasoline, the ban of lead-based paint use in residential buildings, and improvements in corrosion control for drinking water systems. As BLLs have declined over time, so has the concept of an elevated BLL. In 1970, BLLs of greater than 40 µg/dL were considered elevated. From the mid-1970s to the mid-1980s, BLLs of greater than 30 µg/dL were considered elevated. This number dropped to 25 µg/dL from the mid-1980s until 1991, when the CDC defined BLLs of greater than 10 µg/dL as elevated (CDC 1991). As described in Section 3.1.2.1, in 2012, the CDC recommended that the elevated BLL definition for children be revised to a BLL of greater than 5 µg/dL.

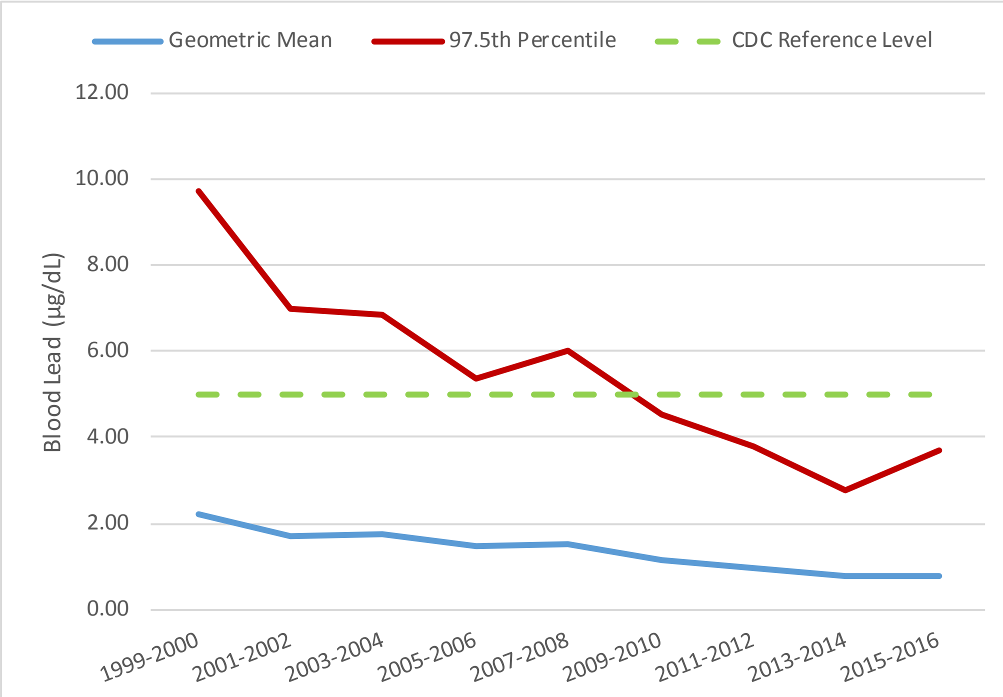
Table 4. Geometric Mean BLL and Percent of BLLs Above 10 µg/dL, U.S. Children 1-5 Years 1976-2002

Children (1–5 Years)	1976–1980	1988–1991	1991–1994	1999–2002
Geometric mean (µg/dL)	15.0	3.6	2.7	1.9
Blood lead ≥10 µg/dL	88.2%	8.9%	4.4%	1.6%

Notes:
Data from NHANES Survey, Years 1976-2002.
Source: ATSDR. 2007c.

Blood lead surveillance conducted as a part of NHANES has played a large role in defining elevated BLLs. The current 5-µg/dL reference level is based on the 97.5th percentile BLL measured in children aged 1 to 5 years in the 2005 to 2008 NHANES datasets (i.e., this is a reference value based on population statistics and is not an indication of a threshold for adverse health effects). More recent NHANES data show a 97.5th percentile reference level lower than 3.5 µg/dL (Figure 3), a level at which many laboratories have difficulty meeting goals for analytical reliability (Caldwell et al. 2017). Nevertheless, it is expected that the CDC will soon reduce the reference level for young children to reflect the current 97.5th percentile BLLs. Because it is a population-based reference value for young children, the current BLL reference level is not directly applicable to adults.

Figure 5. CDC Reference Level, Geometric Mean, and 97.5th Percentile BLLs For U.S. Children, 1999-2016



NHANES blood lead data are based on venous samples and analyzed by state-of-the-art methods that now have detection limits of less than 1 µg/dL. Such data are considered more reliable than data based on the finger stick/capillary tube collection methods (i.e., methods where a child receives a finger stick and blood droplets are collected into a capillary tube) that are most widely used in clinics for blood lead surveillance efforts. Use of these methods (as well as variants where the blood droplets are taken up on filter paper) may result in overestimation of BLLs because of external contamination on the skin. For this reason, elevated BLLs determined by a finger stick method must be confirmed by additional tests, preferably using a venous draw sample, before it can be concluded that a child has an elevated BLL. A portable lead analyzer called LeadCare II is used by many clinics to provide immediate results, which allows for more successful follow-up in the case that blood lead results are elevated. A drawback of the LeadCare II analyzer is that the detection limit is 3.3 µg/dL.

The CDC reference level corresponds to the MDPHHS definition of elevated BLLs in children, which states: "An elevated blood lead level is defined as being greater than or equal to 5 [µg/dL] in children 13 years of age or younger. If the blood lead level was determined by capillary blood method, then the test result must be confirmed by venous method as soon as possible." An elevated BLL for individuals 14 years of age and older has not been defined in the Administrative Rules of Montana.

4.1.2 Arsenic

The most reliable, least invasive, and most widely used screening test to measure recent arsenic exposure is measurement of arsenic in urine (ATSDR 2007b, Orloff et al. 2009). Most arsenic is excreted in urine within a few days of exposure. In contrast, arsenic is cleared from the blood in a few hours, so blood concentrations are highly variable and are not a useful indicator of chronic exposure to low levels of arsenic (ATSDR 2007b). Due to variations in hydration state and physiological function that affect urine output, urinary excretion is most reliably measured by collecting a 24-hour urine sample; however, in most biomonitoring studies, it is considered impractical to collect such samples, and instead a one-time or "spot" sample is collected. Spot urine samples are often reported as "creatinine corrected" (in µg arsenic/g of creatinine) or "specific gravity corrected" (a unitless measure), as well as in µg arsenic/L of urine. A new review confirms that both creatinine correction and specific gravity correction are suitable hydration adjustments (Hsieh et al. 2019); however, other studies have raised concerns about the reliability of creatinine correction for obese subjects, and they propose urinary flow rate as a more reliable indicator for arsenic exposure (Bulka et al. 2017, Middleton et al. 2017).

Creatinine measurements in human urine are considered normal within the range of 0.3 to 3.0 g/L. The normal range for specific gravity in human urine is 1.010 to 1.030 (WHO 1996). Within these normal ranges, creatinine and specific gravity measurements are used to adjust urine arsenic measurements. This corrects for differences in urine output between different individuals or within the same individual across different samples. When creatinine and/or specific gravity measurements fall outside of the normal ranges, the speciated arsenic results cannot be reliably interpreted, with or without correction.

Urine arsenic includes both inorganic arsenic and organic forms of arsenic. Inorganic arsenic is metabolized (primarily in the liver) to monomethyl and dimethyl forms that are excreted in urine along with unmetabolized inorganic arsenic (ATSDR 2007b). More complex organic arsenicals that exhibit little or no toxicity, such as arsenobetaine, are present in most seafood and are also excreted in the urine. Because of the pervasive presence of organic arsenicals in seafood, total urine arsenic is not a reliable indicator of exposure to inorganic arsenic. Often participants in studies of arsenic exposure will be asked to refrain from eating seafood for 3 days prior to giving a urine sample. Improvements in assessing inorganic arsenic exposure can be obtained by measuring individual arsenic species (including arsenite, arsenate, monomethylarsonic acid, and dimethylarsinic acid), as well as total arsenic. The sum of these arsenic species is referred to as "speciated urine arsenic." Speciated urine arsenic is an improved indicator of inorganic arsenic exposure, but it is still influenced by monomethyl and dimethyl arsenic species present in rice, shellfish, and some other foods. For that reason, biomonitoring studies do not provide direct evidence of exposure to arsenic in soil, and statistical analyses must be performed to identify possible soil exposure influence in a population of tested individuals.

ATSDR (2009) indicates that total urinary arsenic concentrations greater than 100 µg/L may be considered abnormal but that recent ingestion of seafood can substantially increase total arsenic measurements in urine. Although there is no generally recognized benchmark for urine speciated arsenic, a value of 30 µg/L has been used as an indicator of elevated inorganic arsenic exposure (ADHS 2002, ENVIRON 2014a). Reference values for the upper end of the normal distribution of inorganic arsenic species may be obtained from 95th percentile values from the Fourth National Report on Human Exposures to Environmental Chemicals (CDC 2019); these values identify levels that will be exceeded by only about 5 of every 100 people tested. During the 2015 to 2016 period, more than 3,000 people provided urine samples that were tested for arsenic. The 95th percentile value for the general population is 14.5 µg/L, while the creatinine corrected value is 16.2 µg/g. As can be seen from Table 5, creatinine corrected values are much higher in young children, who may have more dilute urine than adults. Urine arsenic is also much higher in Asians than in other ethnic groups, likely due to their much greater consumption of seafood and rice.

Table 5. U.S. Population 95th Percentile Urine Arsenic 2015-2016 (CDC 2019)

Categories	Total Arsenic (µg/L)	Total Arsenic Creatinine Corrected (µg/g)	Inorganic-related Arsenic Species (µg/L)	Inorganic-related Arsenic Species Creatinine Corrected (µg/g)
Total Population	44.6	45.8	14.5	16.2
Age 3-5 years	22.4	40.9	13.2	23.7
Non-Hispanic whites	36.1	33.8	11.4	12.5
Non-Hispanic blacks	62.7	41.2	18.1	13.7
All Hispanics	40.6	39.5	17.1	16.4
Asians	92.5	118	30.8	34.9

While urinary arsenic is used as a biomarker of recent exposure, because arsenic accumulates in the keratin-rich integumentary system, arsenic in nails and hair is sometimes used to measure longer-term exposure on the order of months. As noted in Section 4.1, hair and nails are used less frequently because of the need for rigorous processing to remove external contamination and because of the lack of reliable reference values. Typical levels of arsenic in hair and nails are less than 1 µg/g (ATSDR 2007b). Davis et al. (2014) used infant toenails to assess maternal exposure impacts to the fetus throughout the entire gestation period.

4.1.3 Mercury

As described in Section 3.1.2.3, elemental mercury and inorganic mercury are the forms expected to be present at the BPSOU. Methylmercury is the predominant form of mercury in fish and is not a focus of this study. For metallic mercury vapor and inorganic mercury, urine is used to test for recent exposure (IPCS 1991, Boerleider et al. 2017). Exposure to methylmercury is assessed by measurement in blood or hair. Very little methylmercury is excreted into the urine (IPCS 1991), while blood will reflect methylmercury, as well as elemental and inorganic mercury exposures. Hair is considered to be an indicator for methylmercury exposure (ATSDR 2013). After short-term exposures to metallic mercury, mercury vapor can be detected in the breath, but this occurs to a significant extent only within a few days after exposure (Pogarev et al. 2002), and this method is not normally used to determine if mercury exposure has occurred.

Dental amalgams are the primary nonoccupational contributor to elemental mercury exposure (ATSDR 1999). According to the CDC (2019), the 95th percentile urine mercury in Americans declined from 1.83 µg/L (95% confidence interval 1.62 to 2.14) in 2011 to 2012 to 1.18 µg/L (95% confidence interval 0.920 to 1.29) in 2015 to 2016. In children, 95th percentile values in 2015 to 2016 were 0.520 µg/L for ages 6 to 11 and 0.610 µg/L for ages 12 to 19. New York State has a reportable level for urine mercury in adults of 20 µg/L (NYSDOH 2019). The New York reporting system is designed to identify workers who might be exposed to mercury so that measures to reduce exposures can be taken before health effects are expected. The state website notes that mercury levels at or above these values do not mean that a person will develop adverse health effects.

4.2 Butte Studies

Since 1990, two comprehensive lead exposure studies, as well as several more focused studies, have been conducted in Butte. Each of these studies is summarized in the following sections, and their strengths and limitations in informing the Phase 2 study goal of assessing exposures to lead, arsenic, and mercury in soil in the BPSOU are discussed.

4.2.1 1990 Blood Lead and Urine Arsenic Study (BSBDH/UC 1992)

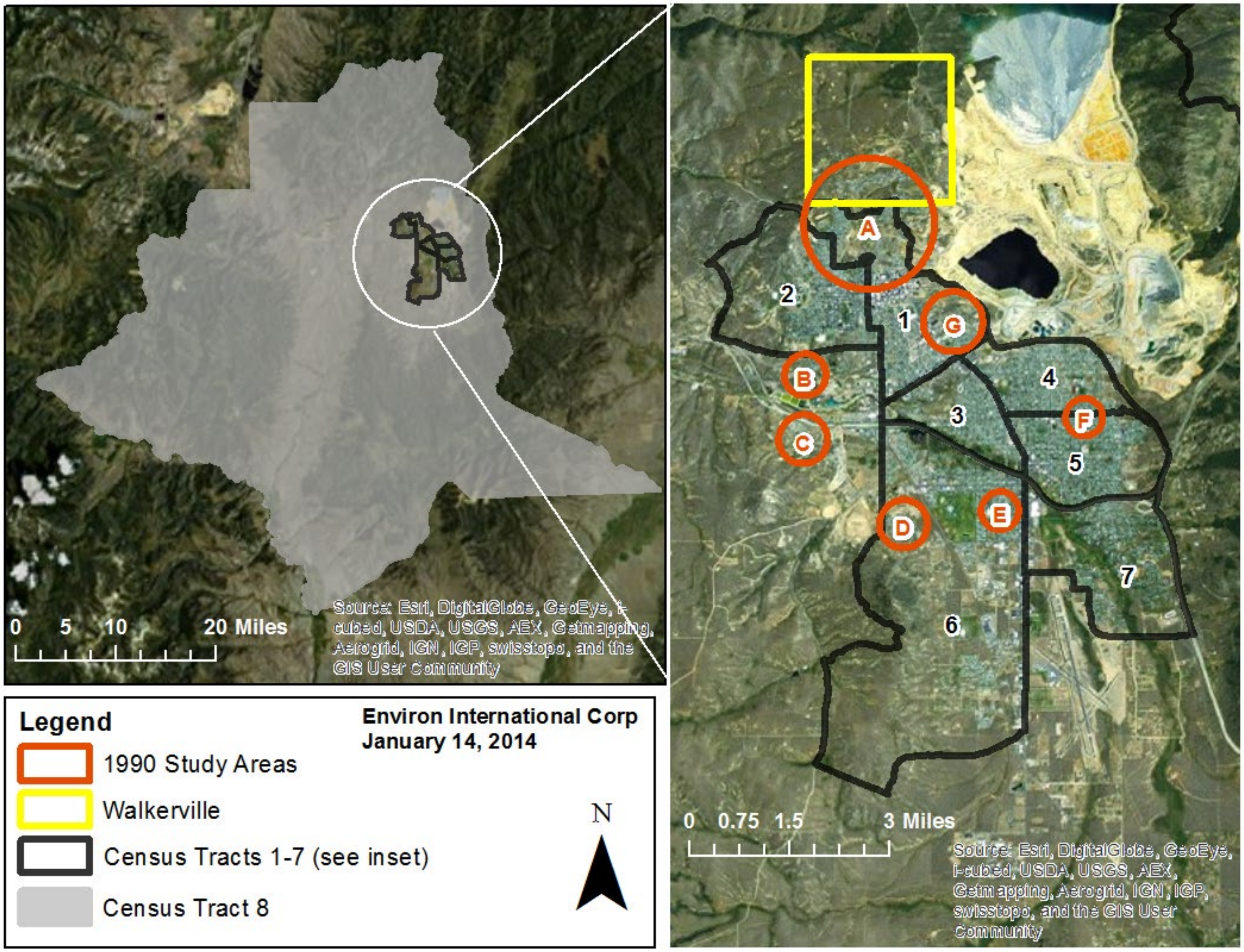
The first exposure/biomonitoring investigation in Butte was an extensive blood lead and urine arsenic exposure study conducted by the University of Cincinnati in 1990. Dr. Robert Bornschein was the principal investigator. A final report of the study findings was issued in 1992 (BSBDH/UC 1992).

4.2.1.1 Study Design

The study included blood lead assessment of 294 children up to age 6, as well as assessment of 53 older children and 48 adults from seven neighborhoods throughout Butte. The study investigators reviewed available soil data for Butte and met with the BSBHD to identify neighborhoods likely to show the widest range of exposures to lead from different sources. A comprehensive door-to-door recruitment effort was conducted to identify study participants from the general Butte population (Figure 6). Urine arsenic samples were also collected in a subset of the study subjects (140 subjects).

The study included environmental samples (i.e., yard soil, dust, tap water, lead paint), as well as blood lead and urine arsenic samples. For each neighborhood, the factors potentially influencing BLLs were characterized; they included house age, the likelihood of lead paint and lead pipe presence, and the potential for exposure to waste rock or mill tailings within the community (e.g., the Berkeley Pit, Colorado Tailings, Montana Pole site, and Clark Tailings). The blood lead data and the environmental data were used to develop a structural equation model of lead exposure pathways. Table 4 summarizes the neighborhood characterizations presented in the 1990 exposure study along with blood lead statistics for the children tested.

Figure 6. Map of Butte Showing Census Tracts and 1990 Study Areas (BSBDH/UC 1992)



4.2.1.2 Blood Lead Results

The geometric mean BLL among young children was 3.5 µg/dL (Table 6), similar to U.S. levels and lower than values from other mining communities tested at that time. More than 230 children from older neighborhoods with more lead sources affecting the soil concentrations (including deteriorated lead paint) had higher geometric mean BLLs than the roughly 60 children from a mobile home park and newer neighborhoods. So, although the community BLLs were not elevated compared with national values, there was evidence of some influence of a combination of soil, dust, and paint lead on BLLs.

Table 6. Blood Lead Results Reported in 1990 Butte Exposure Study

Statistic	1990 Butte Blood Lead (µg/dL)					
	< 72 mo.	72 mo. to 18 yr.	Adults	Nursing Women	Pregnant Women	All
Number	294	53	48	11	24	430
Geometric mean	3.5	3.5	3.1	2.4	2.1	3.4
GSD	1.2	1.8	1.9	1.6	1.5	1.8
95th percentile	10.5	13.6	10.3	5.0	3.3	9.5
Maximum	25.0	18.0	12.0	5.0	3.5	25.0

Table 7 shows blood lead statistics for children in the study by neighborhood and includes information about the relative significance of different lead exposure sources for each neighborhood. The highest average BLLs occurred in areas A, C, D, and G, which were all characterized as medium or high for exposure to waste/tailings and the likely presence of lead paint and lead pipes. Specifically, area A was in an area defined by USEPA as a "Soil Priority Area," had houses built as early as 1886, and included railways used to transport ore, as well as waste rock dumps, giving it a "high" classification for all exposure routes (waste rock, lead paint, and lead pipe). Area C was not in a USEPA Soil Priority Area; however, it was within 1,000 feet of Colorado Tailings piles and the historic Colorado Smelter site (representing a "medium" exposure level to waste/tailings). The houses in this area were built between 1930 and 1970. Area D was in a USEPA Soil Priority Area, was within 1,000 feet of Clark Tailings and the former mill, and had houses built in the same time period as those in area C. Area G, like area A, had a "high" classification for all exposure routes, given that the houses were built between 1891 and 1930 and that it was also surrounded by railways and historic mining sites.

Table 7. Blood Lead Results for Children <72 Months by Neighborhood Reported in 1990 Butte Exposure Study*

	1990 Butte Blood Lead (µg/dL)						
	Area A	**Area B**	**Area C**	**Area D**	**Area E**	**Area F**	**Area G**
Lead Exposure							
Exposure to waste rock or mill tailings	**High**	**Medium**	**Medium**	**Medium**	**Low**	**Low**	**High**
Presence of lead paint	**High**	**Low**	**Medium**	**High**	**Medium**	**Medium**	**High**
Presence of lead pipe	**High**	**Low**	**Medium**	**Medium**	**Medium**	**Medium**	**High**
Statistic							
Number	183	15	12	11	27	17	13
Geometric mean	3.7	2.3	4.6	4.6	2.7	3.0	3.8
GSD	1.8	1.7	1.9	1.8	1.5	1.5	1.7
95th percentile	10.9	4.0	14.5	22.5	5.6	6.5	8.0
Maximum	25.0	4.0	14.5	22.5	6.0	6.5	8.0

Notes:
* The study also reports on 15 children younger than 72 months of age who lived outside of the study areas.

Based on the findings of this study, Dr. Bornschein and his co-investigator, Dr. Clark, recommended to the Board of Health that a blood lead surveillance and abatement program be established in Butte (June 5, 1991 letter included in the 1992 report). The predecessor to the RMAP was implemented in response to these recommendations. The findings of this study also provided site-specific data used by USEPA in the health risk assessment and cleanup goal development.

The structural equation model of lead exposure pathways showed that residence location (i.e., neighborhood) and house age were the strongest predictors of paint lead, soil lead, and dust lead concentrations. Lead-based paint was shown to be associated with lead-contaminated soil, which was in turn associated with lead-contaminated house dust. Only house dust lead was directly related to blood lead in the structural equation model. The indirect effect of soil lead on blood lead was shown to be both small and weak. The investigators concluded that 39% of the variability in soil lead concentrations was attributable to lead-based paint, while the remainder (61%) was attributable to "the heterogeneous distribution of lead in soil, and lead from other sources such as native lead in soil, mine waste and contaminates from ore processing." Gardening or eating homegrown produce was shown not to contribute to elevated BLLs.

4.2.1.3 Urine Arsenic Results

Among the 140 participants providing urine samples, mean urine arsenic concentrations did not increase with increasing soil arsenic concentrations in Butte (Table 8). Thus, this study did not find elevated exposures to arsenic in Butte area children.

Table 8. Urinary Arsenic Results Reported in 1990 Butte Exposure Study

Statistic	1990 Butte Urine Arsenic (µg/L)		
	All soil < 50 ppm As	Soil As 50-100 ppm*	Soil As > 100 ppm*
Number	31	83	26
Mean	13.0	14.1	13.1
Standard deviation	6.5	8.9	7.1
Median	13.0	12.0	11.5
95th percentile	25.0	30.5	27.0
Maximum	26.5	43.5	28.0

Notes:
* One or more yard samples.

4.2.1.4 Strengths and Limitations

This pathbreaking study set a new standard for comprehensive exposure/biomonitoring studies. The design, still relied upon today, included coupling testing of environmental exposure media, in home tests of drinking water and lead in paint, and a detailed questionnaire about activities and exposure sources with biomonitoring data. This combination of data allowed the researchers to develop exposure models that provided insights to exposure sources and pathways. A key strength of this study is that it provides a worst-case evaluation of potential lead and arsenic exposures among young children because it was completed prior to most remediation in residential areas of the BPSOU. The study was also designed to have high sensitivity to detect lead exposure sources in the community, and the design included over-representation of children living in high-risk areas (i.e., Uptown neighborhoods closest to historical mining activity).

The only significant limitation of this study is that it was conducted almost 30 years ago. So, while it provides crucial insights to the fact that lead and arsenic exposures occurring at that time were lower than expected, it cannot inform us about current exposures, except to set an upper bound for exposures given that substantial remediation efforts have further reduced exposure potential.

4.2.2 BPSOU Phase 1 Study of Blood Lead (ENVIRON 2014b)

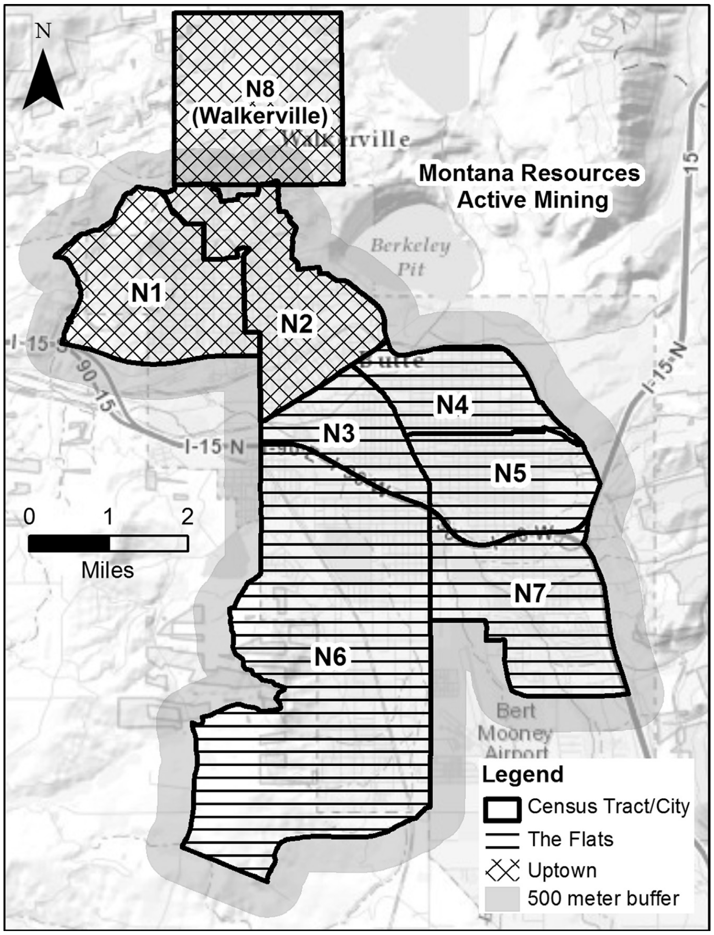
The primary study objective to be addressed by the BPSOU Phase 1 study was the review and evaluation of available RMAP data in order to document objectively the efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP might be needed. Lead was the primary focus of activities conducted under the RMAP at that time, so the Phase 1 study focused on evaluating BLLs in children who resided in Butte from 2003 to 2010 (ENVIRON 2014b, Schoof et al. 2016). The study focused on children from 12 to 60 months of age because children in this age range typically have higher BLLs and are more sensitive to the effects of lead than older people are. Butte blood lead records for nearly 3,000 children tested from 2003 through 2010 were considered in the study, along with additional records collected in 2011 and supplemental information about RMAP assessments and abatements that have been conducted.

4.2.2.1 Study Design

The design and conduct of the Phase 1 study was overseen by a working group of representatives from the same groups overseeing the Phase 2 study. After reviewing available data and medical monitoring study ideas, the working group agreed that the blood lead data compiled by the BSBHD for patients in the WIC program could provide a valuable dataset for assessing RMAP. Under the direction of the BSBHD, a de-identified database was created from paper medical records that included birthdates, BLLs, and dates of testing. To preserve confidentiality, addresses were replaced by codes assigning the address to one of eight neighborhoods in Butte (Figure 7). The neighborhoods focused on seven census tracts (with a 500-meter buffer added to the outer boundaries falling within census tract 8) and included an eighth neighborhood for Walkerville.

After exclusions for lack of complete data or addresses that were not verifiable or were outside the study boundaries, there were 2,796 records from 1,697 children during the study period from 2003 to 2010. One part of the Phase 1 study examined BLLs in different Butte neighborhoods to see if there were differences in lead exposures. As described in Section 4.2.1, the 1990 study found that while overall BLLs of Butte children were not elevated when compared with national BLLs, BLLs were higher in the Uptown area of Butte than in some neighborhoods in the Flats. A statistical model was used to account for differences in known lead exposure risk factors, specifically house age, child age and gender, and test season, and then the neighborhood BLLs were compared.

Figure 7. Approximate Boundaries of Uptown and the Flats (ENVIRON 2014b)



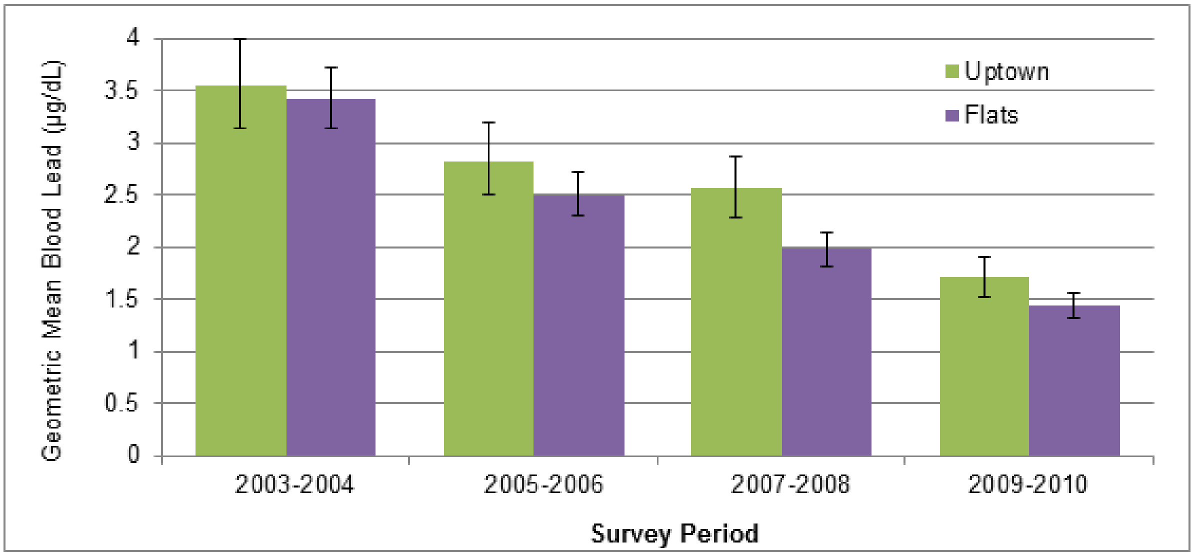
A second part of the Phase 1 study involved comparison of the Butte blood lead dataset with a matched dataset from a reference population. The reference population dataset was developed from blood lead data representative of levels in U.S. children collected as part of NHANES. NHANES is conducted over 2-year periods. This study examined four 2-year periods for which both NHANES and Butte data were available: 2003 to 2004, 2005 to 2006, 2007 to 2008, and 2009 to 2010.

These data were used to develop a reference dataset for this study, with adjustment of the NHANES dataset so that known risk factors for lead exposures were matched to conditions present in Butte. This included adjustments to match the distribution of house age, poverty levels, and races in the Butte study population. The resulting reference population had a sample size of 2,937. Butte blood lead data were then compared with the NHANES reference dataset to assess if Butte children were affected by Superfund sources in addition to lead exposure sources present in non-Superfund communities.

4.2.2.2 Blood Lead Results by Neighborhood

The results showed that the geometric mean in 2010 was less than half of the levels for 2003 for BLLs in children in Butte (Figure 8). Initial comparisons of BLLs across neighborhoods revealed no significant differences among the three Uptown neighborhoods or among the five Flats neighborhoods, so further analysis was focused on comparisons of Uptown with the Flats. During all four study periods (i.e., 2003 to 2004, 2005 to 2006, 2007 to 2008, and 2009 to 2010), children living in neighborhoods in Uptown were found to have higher average BLLs than children living in the Flats. The magnitude of the neighborhood differences was similar to the difference observed in the 1990 study.

Figure 8. Modeled Geometric Mean BLLs for Uptown vs. the Flats by Test Year with 95% Confidence Intervals



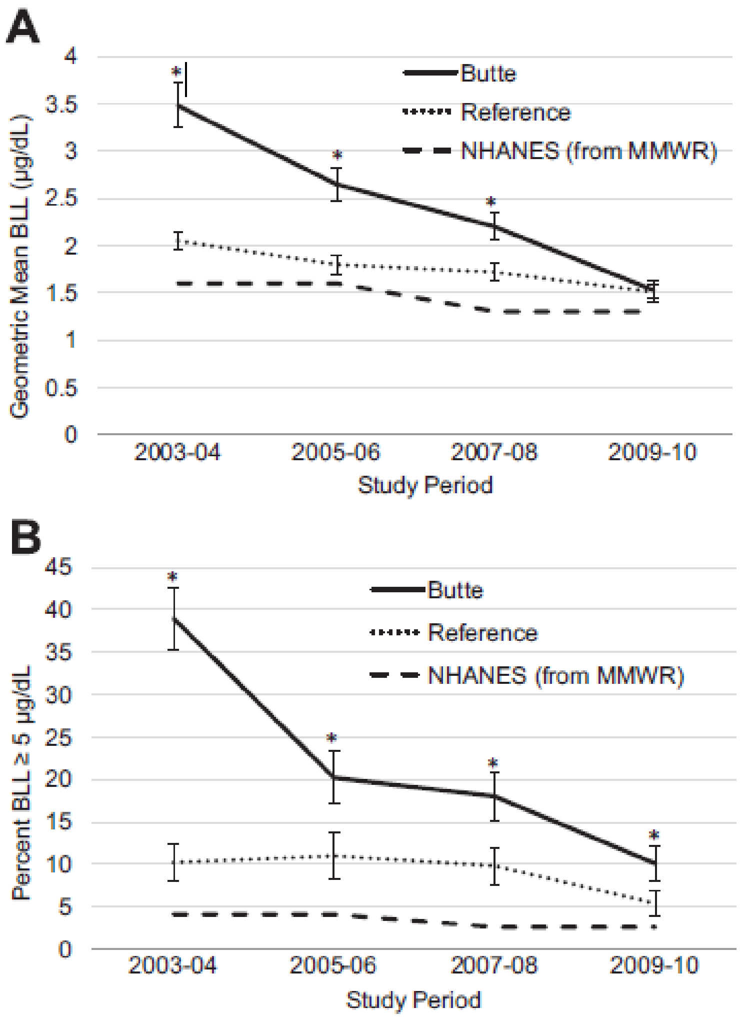
The RMAP assessment and abatement activities conducted within the study area were extensive, but few study area properties include both blood lead and abatement records for soil or paint. For that reason, this study could not directly assess if abatements reduced BLLs in Butte children. However, most RMAP activities occurred in the Uptown neighborhoods, which had similar frequencies of interior/exterior house paint and yard soil abatements. In the Flats, the number of paint abatements exceeded yard soil abatements. Based on this finding, review of the RMAP activities suggests that both soil and paint might be contributing to higher lead exposures in Uptown, while in the Flats, the relative contribution of soil lead to overall exposures is likely lower.

The difference between Uptown and the Flats was greater during the summer, when outdoor exposures would be greatest. ENVIRON (2014b) suggests that this finding means outdoor sources of lead exposures may be more important for Uptown children than for children living in the Flats.

4.2.2.3 Blood Lead Results vs. Reference Population

Average BLLs were found to be higher in Butte children than in the NHANES reference dataset during the first three test periods (i.e., during 2003 to 2004, 2005 to 2006, and 2007 to 2008). This difference disappeared for Butte children tested during 2009 to 2010. For that time period, there was not a statistically significant difference between BLLs in Butte children and the NHANES reference dataset (Figure 9). The percentage of Butte children with BLLs greater than 5 µg/dL also began approaching the percentage above 5 µg/dL in the reference population by the 2009 to 2010 period, although the Butte value was still significantly greater than the value for the reference population.

Figure 9. Comparison of BLLs in Butte, reference dataset, and NHANES* (ENVIRON 2014b)



*Note: Error bars represent 95% confidence intervals around the mean.

This study concluded that Butte BLL declines are likely reflective of the blood lead screening efforts, community-wide remediation, and ongoing RMAP, with additional factors not addressed in this study. Abatement programs that are currently ongoing in Butte include home evaluations and assistance in addressing non-Superfund-related sources of lead exposure. These programs can be important to community-wide soil remediation activities. Recommendations about the RMAP made in this study are discussed in Section 7.

4.2.2.4 Strengths and Limitations

The blood lead dataset developed for this study is the largest known recent dataset for a historical mining community. The large number of samples from the most vulnerable population (i.e., young children from low-income families), as well as house age data, combined with low analytical detection limits and venous verification of elevated BLLs, makes this a highly valuable dataset. Having a consistent dataset over an 8-year period supports analysis of trends in BLLs. The reference population is closely matched to the Butte population. Since this study is specifically examining trends in Butte's BLLs versus the reference population's BLLs, it is a good indicator of whether the abatement programs are lowering BLLs in Butte.

The primary limitation of this study is that individual BLLs could not be linked with individual-level exposure data, as was done in the 1990 study. For that reason, the ability to link BLL declines definitively to reduction in specific exposure sources is limited. The study outlined several additional limitations. For the reference population comparison, there was not a perfect match of available variables and demographic information. These include race, ethnicity, poverty, status of housing, and maternal education. This information was collected by NHANES but had to be inferred for Butte. Butte's data had specific sample dates, but NHANES included only a 2-year sample period and indicated whether it was winter/spring or summer/fall. Weighting could not fully account for the differences between the values of the Butte and the reference dataset, since not all the available data were the same. Another limitation was that the blood collection methods used differed, with NHANES using venous blood draws and Butte using blood from capillary samples. In addition, no specific information on lead exposure sources was available for either dataset.

4.2.3 2000 Blood Lead and Urine Arsenic Study (ATSDR 2001)

In April 2001, ATSDR, in collaboration with the BSBHD, conducted an exposure investigation focused on Walkerville that included blood lead and urine arsenic testing.

4.2.3.1 Study Design

The study targeted the area in Walkerville that had house dust lead concentrations ranging from 1,130 to 4,640 mg/kg and dust arsenic concentrations ranging from 3 to 131 mg/kg, as found by USEPA in 2000. Among the 49 houses listed by USEPA, this study targeted 28 of the houses with the highest indoor lead and arsenic dust concentrations that had resident children or regularly visiting grandchildren. Both children and adults participated in the testing.

4.2.3.2 Blood Lead Results

A total of 23 blood samples were collected and analyzed, from 9 children and 14 adults. All of the sample results were below the level of health concern (i.e., below 10 µg/dL) (Table 9). The results of 14 samples (61%) were below the detection limit of 1 µg/dL. The highest BLL was 5 µg/dL (in a 70-year-old man).

Table 9. Individual Walkerville BLL Results (ATSDR 2001)

Age (Years)	Sex	2000 Butte BLL (µg/dL)
2	Female	≤1
7	Female	≤1
10	Male	≤1
11	Female	≤1
12	Female	≤1
16	Male	<1
46	Female	<1

Age (Years)	Sex	2000 Butte BLL (µg/dL)
48	Female	<1
55	Female	<1
62	Female	<1
65	Male	<1
67	Female	<1
67	Female	<1
69	Male	<1
71	Female	<1
1	Male	1
5	Male	1
6	Female	1
44	Male	1
47	Male	1
74	Male	2
8	Female	3
70	Male	5

4.2.3.3 Urine Arsenic Results

A total of 25 urine samples were collected and analyzed; all of them had arsenic levels below the detection limit, 10 µg/L, and well below the level of health concern. Based on the questionnaire responses, one child reported "eating dirt," and 60% of the children reported "playing in the dirt." ATSDR (2001) concluded that this exposure investigation had "good community participation," and despite the high levels of lead and arsenic present in the dust of the selected homes, "all blood levels and urine arsenic levels were well below levels of health concern." They recommended continuing community education, maintaining homeowner awareness of the risks of exposure, and continuing the monitoring of BLLs through surveillance by Butte-Silver Bow County.

4.2.3.4 Strengths and Limitations

This study showed a lack of elevated exposure to lead and arsenic in one BPSOU neighborhood almost 20 years ago. There was better community participation than expected (a high percentage, i.e., 70%, of the target households participated, as did 100% of the eligible children); however, the study was focused on a small number of homes in one BPSOU neighborhood. Since this study focused on indoor dust exposure, it was conducted during the winter/early spring. This was done in order to look at BLLs in children when they are spending the majority of the time inside their homes. Consequently, soil exposure might have been lower than would be expected during the summer. Additionally, the study goal was to test children, but only 10 out of 24 participants tested for BLLs were under the age of 18 (and only 4 were younger than 7 years of age), and only 9 out of 25 participants for urine analysis were under the age of 18.

4.2.4 2015 Blood and Hair Data, Multiple Metals (Hailer et al. 2017)

A recent study by investigators at Montana Tech and other institutions sought to establish baseline metal concentrations in hair and blood and possible routes of exposure for adults living in Butte, Montana; these concentrations were compared with those in a control group from Bozeman, Montana (Hailer et al. 2017). The focus of this study was on current mining operations, which are unrelated to the historical mining operations that are the subject of the Phase 2 study. Air samples were collected during 2015, and it is assumed that the biological and soil samples were also collected that year.

4.2.4.1 Study Design

All study participants (116 from Butte and 86 from Bozeman) were at least 18 years of age. Butte participants had lived in Butte for a minimum of six consecutive months, and the Bozeman participants had not lived in Butte during any point in their lives. The Butte participants were older than the Bozeman participants, with the median age being 20 years higher, and they also had a higher basal metabolic index. Each participant filled out a lifestyle survey.

Hair samples were collected from all 116 participants from Butte and all 86 from Bozeman and were analyzed for metal content. No washing or sample preparation methods are described for the hair samples. As discussed in the introduction to Section 4, rigorous washing and sample preparation procedures are required to remove external contamination from hair samples. Blood samples were collected from a subset of the participants, including 81 from Butte and 72 from Bozeman. Soil samples were collected from residences of 32 Butte participants but not from any Bozeman participants. Soil samples appear to have been single grab samples collected from a 1-inch depth and sieved to less than 250 microns in diameter. The area of the yard sampled was not specified. Air samples were collected from two locations in Butte, one closer and one further away from the mine concentrator.

4.2.4.2 Hair Results

Concentrations in hair samples were measured for 36 elements. Seven elements (aluminum, arsenic, cadmium, copper, manganese, molybdenum, and uranium) exhibited statistically higher concentration levels in Butte participants than in Bozeman participants. Notably, levels of lead, which is the primary soil contaminant of concern in the BPSOU, were not elevated in hair. Because of the significant differences in age and other characteristics between the Butte and the Bozeman participants, significance of the differences in hair metal concentrations was reevaluated by regression analysis controlling for age, gender, and smoking status. In this analysis, only arsenic, manganese, and copper had significantly higher hair metal concentrations in Butte participants than in Bozeman participants.

4.2.4.3 Blood Results

Concentrations in blood samples were measured for 11 elements. Only arsenic had statistically higher concentrations in Butte participants than in Bozeman participants. Controlling for the same covariates described above, the median blood copper concentration was determined to be depressed in Butte participants, while there was no statistical difference in median blood manganese concentration.

4.2.4.4 Soil and Air Results

The soil samples were analyzed for 35 elements and compared with background samples collected in Silver Bow and Gallatin counties. Most lead, copper, and zinc concentrations were found to exceed concentrations for two Silver Bow County background samples (selected from the MDEQ background database). Soil lead and arsenic concentrations were all much lower than the Superfund action levels. No analysis of soil versus hair concentrations was reported. The air particulate samples were collected for 18 weeks from late May until October 1. The collected data were compared with ambient air concentrations in the U.S. Arsenic and manganese were stated to have higher concentrations than typical ambient concentrations.

4.2.4.5 Strengths and Limitations

This study focused on adults, whereas previous studies focused on children. It is also the first Butte study to incorporate measures of metals in hair, supporting assessment of exposures over the prior several months. Another strength is that more metals were analyzed in this study than in previous studies. The focus was more on assessing the impacts of current mining operations, especially on air quality, than on historical mining impacts in the BPSOU.

A primary limitation of this study was the significant disparity in ages between the Butte participants and the Bozeman participants. The regression analysis on metal levels in hair did control for participant ages, but concern remains that variations in metal toxicokinetics with age may not be adequately accounted for. Another concern is the lack of clarity about the hair processing method and whether it was adequate to remove external contamination. As described in Section 4.1.2, arsenic is cleared from the blood in a few hours, so blood concentrations are highly variable and are not a useful indicator of chronic exposure to low levels of arsenic (ATSDR 2007b). There is also no evidence that the study participants refrained from eating seafood for 3 days prior to the blood draws, which renders the results difficult to interpret.

As noted by the authors, urine arsenic data would provide a better indicator of exposure than blood arsenic data. Although soil samples were collected for a subset of Butte participants, they may not have been representative of yard soil for each participant, and no analysis of hair versus soil concentrations was presented. The authors also note a limitation in the air sampling data: Butte had wildfire smoke in the valley during weeks 12 to 14 of sampling, which could explain the high concentrations of arsenic and manganese in the air.

4.2.5 Summary of Butte Exposure Studies

Since 1990, a series of biomonitoring studies have been conducted in Butte, resulting in a more comprehensive picture of lead exposures than for almost any other U.S. mining community. The 1990 University of Cincinnati study (BSBDH/UC 1992) included almost 300 children and provided comprehensive analysis of lead and arsenic exposure. Exposures were not found to be markedly elevated, but differences among neighborhoods prompted formation of RMAP program. The ATSDR (2001) Walkerville study in 2000 included 23 blood lead samples, and 25 urine arsenic samples. Despite targeting homes with elevated dust concentrations, exposures were not elevated (all BLLs were below levels of concern and all urine arsenic was below limit of detection). The 2014 Phase 1 medical monitoring study (Ramboll 2014, Schoof et al. 2016) included BLLs for nearly 3,000 Butte children collected from 2003 through 2010. By 2010 mean BLLs were the same as expected for a comparable community with no mining influence, but the percentage above 5 µg/dL was still elevated. The Hailer et al. (2017) study focused on adults and incorporated measures of metals in hair and blood, finding elevated levels of some metals in hair, the study limitations preclude any conclusions about the source of the arsenic or the significance of the finding to exposure and risk from historic mine materials.

5. REVIEW OF DISEASE PREVALENCE AND RATE STUDIES

This section provides a brief review of epidemiological methods to study rates of diseases and linkages to possible causes, followed by a summary of five epidemiological studies conducted in Butte-Silver Bow County (only studies published by September 2019 are included). The results of self-reported disease prevalence studies conducted as part of the periodic community needs assessments conducted by BSBHD are described in Section 2.2.1.

5.1 Review of Epidemiological Study Methods

According to the World Health Organization, "Epidemiology is the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems" (WHO 2019). Epidemiology studies may be either clinical or observational (IPCS 2000). In clinical studies, exposures are varied by the investigators and the outcome is studied as, for example, in clinical trials of new drugs. In observational studies, disease rates are observed without intervention. Studies conducted in Butte have all been observational. Observational studies fall into two primary categories: descriptive and analytical (IPCS 2000).

- *Descriptive studies* include surveillance studies and surveys that are used to describe disease distribution. Another kind of descriptive study is an ecological study, which has exposure and disease information only for groups of people, as opposed to individuals. Ecological studies are hypothesis-generating studies primarily used to suggest future studies that should be done. All of the epidemiologic studies conducted in Butte-Silver Bow County fall into this general category of descriptive studies: none provides direct evidence of cause and effect, but they can be used to identify issues for future study or to generate hypotheses.
- *Analytical studies*, such as cohort and case-control studies, are more rigorous and are used to study determinants of disease. In cohort studies, exposure is known for individuals, and these individuals are followed to determine rates at which diseases develop. For example, numerous cohort studies have been used to link arsenic inhalation exposures to lung cancer among Anaconda smelter workers (Erraguntla et al. 2012). In case-control studies, groups of people with and without a disease are compared for different sources of exposure.

In the context of environmental epidemiology, the "environment" includes any and all factors that can influence a population's health status (Merrill 2008). According to Merrill (2008), "Confounding occurs when the relationship between a risk factor and outcome is influenced by an extrinsic factor."

The best way to assess the effects of environmental exposure on disease risk is to measure the incidence of the disease. Disease incidence measures the number of newly diagnosed cases in a population each year. Disease mortality, on the other hand, is the number of deaths that occur each year from the disease. Mortality reflects both the risk of getting the disease and the ability to get effective diagnosis and medical treatment. Two communities can have similar incidence rates, but very different mortality rates. In fact, a community can have a relatively low incidence rate, but a relatively high mortality rate because of limited access to services. Therefore, incidence rates are the best way to compare the risk of getting a disease and mortality rates are a way to compare access to care and treatment after people become ill.

Based on the community description presented in Chapter 2, examples of factors that affect death rates that may be different in Butte than in Montana or the U.S. (or have been different in the past) include smoking rates, alcohol and drug use, age distribution, urbanization, obesity rates, and socioeconomic status. Many of these factors have been identified in the Butte community needs assessments (PRC 2014, 2017; Section 2.2) as possibly adversely affecting health status in Butte, although some have changed over time. For example, a high percentage of Butte adults are overweight, whereas smoking rates and risk factors for cardiovascular disease declined to levels at or below those seen throughout Montana between the 2014 and 2017 assessments.

These current and historical lifestyle attributes are risk factors for many diseases. Environmental factors other than historical mining operations may also be affecting health in Butte. Historically, air quality was affected by residential wood-burning but after a woodstove change-out program was conducted, resulting in the change-out of more than 40 old, inefficient woodstoves and the installation of new, EPA-certified stoves, woodstove emissions have lessened. A chemical mass balance study to confirm the emissions reduction is under way. Thus, the interrelationships between these various extrinsic factors (i.e., physical, chemical, biological, psychosocial, demographic, etc.) over time must be considered to allow meaningful interpretation of population-level health comparisons, and epidemiology results need to be interpreted in the context of the strengths and limitations of each study in accounting for these extrinsic factors. All scientific studies have their particular strengths and limitations, which is why we review all pertinent studies in this report to develop informed judgements about health concerns in Butte.

5.2 Butte-Silver Bow Disease Studies

Wong et al. (1992) conducted an early ecologic study of skin cancer for Silver Bow and Deer Lodge counties. The first Butte-Silver Bow County cancer incidence study examining multiple types of cancer was conducted by ATSDR in 2002. In 2012, MDPHHS conducted an analysis of cancer incidence and mortality in Butte-Silver Bow County, which was followed by an update in 2018. Also, Davis et al. (2019) published a study that examined mortality rates for Deer Lodge and Silver Bow counties combined. These studies are described in the following sections.

5.2.1 An Ecologic Study of Skin Cancer and Arsenic Exposure (Wong et al. 1992)

This ecologic study of skin cancer incidence compared Silver Bow and Deer Lodge counties (the “exposed” study areas) with Gallatin and Park counties (the “control” study areas).

5.2.1.1 Methods

Wong et al. (1992) obtained records for skin cancers diagnosed from January 1980 through June 1986 from pathologist and hospital records and dermatologists’ office records in the four counties studied, as well as in nearby referral areas (Missoula, Helena, and Great Falls). These records included surgical and biopsy specimen reports. A total of 1,616 skin cancer patients accounted for 2,252 cases (National Cancer Institute definitions) or 2,451 cases (study definition). Each “case” represented an independent cancer. The primary risk factor for skin cancer is ultraviolet (UV) light exposure. The exposed and control study areas were at similar latitude and elevation, helping to reduce variation in UV exposures.

5.2.1.2 Results

Contrary to their hypothesis, Wong et al. (1992) found higher age-adjusted annual skin cancer rates for the control counties than for the exposed counties (Table 10). The rates in Deer Lodge County were significantly lower than the rates in Gallatin and Park counties. The rates in Gallatin County were significantly higher than the rates in Silver Bow and Park counties. The overall skin cancer rates in Silver Bow and Deer Lodge counties were "well within the range of skin cancer rates observed for other locations in the United States." Only two cancer cases similar to those reported for arsenic exposure (i.e., squamous cell carcinoma of the palms and soles) were reported in the entire cohort, and both occurred in Gallatin County.

Occupation data revealed a significant difference between the exposed and control counties, with Gallatin and Park having a much higher proportion of individuals with outdoor occupations, including agriculture, forestry, gardening, and logging. Because these occupations predispose people to greater UV exposure, this difference could account for much of the difference in rates across the counties.

Table 10. Age-adjusted Annual Skin Cancer Rates per 100,000 by County and Gender for Individuals

Sex	Silver Bow	Deer Lodge	Gallatin	Park
Male				
Rate	203.1	119.9	342.3	230.0
95% CI	177.8-232.0	88.3-162.3	313.8-373.4	187.3-282.0
Female				
Rate	181.5	135.7	315.5	209.0
95% CI	158.3-207.9	101.1-181.5	287.2-346.6	168.7-258.6
Total				
Rate	192.3	127.7	329.0	219.6
95% CI	175.0-211.4	103.6-157.3	308.7-350.6	189.5-254.2

Notes: CI = confidence interval. Rate = skin cancer cases normalized per 100,000 people.

5.2.1.3 Strengths and Limitations

Studies of skin cancer are not commonly available because the most common kinds of skin cancers (squamous cell and basal cell carcinomas) are not collected by central cancer registries.[5] Collecting surgical and biopsy data from individual sources is labor intensive and seldom done, making this a particularly valuable study. The study was also large enough to have power to detect relatively small increases in skin cancer rate. The authors estimated that for Silver Bow, the study had 89% power to detect a 10% increase in rate.

A major limitation of this study is the lack of occupational data that could be used to adjust skin cancer rates. There was also no way to assess the impact of emigration on the study populations. During the decade in which the study occurred, populations were declining in the exposed counties and growing in the control counties, although the authors note it is more commonly young people emigrating. In contrast, the average age of patients at diagnosis was 65 years of age. As described above, ecological studies such as this cannot determine casual inferences. Such inferences would be better supported by a case-control study in which individual residential and occupational histories were known.

[5] Melanoma skin cancer data are collected by central cancer registries in all U.S. states, including Montana's Central Tumor Registry.

5.2.2 Butte-Silver Bow County Cancer Incidence 1979-1999 (ATSDR 2002)

ATSDR (2002) conducted a study comparing cancer incidence rates in Silver Bow County residents with rates in the rest of Montana and the U.S.

5.2.2.1 Methods

Cancer incidence data were obtained from the Montana Central Tumor Registry in summer 2001. The data included all newly diagnosed cancer cases in Silver Bow County residents and the entire state of Montana from 1979 to 1999. Cancers analyzed included those of the urinary bladder, kidney, liver, lung, prostate, and skin. These cancers were chosen because of their association with arsenic exposure. For the representative population of the U.S., data were obtained from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program, from 1989 to 1998. The expected number of cancer cases among Silver Bow County residents was calculated for each cancer site by age group (20 to 54, 55 to 64, 65 to 74, and 75+). The expected number is how many cases there would be if the incidence rate in Silver Bow County were the same as the rate in the comparison populations, Montana or the United States.

5.2.2.2 Results

ATSDR (2002) found statistically significantly higher standardized incidence rates (SIRs) of skin cancer among Silver Bow County residents compared with residents of Montana and the U.S. (Table 11). A contrasting trend was apparent in the SIRs when Silver Bow rates were compared with those in Montana versus U.S. populations. The SIR in Butte-Silver Bow was highest for people 20 to 54 years old when Montana was used as a reference, while the SIRs were highest among people 65 years of age and older when the U.S. was used as a reference. ATSDR (2002) notes that skin cancers are more prevalent in white populations, and there is a higher percentage of Caucasians in Silver Bow County than in the U.S., but the demographics of Butte-Silver Bow are similar to those of Montana as a whole, so demographics would not account for differences when Montana is used as the reference. Another factor to consider when comparing Butte to the rest of Montana and the U.S. is elevation. UV light exposure is the major cause of nonmelanoma

Table 11. Standardized Skin Cancer Incidence Ratios Using the Montana or the U.S. Population as a Reference, 1979-1999 (ATSDR 2002)

Montana Reference					
Age Categories	**Observed Cases**	**Expected Cases**	**SIR***	**Lower 95% CI**	**Upper 95% CI**
20-54	43	28.4	**1.51**	1.10	1.99
55-64	25	19.8	1.26	0.82	1.79
65-75	39	30.3	1.29	0.92	1.72
75+	39	39.8	0.98	0.70	1.31
20+ (all ages combined)	146	118.3	**1.23**	1.04	1.44

U.S. Reference					
Age Categories	**Observed Cases**	**Expected Cases**	**SIR**	**Lower 95% CI**	**Upper 95% CI**
20-54	43	44.1	0.98	0.71	1.28
55-64	25	21.4	1.17	0.75	1.65
65-75	39	26.7	**1.46**	1.04	1.95
75+	39	25.4	**1.54**	1.09	2.05
20+ (all ages combined)	146	117.6	**1.24**	1.05	1.45

Notes: *SIR = standardized incidence rate, bolded values indicate statistically significant increases. CI = confidence interval.

skin cancer, and the higher UV exposure at higher elevations such as Butte's is associated with higher skin cancer rates (Narayanan et al. 2010).

No other cancer rates were consistently elevated. Urinary bladder, kidney, and lung cancer had elevated rates in some age groups, but results were not consistent throughout the whole dataset. Liver and prostate cancer had no elevated rates.

5.2.2.3 Strengths and Limitations

A strength of this study was the use of age-adjusted incidence rates and comparison of incidence rates over a long period of time (20 years). The previous analysis by Wong et al. (1992) looked at skin cancer incidence for a shorter period of only 6 years.

Many study limitations were noted by ATSDR (2002), but these were generally not judged to consistently bias SIRs towards positive or negative associations. Limitations described by ATSDR (2002) include the inability to account for in- and out-migration, the inability to adjust for demographics other than age, and the absence of assessment of temporal variables (i.e., were subjects exposed before the occurrence of disease, and were these exposures early enough to account for cancer latency). The ability to determine if the increased skin cancer rates were associated with arsenic exposure from soil was limited by a lack of exposure data. Additionally, arsenic is associated only with nonmelanoma skin cancers, and ATSDR (2002) was able to assess only total skin cancer incidence (malignant melanoma and nonmelanoma skin cancers).

5.2.3 Butte-Silver Bow Cancer Incidence and Mortality 1981-2010 (MDPHHS 2012)

As part of the Phase 1 study and to address broader community concerns, the working group identified the need for an update to and expansion of the 2001 ATSDR study of Silver Bow County cancer incidence rates (ATSDR 2002).

5.2.3.1 Methods

The updated study was conducted by the MDPHHS (2012) and included consideration of the most common cancers, as well as cancers associated with exposure to Superfund COCs. MDPHHS evaluated cancer incidence and mortality from 1981 through 2010 among Silver Bow County residents using data from Montana death records and the Montana Central Tumor Registry (MCTR). Cancer incidence and mortality rates among Silver Bow County residents were compared with state and national rates to assess whether or not cancer rates were elevated in Silver Bow County. Cancers that are diagnosed or treated among Montana residents are required, by state law, to be reported to the MCTR. Similarly, all deaths that occur among Montana residents are also to be reported to MDPHHS. It is estimated that MDPHHS has records of more than 95% of all cancers diagnosed and treated among Montana residents.

According to MDPHHS, the best way to assess the effects of environmental exposure on cancer risk is to measure cancer incidence. Cancer incidence measures the number of newly diagnosed cancer cases in a population each year. Cancer mortality, on the other hand, is the number of deaths that occur each year from cancer. Mortality reflects both the risk of getting cancer and the ability to get effective diagnosis and medical treatment. Two communities can have similar incidence rates but very different mortality rates. In fact, a community can have a relatively low incidence rate but a relatively high mortality rate because of limited access to services. Therefore, incidence rates are the best way to compare the risk of getting a disease, and mortality rates are a way to compare access to care and treatment after people become ill.

Cancer is not a single disease. Cancer is a general term that includes over 100 different kinds of cancer. Each type of cancer has its own risk factors. The four most common types of cancer are prostate, female breast, colorectal, and lung and bronchus. The cancers known to be associated with exposure to arsenic, a chemical of concern in the BPSOU, are lung and bronchus cancer, bladder cancer, kidney cancer, and liver cancer.

5.2.3.2 Results

Most of the residents of Silver Bow County reside in Butte, often near historical mining operations. To establish a background rate of cancer, MDPHHS assessed the incidence rate of all cancers combined, as well as the rates for each of the four most common cancers (i.e., prostate, female breast, lung and bronchus, and colorectal cancers). MDPHHS found that the age-adjusted incidence rates among Silver Bow County residents for all cancers combined, and for each of the four most common cancers were statistically the same as or lower than those for Montana and the U.S. during three 10-year time periods from 1981 through 2010. MDPHHS assessed cancers known to be caused by or associated with the Superfund-related metals, specifically lung and bronchus, bladder, kidney, and liver cancers. MDPHHS found that the incidence rates for each of these cancers were statistically lower than those for Montana and the U.S. during three 10-year time periods from 1981 to 2010.

MDPHHS also examined cancer mortality rates. The MDPHHS cancer mortality rates for all cancers combined were lower in Silver Bow County than in Montana in two of the three 10-year time periods. Mortality rates for cancers of the prostate, breast, and lung and bronchus were not elevated in Silver Bow County, while the mortality rate for colorectal cancers was elevated in all three time periods. The disparity in cancer incidence versus mortality findings for colorectal cancers suggests possible issues in Butte with early screening and access to care. Section 2.2.1 describes how colorectal screening rates in Butte were in fact low until quite recently. For arsenic-related cancer sites, MDPHHS found that mortality rates for lung and bronchus and bladder cancers were statistically the same in Silver Bow County as in the rest of Montana for three 10-year time periods from 1981 to 2010. There were too few kidney and liver cancer deaths for MDPHHS to calculate stable mortality rates for the three 10-year time periods.

5.2.3.3 Strengths and Limitations

A key strength of this cancer registry study is the completeness of the MCTR which contains over 95% of all cancers diagnosed and treated in MT. The data are collected in standardized way so that they may be compared to national cancer incidence data. Cancer incidence can be compared year to year since 1979.

A limitation of all registry studies is that they cannot assess environmental exposures of cancer patients. The MCTR only collects information on where a person lived at the time of cancer diagnosis, therefore, their residential history, that may affect their historical exposures, is not captured. The MCTR also collects only limited occupational information; only one occupation is recorded, and it is often the most recent job a patient had before their diagnosis or the information may be missing.

5.2.4 Butte-Silver Bow Cancer Incidence and Mortality 2002-2016 (MDPHHS 2018)

In 2018, the Montana Department of Public Health and Human Services (MDPHHS) updated the 2012 Silver Bow County cancer mortality and incidence analysis extending the analysis through 2016.

5.2.4.1 Methods

As before MDPHHS (2018) used data from Montana death records and the MCTR to examine the incidence and mortality of all cancers combined, the most common types of cancer (female breast, lung and bronchus, colorectal, and prostate cancers), and specific cancer sites associated with the Superfund contaminants of concern (lung and bronchus, bladder, kidney, and liver) (MDPHHS 2018). MCTR data on cancer mortality is based on the underlying cause of death on the death certificate and was provided by the Montana Office of Vital Statistics. All incidence and mortality rates in the MDPHHS (2018) analysis are age-adjusted to the U.S. Standard Million Population.[6]

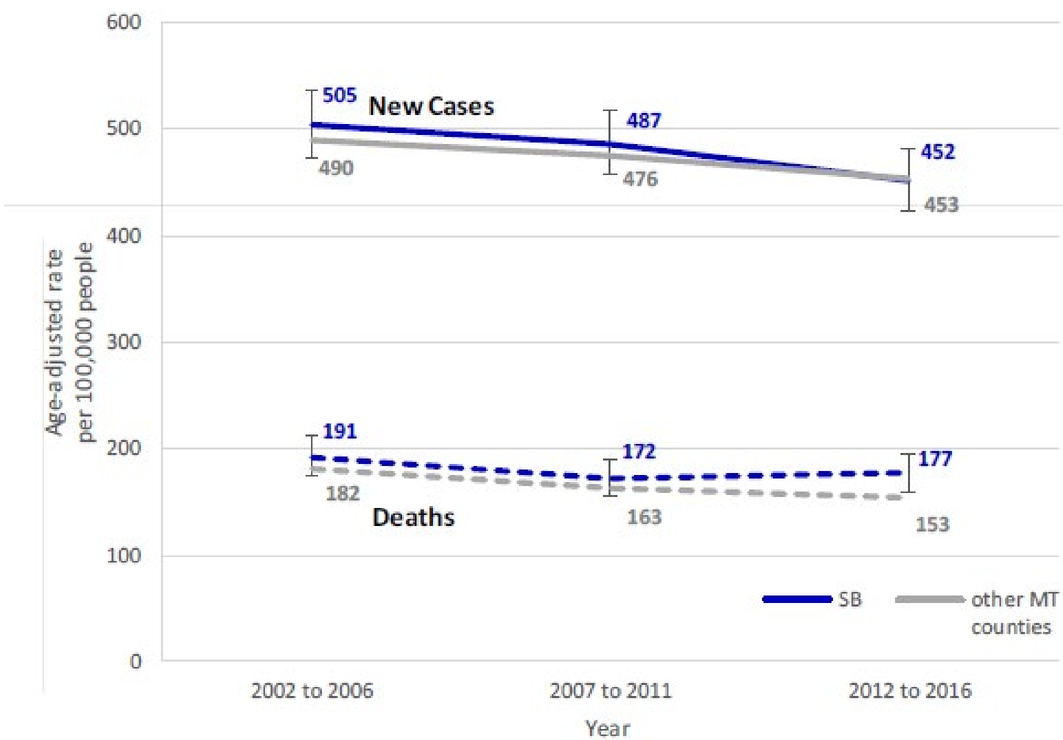
According to MDPHHS (2018), there are about 200 new cases of cancer and 80 cancer deaths among Silver Bow County residents each year. Cancer incidence and mortality rates among Silver Bow County residents were compared to the rates in other Montana counties to assess whether or not cancer is elevated in Silver Bow County. Cancers which are diagnosed or treated among Montana residents are required, by state law, to be reported to the MCTR.

5.2.4.2 Results

MDPHHS found that age-adjusted incidence rates for all cancers combined were statistically the same as rates for other Montana residents from 2002 through 2016 (Figure 10). This finding extends and confirms the findings of the prior study. Age-adjusted mortality rates for all cancers combined were significantly higher among Silver Bow County residents compared to other Montana residents from 2012 to 2016, whereas from 2002 through 2011 the rate of cancer deaths was the same among Silver Bow County residents as other among other Montana residents (Figure 10).

[6] Standard populations, often referred to as standard millions, are the age distributions used as weights to create age-adjusted statistics. Files containing standard population data for use in statistical software are available from the National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program. https://seer.cancer.gov/stdpopulations/

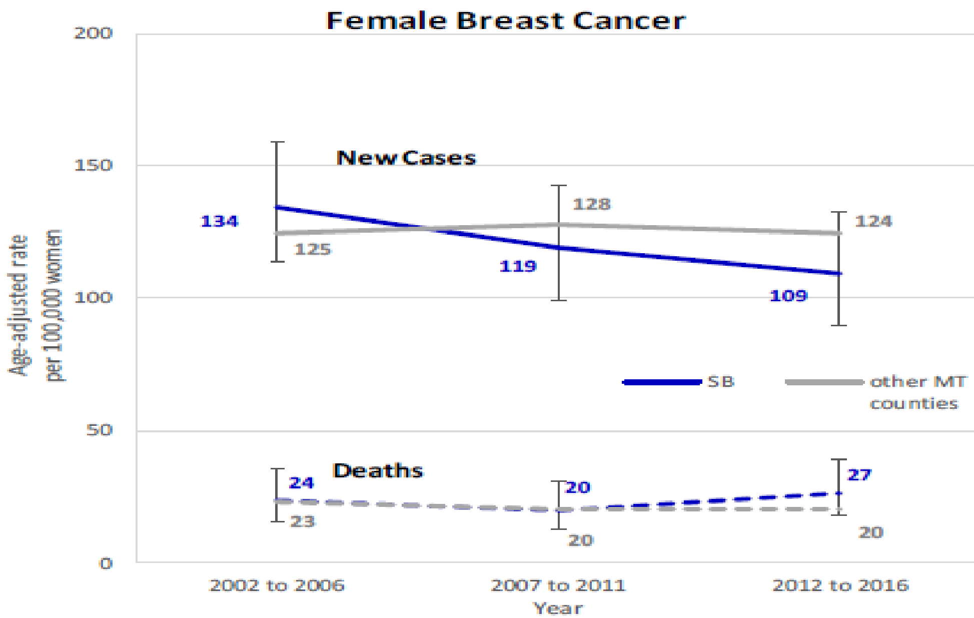
Figure 10. New Cancer Cases and Cancer Death Rates Among Silver Bow County Compared to Other Montana Counties (MDPHHS 2018)



As discussed in Section 5.2.3, incidence rates are the best way to compare the risk of getting a disease and mortality rates are a way to compare access to care and treatment after people become ill. The following figures show the incidence and mortality rates for the most common types of cancer (female breast, prostate, lung and bronchus, and colorectal cancers).

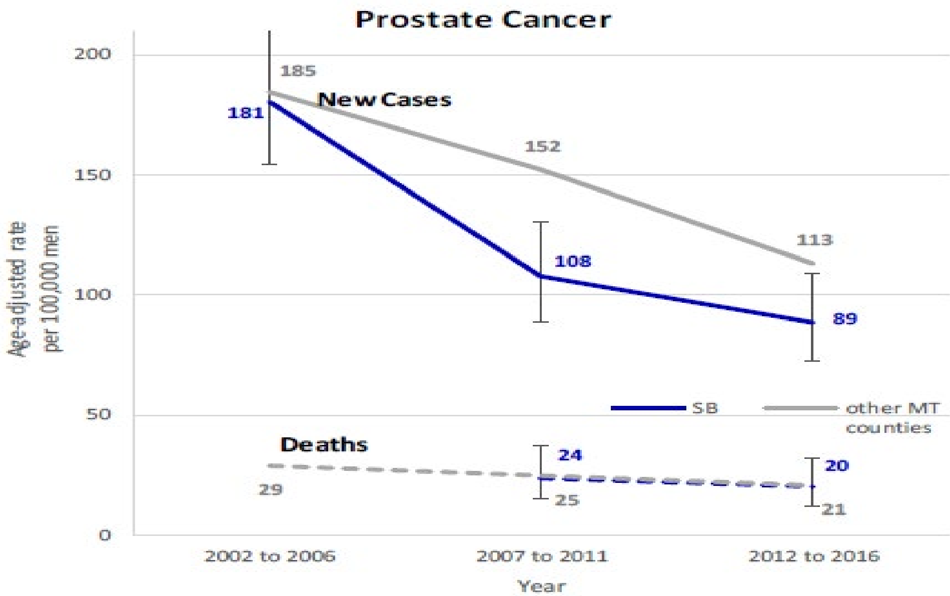
The rate of new female breast cancer cases and the rate of breast cancer deaths in Silver Bow County were statistically the same as the rate for other Montana counties from 2002-2016 (Figure 11).

Figure 11. Incidence and Mortality Rates for Female Breast Cancer in Silver Bow County Compared to Other Montana Counties (MDPHHS 2018)



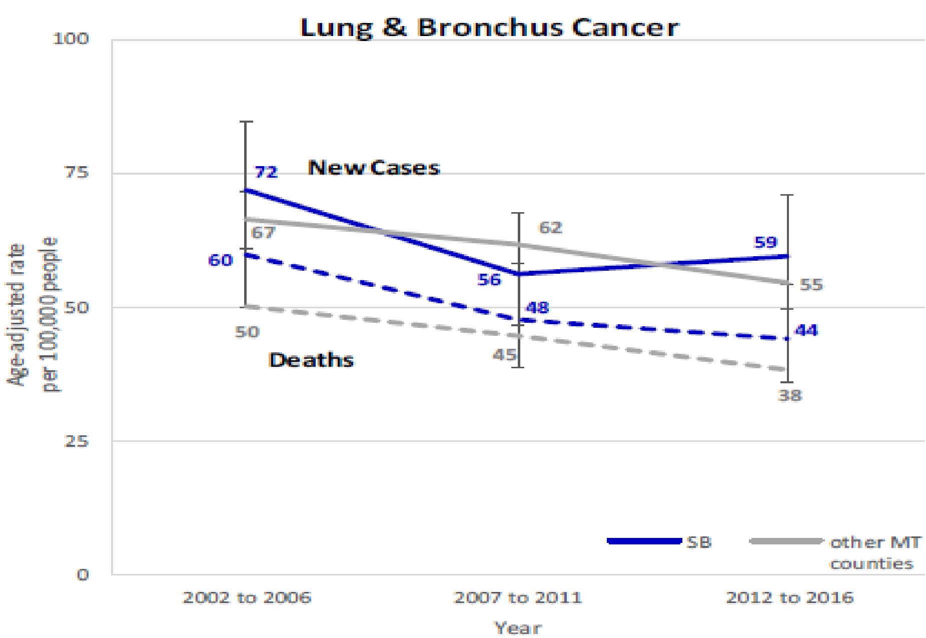
Since the 2002 to 2006 period, prostate cancer rates have been declining in both Silver Bow County and the rest of Montana. The rate of new prostate cancer cases in men in Silver Bow County compared with the rest of Montana was significantly lower from 2007-2016, while from 2002 through 2006 the Silver Bow County rate was the same as for the rest of Montana (Figure 12). The deaths from prostate cancer was the same in both groups.

Figure 12. Incidence and Mortality Rates for Prostate Cancer in Silver Bow County Compared to Other Montana Counties (MDPHHS 2018)



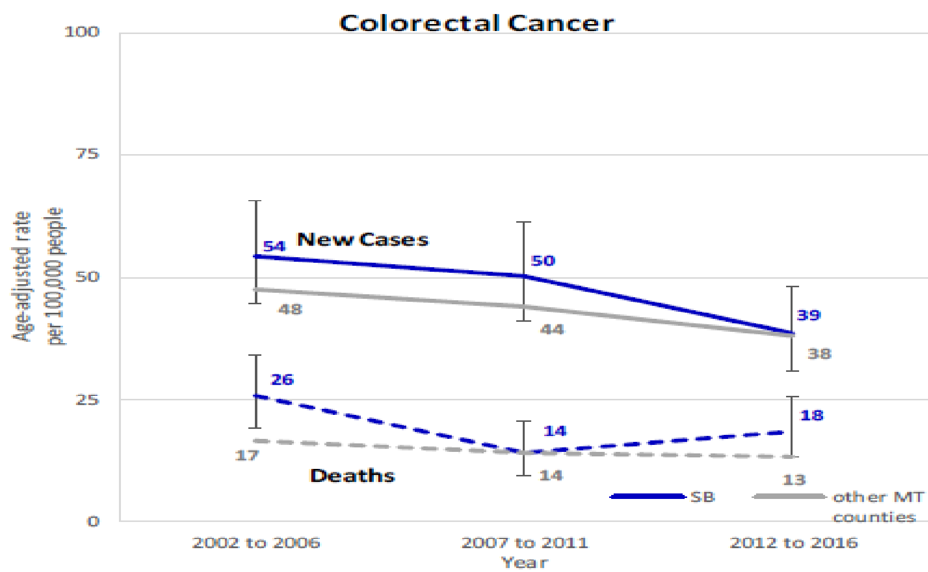
The rate of new lung and bronchus cancer cases and the rate of deaths due to lung and bronchus cancer were statistically the same in Silver Bow County and the rest of Montana throughout the study period (Figure 13).

Figure 13. Incidence and Mortality Rates for Lung and Bronchus Cancer in Silver Bow County Compared to Other Montana counties (MDPHHS 2018)



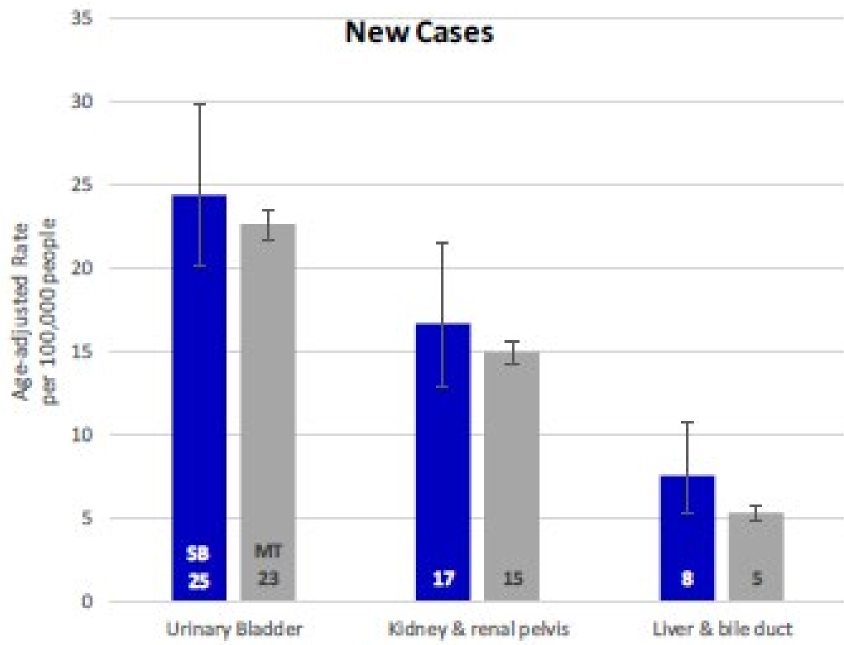
The rate of new colorectal cancer cases was the same statistically in Silver Bow County and the rest of Montana throughout the study period (Figure 14). Since 2006, deaths due to colorectal cancers have declined in Silver Bow County and are no longer statistically elevated in comparison to the rest of Montana.

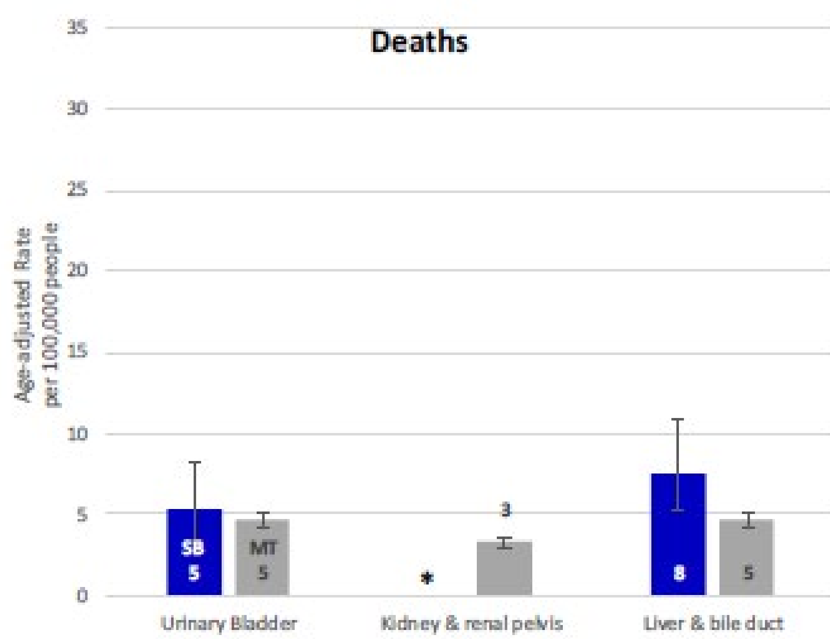
Figure 14. Incidence and Mortality Rates for Colorectal Cancer in Silver Bow County Compared to Other Montana Counties (MDPHHS 2018)



In addition to the most common cancers, rates of cancers of bladder, kidney and liver were also examined for the period from 2007 through 2016 due to potential association of these cancers with Superfund-associated metals (Figure 15). No significant differences in bladder cancer incidence or mortality were observed. MDPHHS (2018) notes that smoking is a significant risk factor for bladder cancer and risk of bladder cancer is there times higher in smokers as compared with nonsmokers. Kidney cancer incidence was also not statistically elevated, and there were too few kidney cancer deaths for MDPHHS to calculate stable mortality rates. Liver cancer incidence was not statistically elevated, but mortality was statistically elevated among Silver Bow County residents compared to other Montana residents from 2007-2016.

Figure 15. Incidence and Mortality Rates of Selected Cancer Sites in Silver Bow County Compared to Other Montana Counties (MDPHHS 2018)





* too few deaths to calculate a stable rate.

5.2.4.3 Strengths and Limitations

Consistent with the prior MDPHHS (2012) analysis, a key strength of this cancer registry study is the completeness of the MCTR which contains over 95% of all cancers diagnosed and treated in MT. The data are collected in standardized way so that they may be compared to national cancer incidence data. Cancer incidence can be compared year to year since 1979.

A limitation of all registry studies is that they cannot assess environmental exposures of cancer patients. The MCTR only collects information on where a person lived at the time of cancer diagnosis and their most recent occupation, therefore, their residential and occupational histories, that may affect their historical exposures, are not captured. Many of the cancers studied have other known risk factors that could not be controlled for in this study. For example, controlling for smoking is a key factor in comparing rates of lung, bladder, and other cancers. Differences in smoking rates between Silver Bow county and other Montana counties could obscure other associations. Smoking rates are a risk factor for many diseases. The Butte community health assessment results summarized in Section 2 showed that the 2017 smoking rate in the study area (12.4%) demonstrated a marked decline from 2014 (20.9%). The 2017 study area rate was significantly less than the Montana rate of 18.9% and is also less (but not significantly) than the U.S. rate of 14.0%. Nevertheless, historically higher smoking rates in Butte could be factors in currently reported new cancer cases.

5.2.5 Disease Mortality Deer Lodge and Butte-Silver Bow Counties (Davis et al. 2019)

Davis et al. (2019) sought to examine the health effects of living in proximity to two regional Superfund sites with a long history of ongoing remediation.

5.2.5.1 Methods

The study approach was to examine mortality rates from 2000 to 2015 of residents in Deer Lodge and Silver Bow counties compared to other Montana residents. Davis et al. (2019) tested two different hypotheses:

- "There will be significantly higher standardized mortality ratios for a priori selected causes of mortality related to heavy metal exposure, during 2000–2015, for residents of Deer Lodge and Silver Bow compared to the comparison counties.
- There will be significant decreases in the standardized mortality ratios for a priori selected causes of mortality related to heavy metal exposure for residents of Deer Lodge and Silver Bow compared to the comparison counties over the 2000-2015 study period."

First, the investigators selected mortality outcomes associated with the metals identified as associated with each Superfund site. In Deer Lodge, it was reported that arsenic, cadmium, copper, lead, and zinc had elevated levels in soil, air, water, and house dust. In Silver Bow it was reported that there were elevated levels of the same metals plus aluminum, iron, manganese, mercury, molybdenum, silver, and uranium.

Mortality data was then obtained from the Centers of Disease Control and Prevention (CDC) WONDER site. Mortality due to select cancers, cerebrovascular and cardiovascular diseases, neurological conditions, and organ failures included in the multiple causes of death recorded on the death certificate were analyzed. The comparison counties included the other 54 counties of Montana. The data was also age and sex-adjusted to limit confounding factors.

5.2.5.2 Results

For cancers, cerebrovascular and cardiovascular conditions, and organ failures, Deer Lodge and Silver Bow had overall higher mortality compared to the rest of Montana from 2000 to 2015. Neurological conditions mortality was not elevated compared to the rest of Montana. From 2000 to 2015 mortality due cancer, cerebrovascular and cardiovascular, and neurological conditions decreased among Silver Bow and Deer Lodge county residents. The organ failure mortality remained the same over the study period.

Overall, the authors conclude the first hypothesis that there would be significantly higher SMRs in Deer Lodge and Silver Bow compared to the other counties was supported by three groups of conditions (i.e., cancers, cerebrovascular and cardiovascular conditions, and organ failures). They conclude the hypothesis was not supported for mortality due to neurologic conditions. They conclude the second hypothesis that there would be a significant decrease in SMRs in Deer Lodge and Silver Bow compared to other counties over the study period was supported for all conditions except for mortality due to organ failure.

5.2.5.3 Strengths and Limitations

A strength of this study is consideration of a multiple health endpoints in addition to cancer. The finding that neurological conditions had about equal mortality compared to the comparison group is of particular interest due to community concerns about neurological diseases in Butte combined with the lack of identified approaches to examine this health endpoint.

One limitation of this study compared with the Butte medical monitoring study goals is that the results are for combined data for Deer lodge and Silver Bow counties, limiting the ability to identify Butte Silver Bow associations.

A methodological limitation is due to the use of “multiple case of death” rather than “underlying cause of death” to define its mortality outcomes. Multiple cause of death includes not only the underlying cause but also the immediate cause of death and other contributory conditions listed on the death certificate. Multiple cause of death counts more deaths than underlying cause of death and may overestimate deaths due to cancer and cardiovascular disease. While Davis et al. acknowledge that reliance on death certificates is a limitation of their study, they do not explore this limitation further.

As described by the authors, this was an ecological study so data on the exposure levels of metals was not available for individuals. Because their data were not linked to exposures the results do not adequately support the conclusions that elevated mortality rates are associated with metals exposure or that reductions in rates are associated with ongoing remediation.

5.2.6 Summary of Butte Epidemiology Studies

Five studies of disease prevalence in Butte were identified, beginning with an ecological study of skin cancer published in 1992, and followed by three surveillance studies of cancer incidence for the Butte population compared with state and/or national data in 2002, 2012 and 2018, and a study of multiple diseases published in 2017. The 2012 and 2018 studies also considered cancer mortality rates. The periodic community needs assessments conducted by BSBHD also provide self-reported disease prevalence rates in comparison with rates in Montana and the U.S. (described in Section 2).

Wong et al. (1992) conducted an early ecologic study of skin cancer for Silver Bow and Deer Lodge counties that showed higher skin cancer rates in the two control counties, likely due to higher rates of farming and associated exposure to sunlight. In contrast, the first Butte-Silver Bow County cancer incidence study examining multiple types of cancer conducted by ATSDR in 2002 found elevated skin cancer rates, while skin cancer prevalence has not been found to be elevated in the most recent community needs survey. In 2012, MDPHHS conducted an analysis of cancer incidence and mortality in Butte-Silver Bow County, which was followed by an update in 2018. Davis et al. (2019) published an ecological study that examined mortality rates for Deer Lodge and Silver Bow counties combined. No consistent trends have emerged from these studies to suggest there are elevated rates of disease that are likely associated with environmental exposures.

None of the disease prevalence and rate studies conducted to date in Butte-Silver Bow included individual level exposure data or occupational history. As described in Section 5.1, such surveillance and ecological studies are hypothesis generating studies primarily used to suggest future studies that should be done. So, none of these studies can be linked to causes of observed elevated incidence or mortality. They are all valuable for use in identifying areas of focus for future studies.

MDPHHS (2012, 2018) and ATSDR (2002) defined cancer-related mortality using underlying cause of death (i.e., the immediate cause of death) recorded on the death certificate rather than using multiple cause of death (i.e., intermediate causes), as Davis et al. (2019) did. MDPHHS's approach to defining cancer-related mortality in this way is a standard surveillance method used by state and federal public health agencies. Studies have shown that the two methods of defining cause-specific mortality can yield greatly different results, with the multiple cause definition counting more deaths than underlying cause (Redelings et al. 2006). The different methods in defining cancer-related mortality may account for the different conclusions of the MDPHHS analysis and Davis et al. study the immediate cause of death, and not intermediate causes, underlying causes, or other health disorders a person had at the time of death, is used by state health departments in calculating mortality rates.

6. PHASE 2 BLOOD LEAD STUDY

The Phase 2 study was conducted using available data collected under the RMAP to evaluate trends in BLLs in young children over time, by Butte neighborhood, and to the extent possible, in comparison to a reference population. The objective of this study was to determine if there are trends in the data that show whether the BLLs have changed since the Phase 1 study and if there are differences in the BLLs due to demographic or geographic differences. This section includes a description of the refinement of the database to support the study objectives, summary statistics including comparisons with Phase 1 study results, review of demographic and geographic parameters, a neighborhood comparison, and comparison of trends in Butte versus national data.

6.1 Compilation of the Blood Lead Database

Blood lead data used in this study originated from BSBHD blood lead testing records for the period from 2011 through 2017. Most of the blood lead records came from patients recruited for regular blood lead testing through the WIC program in Butte.

Compilation of data for the current study followed the same approach as for the Phase 1 study in terms of focusing on individuals tested at ages that fell within the study age range of 12 to 60 months. Complete records were defined in the study as those that included individual birthdate and gender, as well as test date and test result. Only records located in one of the Butte neighborhoods from the Phase 1 study were included. To ensure that individuals could not be identified by the study investigators, data acquisition was conducted in a two-phase approach. First, the BSBHD provided coded addresses. The addresses were used to identify house age and associated neighborhood, and the addresses were then deleted. Separately, the BSBHD provided the blood lead data, with test dates, gender, and age linked to a code without an address.

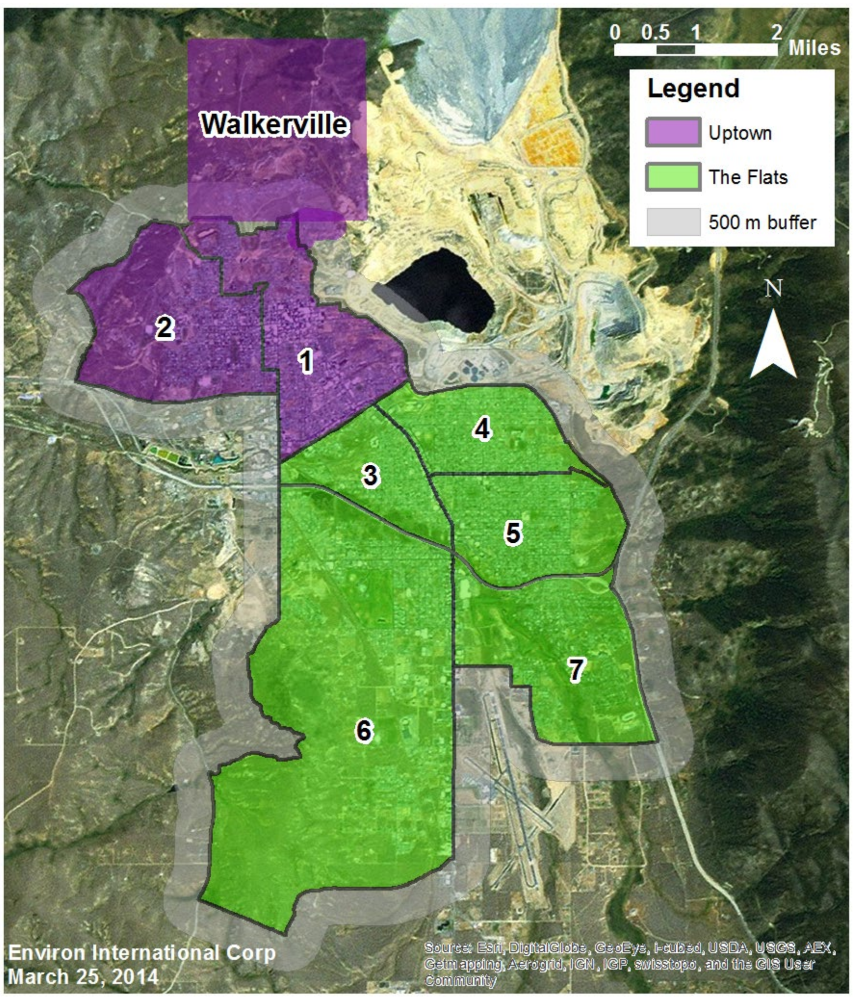
Compilation of 2011 through 2017 data and presentation of summary statistics are based on the design of the Phase 1 study. For that reason, the data and the study area used in the Phase 1 study are described before the data for the current study are presented.

For the Phase 1 study, blood lead data were compiled from the BSBHD blood lead testing records, resulting in a blood lead database containing over 7,000 blood lead records with collection dates primarily from 2002 to 2012. Individuals represented in the database included infants, children, and adults with age at time of testing ranging from 1 month to 70 years. Summary statistics are presented for all age categories, but only data for individuals tested at ages that fell within the study age range of 12 to 60 months were included in the subsequent analyses. Complete records included in the study encompassed individual birthdate and gender, as well as test date and test result.

The database included results from both capillary (finger or heel stick) and venous (whole blood) sample collection methods. Most blood lead samples had been submitted for laboratory analysis with a detection limit of 1.0 µg/dL; however, in December 2011, the BSBHD began using a portable lead analyzer, LeadCare II, with a detection limit of 3.3 µg/dL. Use of the LeadCare II analyzer was initiated to allow for more immediate follow-up when blood lead results were elevated. Prior to March 2013, WIC was referring its clients for venous confirmation sampling if LeadCare II results exceeded 9.9 µg/dL. Since then, confirmations are recommended whenever a LeadCare II result exceeds 5.0 µg/dL, the level CDC currently recommends for identifying children with elevated BLLs. The CDC (2012) states: "This new 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." Records obtained by use of the LeadCare II device were excluded as these lacked sufficient sensitivity and precision to support the Phase 1 study objectives.

The BSBHD records did not include house age information. When it could be located, this information was later added to the database from land survey and property tax data. Additionally, using the address data, all records were mapped to a census tract where the tested individual's residence was located, and these census tract assignments were also added to the database. The Phase 1 study area included eight neighborhoods (N1 to N8) derived from Silver Bow County census tracts 1 through 8, with several modifications (Figure 16). Census tract 8 essentially surrounds census tracts 1 through 7, and it has very low population density, except for the Walkerville area. For that reason, the Walkerville area was identified as N8. As shown in Figure 16, a 500-meter buffer area was added at the outer boundaries of census tracks 1 through 7 to create neighborhoods N1 through N7. This was done to ensure that data for individuals living close to those census tracts were included in the study.

Figure 16. Butte Blood Lead Study Neighborhoods



6.2 Refinement of the Blood Lead Database

As part of the Phase 2 study, approximately 3,400 records of blood lead data were received. A unique identifier, called a Butte State Bureau code, was assigned to each of the records to ensure BLLs could be matched anonymously to the address location for analysis. Of these records, 3,278 were determined to be within the study area (see Section 6.3). Most of the records were for children from 12 to less than 60 months of age (i.e., 2,330, with more than 400 records each year from 2012 to 2015, and less than 300 in 2016 and in 2017) (Table 12). In most years, relatively few records were available for other age groups, although there were over 100 records for infants in 2016 and 2017 and over 100 records for adults in 2012 and 2013. The reasons for the variation in populations tested from year to year are not known.

Table 12. Counts of Blood Lead Samples by Year, Gender, and Age Group

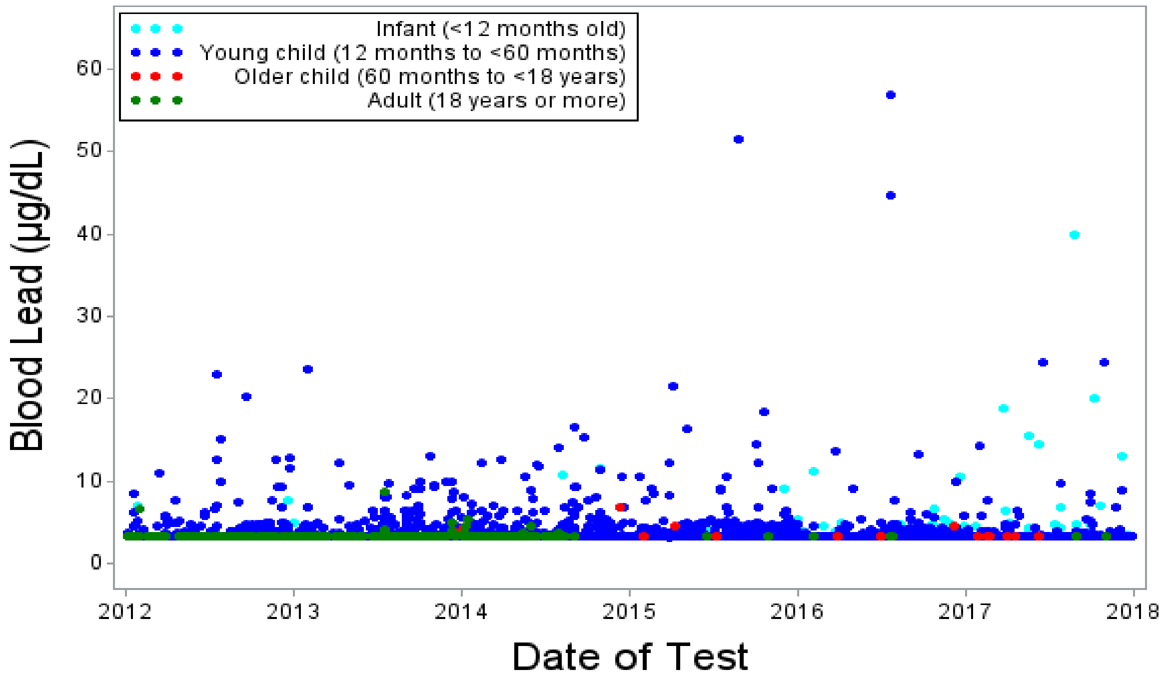
Year	Total Count	Male	Female	Infant < 12 mo.	12 to <60 mo.	5 to 18 years	≥18 years
2012	602	212	390	10	447	10	135
2013	591	229	362	17	454	12	108
2014	542	222	320	11	445	10	76
2015	475	255	220	33	436	4	2
2016	467	245	222	182	277	5	3
2017	400	211	189	120	271	7	2

Summaries of the distribution of BLLs are provided in Table 13 and Figure 17. Among the infants less than 12 months old, 20 of 373 tested (or 5.4%) had BLLs greater than 5 µg/dL. Among children 12 to 60 months of age, 172 of 2,330 (or 7.4%) had BLLs greater than 5 µg/dL. Only 3 of the 326 (0.9%) adults tested had BLLs greater than 5 µg/dL. These data confirm that it is appropriate to focus the Phase 2 study on children from 12 to less than 60 months of age.

Table 13. Counts and Percent by BLL and Age Group

Age Group	Blood Lead Category Counts (percent of age group)				
	Limit of Detection or below (3.33 µg/dL)	>3.3 to <=5 (µg/dL)	>5 to <=10 (µg/dL)	>10 (µg/dL)	Total
Infant (<12 months old)	307	46	10	10	373
	(82.3)	(12.3)	(2.7)	(2.7)	
Young child (12 months to <60 months)	1,772	386	135	37	2,330
	(76.0)	(16.6)	(5.8)	(1.6)	
Older child (60 months to <18 years)	42	5	1	0	47
	(87.5)	(10.4)	(2.1)	0.0	
Adult (18 years or more)	315	8	3	0	326
	(96.6)	(2.5)	(0.9)	0.0	
Total	2,436	445	149	47	3,077
	(79.2)	(14.4)	(4.8)	(1.5)	

Figure 17. Blood Lead Data by Date of Test and Age Group



Note: Figure 17 shows that the majority of BLLs were clustered at the limit of detection (LOD) (3.3 µg/dL). Less than 2% of the samples had results above 10 µg/dL, with all of those samples from children under the age of 60 months.

6.2.1 Butte Address Geocoding and House Age Assignment

To address the need to examine trends in BLLs by neighborhood, while maintaining the confidentiality of individual data, the locations for all records were coded to one of eight neighborhoods. Of the 3,400 records received, there were approximately 1,445 unique addresses. The addresses were mapped by first standardizing and geocoding each address. Each address was standardized to adhere to the United States Postal Service standards (e.g., "Street" was standardized to "ST") and geocoded with geographic coordinates (e.g., latitude and longitude). Once addresses were geocoded and mapped, they were assigned corresponding property characteristics (e.g., census tract, neighborhood identifier, and house age).

6.2.1.1 Data Sources

Several sources of data were used to map and assign the locations of the BLL data addresses to corresponding property characteristics. All Phase 2 addresses were initially screened to identify "repeat" addresses, or those that had already been located and assigned a neighborhood, census tract, and house age in the Phase 1 study. Phase 1 information for repeat addresses was preserved in Phase 2, except as noted below for house ages. Addresses that did not match locations in the Phase 1 study were considered "new" addresses.

New addresses were located and assigned corresponding property characteristics using the following data and resources:

- The Montana State Cadastral website database (Montana Cadastral), an online land survey repository containing information on commercial and residential properties throughout

Montana, was accessed to provide individual tax parcel location data (associated with a property address) and house age data from Silver Bow County.

- Google Earth Pro was also used to geocode address locations that were not listed in the Montana Cadastral tax parcel maps.
- Census tract boundaries were obtained from the United States Census Bureau website mapping files.
- Neighborhood boundaries were replicated from the Phase 1 study.

6.2.1.2 Geocoding

Prior to geocoding, Phase 2 addresses were compared with those plotted in Phase 1 to identify repeat addresses. If addresses did not have an exact match, they were flagged and reviewed. After review, the remaining new addresses were geocoded in Google Earth Pro, then individually checked for quality control to confirm that the automated geocoding results were accurate.

In some cases, special decisions were made to standardize and geocode new addresses. For example, addresses from the same apartment complex were assigned to a single standardized address and location, consistent with the Phase 1 study. Post office box addresses were grouped and plotted in the center of Butte. Only seven addresses were determined to be untraceable and, as a result, were excluded from the study.

6.2.1.3 Census Tract, Neighborhood, and House Age Assignment

Once all new addresses were standardized and geocoded, additional information such as census tract number, Phase 1 study neighborhood identifier, and house age were assigned to the locations.

Census tract boundaries from the 2010 census were used to determine census tract identification numbers (census tracts 1 to 8) for each new address based on location. The new addresses were plotted in ArcGIS and assigned a census tract identification number based on the location relative to the boundaries. All addresses falling within census tracts 1 through 8 were assigned the corresponding census tract number. New addresses located out of census tract boundaries remained unassigned.

Neighborhoods for the Phase 2 study were defined based on the eight neighborhoods established in the Phase 1 study: N1 to N7 and N8 (Walkerville). The boundaries of N1 through N7 closely match the census tract boundaries, but they extend to include a 500-meter buffer (approximately 1,640 feet) into surrounding census tract 8 (Figure 16). New Phase 2 addresses that did not have neighborhood identifiers were plotted in ArcGIS and assigned a neighborhood identification number based on their location relative the neighborhood boundaries. The new addresses in census tract 8 and within the buffer of N1 to N7 were plotted in ArcGIS and manually assigned to the closest neighborhood. Addresses located outside of the buffer zone are listed as outside of the study area. Of the unique addresses located for Phase 2, there are 1,307 addresses inside the study area and 138 outside the study area.

The house age (or year built) was assigned to each Phase 2 address based on house ages from the Phase 1 study or the 2018 Montana Cadastral database. In some cases, multiple ages were listed for a house, or the house ages obtained from the Montana Cadastral database in the Phase 1 study did not match house ages obtained through the 2018 Montana Cadastral database. In these instances, the final house age was determined on a case-by-case basis. If the age of the home could not be confirmed or if the home had been remodeled, the oldest age associated with the home was preserved. For the mobile home park in Butte, home ages were obtained from the Montana Cadastral database. Addresses with multiple single-family residences were cross-checked with online housing resources (e.g., Zillow), and the oldest age among all listed residences was preserved. Not all of the addresses associated with blood lead records could be matched to locations in the Montana Cadastral repository. Unmatched addresses were given a code of "UNA" for house age information. House age was assigned to approximately 84% of the records (i.e., 2,679 of 3,176 records from inside the study area).

6.2.2 Blood Lead Data Overview

During the Phase 1 study, venous confirmation values were examined for BLLs greater than 5 µg/dL that were initially obtained from samples collected by finger stick/capillary tubes. Among 3,500 records, only 108 were based on venous sample collection. To avoid double counting individual children with duplicate samples, venous data were excluded from the Phase 1 dataset. Very often the elevated BLLs were not confirmed by the venous sampling conducted soon after the initial sample was collected, suggesting that external contamination may have caused spuriously high results (ACCLPP 2012).

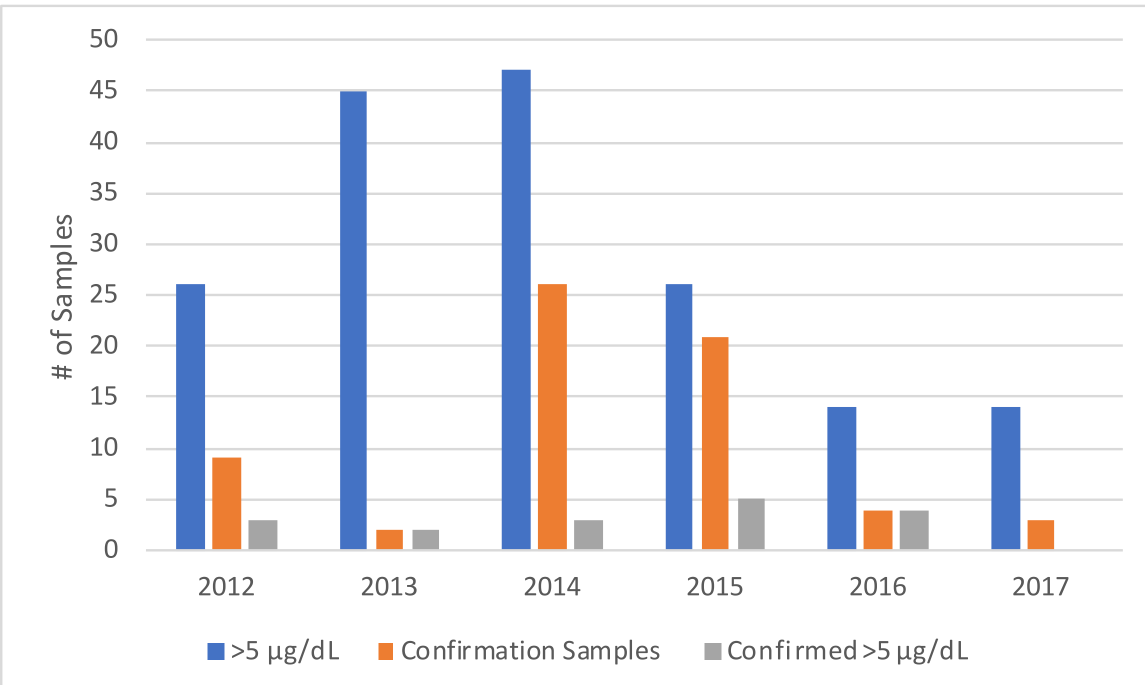
For the Phase 2 study, venous confirmation data were available for only 37% of the samples that exceeded 5 µg/dL (Table 14, Figure 18), and venous samples were excluded from the dataset. On average, only 26% (17 of the 65 confirmation samples) of the BLLs greater than 5 µg/dL were confirmed as elevated after venous testing. Dates for the venous samples could not initially be linked with the dates of the initial elevated sample. Dates were subsequently provided by BSBHD for many of the samples for the years 2014-2017. In most years very few children were retested within two months of the original test showing an elevated BLL. During 2015 a much higher rate of retesting occurred within two months. Those results showed that 16 of the 21 children with confirmation samples were retested within two months. Of those 16 children, 14 were confirmed to have BLLs less than 5 µg/dL (Figure 19).

The lower venous results for the majority of the children likely reflect external contamination at the time of the initial sample. When the venous confirmation sampling was delayed beyond two months it is not possible to determine if the initial result was a false positive (i.e., due to external contamination) or if there was a true reduction in BLL due to reduced exposure to a source (Wang et al. 2019). Based on the confirmation data from 2015, it is expected that a high percentage of the elevated LeadCare II results are false positives, and that the counts of elevated BLL values based on the LeadCare II data significantly overestimate the actual elevated BLLs. Several recent studies have confirmed the need for rapid retesting to confirm initial reports of elevated BLLS. For example, in Michigan half of children initially reported to have elevated BLLs during 2015 were found to not have elevated BLLs when retested by venous sampling (MDHHS 2017). In Minnesota between 2011 and 2017, 55% of the children initially reported to have elevated BLLs were predicted to be false positives based on confirmation testing (Wang et al. 2019).

Table 14. Confirmation Sampling (Ages 12 months to <60 months)

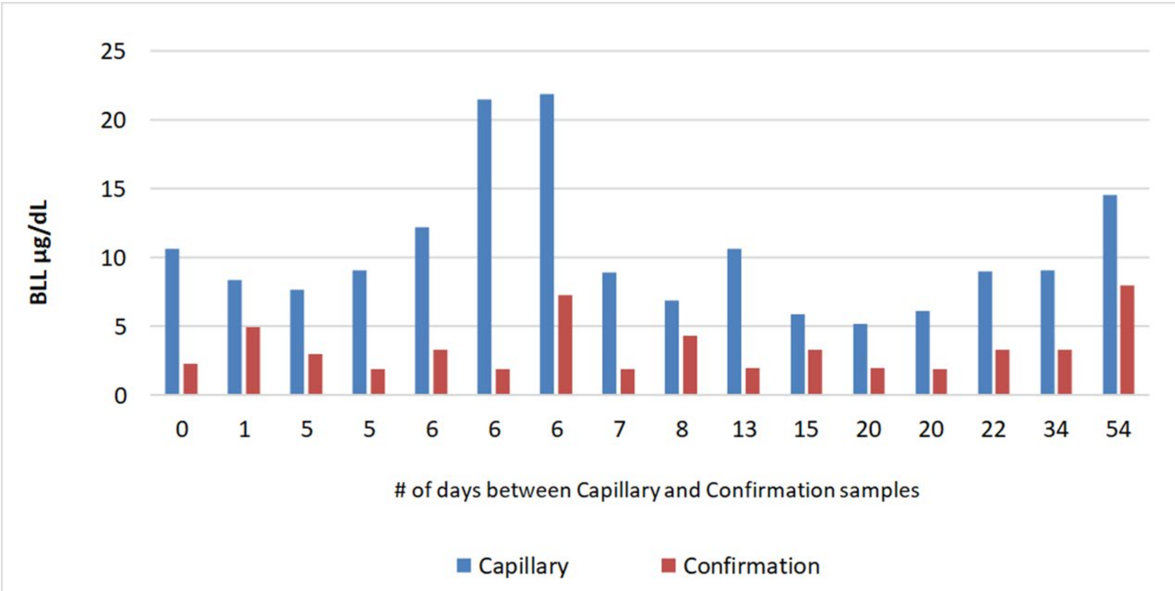
Year	Overall			
	<= 5 µg/dL	>5 µg/dL	Confirmation Samples	Confirmed >5 µg/dL
2012	421	26	9	3
2013	409	45	2	2
2014	398	47	26	3
2015	410	26	21	5
2016	263	14	4	4
2017	257	14	3	0

Figure 18. Number of Samples Confirmed Compared with Total Reported >5 µg/dL



Note: Table 14 and Figure 18 show that the most confirmation samples were taken in 2014 and 2015, and that most of the confirmation samples did not confirm the capillary results. No samples were confirmed to be greater than 5 µg/dL in 2017.

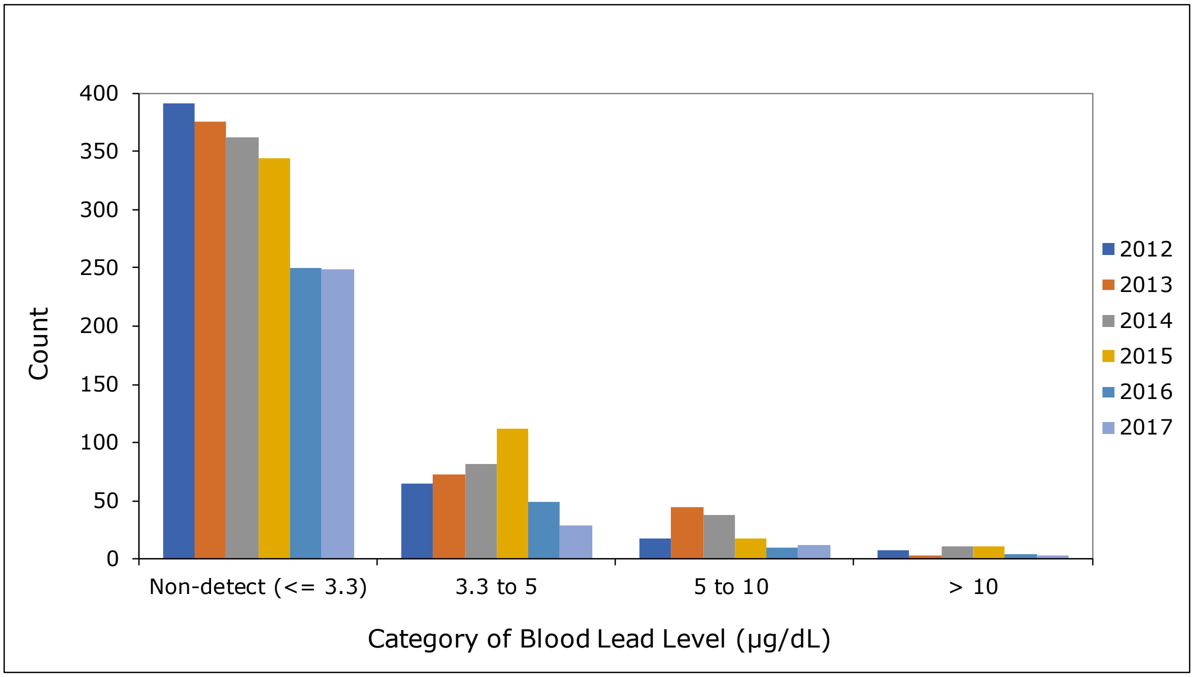
Figure 19. Confirmation Sampling Results for 2015 by Number of Days After the Initial Test



6.3 Butte Blood Lead Summary Statistics and Detection Limit Limitations

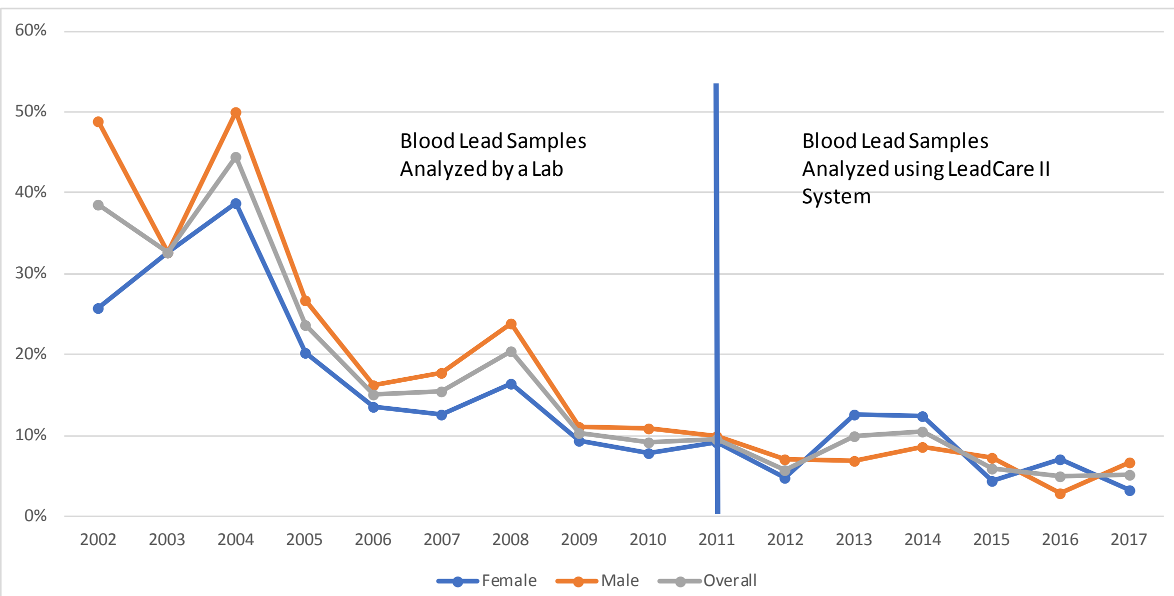
The refinements described above resulted in a database that includes 2,330 records for children aged 12 months to less than 60 months in the 2012 through 2017 time period. The database also includes the 2,724 records from Phase 1 (2003 to 2010), along with some additional data from 2002 and 2011, to form an overall database with 5,584 records from 2002 through 2017. A summary of the distribution of BLLs for the current study period (i.e., 2012 to 2017) is shown in Figure 20. The trends in BLLs greater than 5 µg/dL over the entire period for both Phase 1 and Phase 2 studies is shown in Figure 21.

Figure 20. Overall Distribution by Years for Children 12 to <60 months Old



Note: Figure 20 shows that the majority of blood lead samples were non-detects with values less than the LOD of 3.3 µg/dL.

Figure 21. Trend (2002-2017) in Percent of BLLs > 5 µg/dL for Children 12 to <60 Months Old



Note: Figure 21 shows that the percentage of children with BLLs greater than 5 µg/dL declined more in the earlier period (2002 to 2011) than it did in the more recent phase (2012 to 2017). Note that the earlier samples were analyzed in a laboratory, whereas after 2011 the samples were analyzed using the LeadCare II system, which provides a more immediate result but has a higher LOD than the laboratory results (3.3 µg/dL vs. 0.1 µg/dL).

Following refinement of the Butte blood lead database for use in the study, specific data treatments were evaluated and applied as appropriate to support statistical evaluation of the data in addressing each of the primary study questions. First considered were the evaluations used in the Phase 1 study. However, because the LOD with the LeadCare II analyzer method was 3.3 µg/dL versus the 1 µg/dL LOD for the venous blood method used in the first medical monitoring study, many more of the blood lead samples were less than the limit of detection. Over the years from 2012 to 2017, the percentage of blood lead samples below the LOD (3.3 µg/dL) ranged from 70% to 85%; overall, 76% of the samples over that entire time period were below the LOD (Table 17). This makes it more difficult to determine average BLLs, as the methods used to evaluate means from data including non-detected values work best when the percentage of non-detects is less than 50% of the total samples. Therefore, the analyses of the 2012 to 2017 data were performed on the percentage of blood lead samples either above the LOD or above the reference value of 5 µg/dL (referred to as the cut points below). See Tables 16 through 116 for a breakdown of the number of samples that fall into different categories when stratified by year or year plus age, season, or neighborhood.

6.4 Controlling for Variation of BLLs by Neighborhood, House Age, and Season

In the Phase 1 study, univariate statistics determined that the significant variables for the Butte data were the child's test age, the child's gender, the house age, the sample collection year, and the season in which the samples were collected. For the Phase 2 assessment, similar demographic and geographic parameters (including the child's age and gender, the neighborhood and age of housing, and the season in which the blood samples were collected) were used to determine if these variables had a significant effect on the BLLs. As some of the variables had many values, most of these variables were categorized into subgroups for this analysis, and the categories were similar to those used in the Phase 1 analyses. Two of these variables, house age and neighborhood, had two different options in the way that they were categorized. Table 15 lists the categories that each variable was subset into to define the different demographic and geographic parameters. Because of the large number of houses for which information was not available on the year the house was built, an "Unknown" category was added to the options for that parameter, so records would not be excluded when the housing age was considered.

Table 15. Demographic and Geographic Parameters

Parameter	Option 1	Option 2
Age category	12 to <36 months	
	36 months to <60 months	
Gender	Male	
	Female	
Season of blood sample	May 1 through Oct 31 Nov 1 through April 30	
Neighborhood	Using each of the eight neighborhoods	Grouped into Uptown and Flats
Year that housing was built	Unknown	Unknown
	Before 1940	Before 1940

Parameter	Option 1	Option 2
	1940 to 1949	1940 to 1959
	1950 to 1959	1960 and later
	1960 to 1977	
	1978 to 1989	
	1990 and later	

Table 16 shows the breakdown of the number of samples taken per year from children in the 12 months to less than 60 months age range. The number of samples is approximately between 300 and 350 for each year included in the Phase 1 and Phase 2 studies, more than 440 samples in each year from 2010 through 2015, and less than 300 samples each in 2016 and 2017. This table shows that the percentage of samples greater than the LOD or reference value has been decreasing over the course of the entire study.

Table 16. Number and Percentage of Samples by Year >3.3 µg/dL or >5 µg/dL

Year	# of samples	>3.3 µg/dL	% >3.3 µg/dL	>5 µg/dL	% >5 µg/dL
2003	343	--*	--	112	32.65%
2004	308	--	--	137	44.5%
2005	303	--	--	72	23.8%
2006	319	--	--	48	15.05%
2007	337	--	--	52	15.4%
2008	319	--	--	65	20.4%
2009	352	--	--	36	10.2%
2010	443	--	--	41	9.3%
2011	452	--	--	43	9.5%
2012	447	86	19.2%	26	5.8%
2013	454	114	25.1%	45	9.9%
2014	445	124	27.9%	47	10.6%
2015	436	130	29.8%	26	6.0%
2016	277	63	22.7%	14	5.05%
2017	271	41	15.1%	14	5.2%
2003-2010	2,724	--	--	563	**20.7%**
2012-2017	2,330	558	**23.9%**	172	**7.4%**

Note:
*-- indicates not applicable, LOD was lower than 3.3 µg/dL in these years.

Table 17 shows the distribution over the years of the samples taken for children broken into two categories, 12 to 35 months and 36 months to less than 60 months. There are slightly more samples in the younger group than in the older group. In 12 of the 15 years reported, there is a greater percentage of samples exceeding 5 µg/dL in the younger group. This finding is consistent with literature reporting the BLLs peak at around age 2 years in U.S. populations (ACCLP 2007).

Table 18 shows the distribution over the years by gender. There were more samples taken in females for most years. In 8 of the 15 years reported, there was a higher percentage of males with blood lead values greater than 5 µg/dL as compared with females. This finding shows that BLLs are similar in boys and girls and is consistent with the literature (ATSDR 2019c).

Table 17. Number and Percentage of Samples >5 µg/dL by Age Category

Year	12 to 35 months		36 to <60 months	
	N	% >5 µg/dL	N	% >5 µg/dL
2003	201	31.8%	142	33.8%
2004	173	45.1%	135	43.7%
2005	155	27.7%	148	19.6%
2006	172	15.7%	147	14.3%
2007	184	20.1%	153	9.8%
2008	173	22.5%	146	17.8%
2009	195	11.3%	157	8.9%
2010	270	10.0%	173	8.1%
2011	271	9.2%	181	9.9%
2012	279	6.8%	168	4.2%
2013	243	12.8%	211	6.6%
2014	265	11.7%	180	8.9%
2015	254	5.9%	182	6.0%
2016	154	6.5%	123	3.3%
2017	128	5.5%	143	4.9%
2003-2010	1,523	22.1%	1,201	18.8%
2012-2017	1,323	8.2%	1,007	5.6%

Table 18. Number and Percentage of Samples >5 µg/dL by Gender

Year	Males		Females	
	N	% >5 µg/dL	N	% >5 µg/dL
2003	165	32.7%	178	32.6%
2004	156	50.0%	152	38.8%
2005	169	26.6%	134	20.1%
2006	178	16.3%	141	13.5%
2007	186	17.7%	151	12.6%
2008	172	23.8%	147	16.3%

Year	Males		Females	
	N	% >5 µg/dL	N	% >5 µg/dL
2009	181	11.0%	171	9.4%
2010	201	10.9%	242	7.85%
2011	221	10.0%	231	9.1%
2012	198	7.1%	249	4.8%
2013	217	6.9%	237	12.7%
2014	211	8.5%	234	12.4%
2015	232	7.3%	204	4.4%
2016	135	3.0%	142	7.0%
2017	148	6.8%	123	3.3%
2003-2010	1,408	22.9%	1,316	18.3%
2012-2017	1,141	6.8%	1,189	7.9%

6.4.1 Comparison of BLLs by Butte Neighborhood

Table 19 shows the number and percentage of samples greater than 5 µg/dL in each of the 8 neighborhoods for each year. In some cases, very few samples occurred in a neighborhood in a given year. All neighborhoods show a decrease over time in the percentages (Figure 22A). As with the other trend comparisons, values for the Phase 2 years (2012 to 2017) show little difference (Figure 22B).

The Phase 1 study showed that there were not significant differences in BLLs among the Uptown neighborhoods (i.e., N1, N2, and N8) or among the Flats neighborhoods (i.e., N3, N4, N5, N6, and N7), so as before data were compiled to compare Uptown with the Flats (Table 20). The Uptown neighborhoods continue to show higher percentages of samples greater than the 5 µg/dL throughout both study periods, but in both Uptown and the Flats the percentage of elevated BLLs declined from the 2003-2010 period to the 2012-2017 period. In the prior study period (i.e., 2003-2010), 27.6% of Uptown BLLs exceeded 5 µg/dL, while 11.7% of the Flats BLLs exceeded 5 µg/dL. In the current study period (i.e., 2012-2017), 15.2% of the Uptown BLLs exceeded 5 µg/dL, while 4.1% of the Flats BLLs exceeded 5 µg/dL. The differences between Uptown and the Flats likely primarily reflect both the older housing stock Uptown (see Section 6.4.2) and the greater extent of mine waste affecting soil concentrations, both factors being addressed by the RMAP.

Table 19. Number of Samples by Neighborhood and Percentage >5 µg/dL

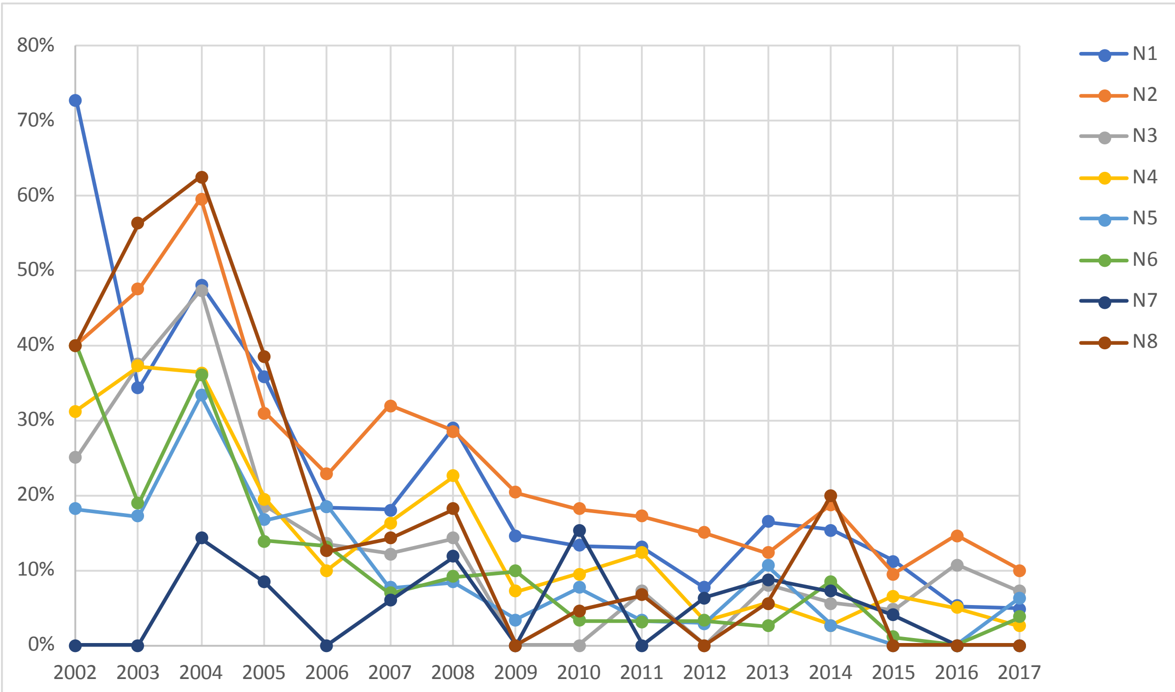
Year	N1		N2		N3		N4		N5		N6		N7		N8 (Walkerville)		Total
	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	
2003	102	34%	40	48%	32	38%	51	37%	29	17%	69	19%	4	0%	16	56%	343
2004	79	48%	42	60%	38	47%	44	36%	21	33%	61	36%	7	14%	16	63%	308
2005	84	36%	29	31%	27	19%	41	20%	18	17%	79	14%	12	8%	13	38%	303
2006	76	18%	35	23%	37	14%	30	10%	27	19%	84	13%	14	0%	16	13%	319
2007	83	18%	50	32%	33	12%	49	16%	26	8%	72	7%	17	6%	7	14%	337
2008	93	29%	56	29%	21	14%	31	23%	24	8%	66	9%	17	12%	11	18%	319
2009	96	15%	49	20%	26	0%	56	7%	30	3%	71	10%	13	0%	11	0%	352
2010	121	13%	55	18%	37	0%	63	10%	39	8%	93	3%	13	15%	22	5%	443
2011	131	13%	64	17%	42	7%	57	12%	31	3%	97	3%	15	0%	15	7%	452
2012	117	8%	67	15%	42	0%	63	3%	34	3%	92	3%	16	6%	16	0%	447
2013	134	16%	65	12%	25	8%	71	6%	38	11%	80	3%	23	9%	18	6%	454
2014	104	15%	80	19%	36	6%	76	3%	38	3%	82	9%	14	7%	15	20%	445
2015	107	11%	63	10%	42	5%	61	7%	38	0%	91	1%	25	4%	9	0%	436
2016	57	5%	41	15%	28	11%	40	5%	31	0%	55	0%	16	0%	9	0%	277
2017	62	5%	40	10%	28	7%	40	3%	32	6%	54	4%	10	0%	5	0%	271
2003-2010	734	25.7%	356	31.7%	251	18.7%	365	19.5%	214	13.1%	595	13.1%	97	7.2%	112	26.8%	2,724
2012-2017	581	11.2%	356	13.8%	201	5.5%	351	4.3%	211	3.8%	454	3.3%	104	4.8%	72	5.6%	2,330

Note:

This table shows the number of blood lead samples taken in children 12 to 60 months old over the years of 2003 to 2017. It is stratified by the neighborhood.

Figure 22. Percentage of Blood Lead Samples >5 µg/dL for Children 12 to <60 Months Old by Neighborhood (A: All years, B: Phase 2 years 2012-2017)

A



B

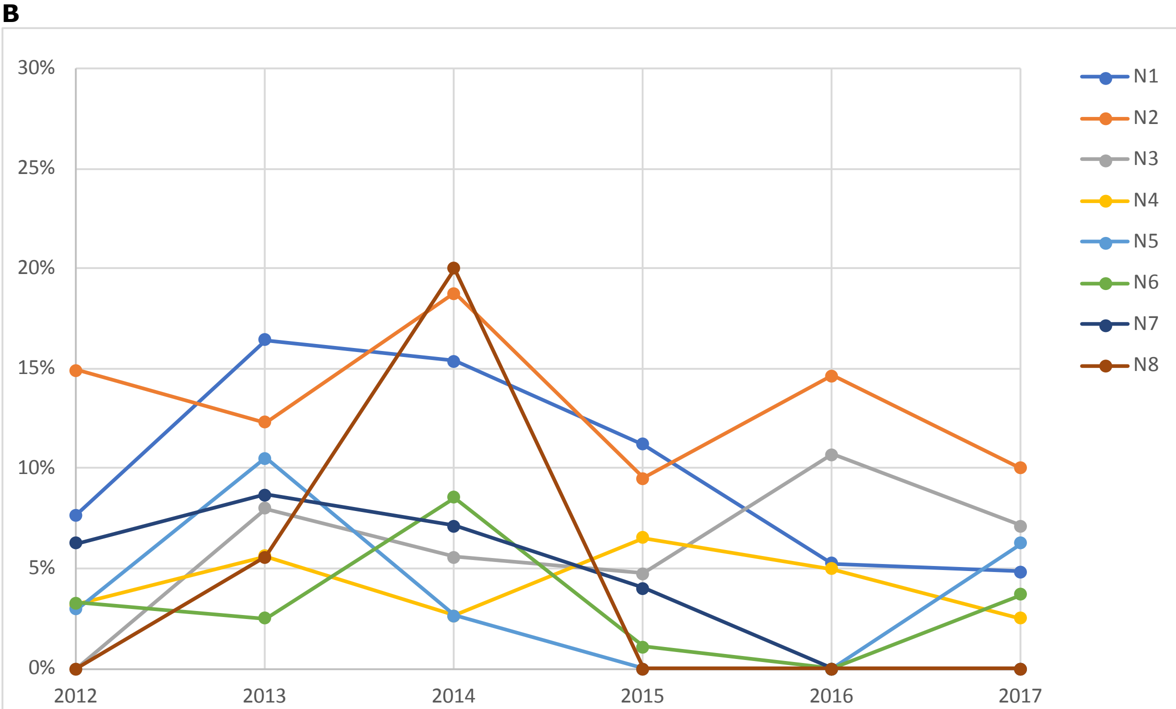


Table 20. Number and Percentage of Samples >3.3 µg/dL or >5 µg/dL, Grouped by Neighborhoods

Year	Uptown (1, 2, & 8)			Flats (3, 4, 5, 6 & 7)		
	N	% >3.3 µg/dL	% >5 µg/dL	N	% >3.3 µg/dL	% >5 µg/dL
2003	158	--*	39.9%	185	--	26.5%
2004	137	--	53.3%	171	--	37.4%
2005	126	--	34.9%	177	--	15.8%
2006	127	--	18.9%	192	--	12.5%
2007	140	--	22.9%	197	--	10.2%
2008	160	--	28.1%	159	--	12.6%
2009	156	--	15.4%	196	--	6.1%
2010	198	--	13.6%	245	--	5.7%
2011	210	--	13.8%	242	--	5.8%
2012	200	28.5%	9.5%	247	11.7%	2.8%
2013	217	33.2%	14.3%	237	17.7%	5.9%
2014	199	37.2%	17.1%	246	20.3%	5.3%
2015	179	34.1%	10.1%	257	26.8%	3.1%
2016	107	30.8%	8.4%	170	17.6%	2.9%
2017	107	21.5%	6.5%	164	11.0%	4.3%
2003-2010	1,202	--	27.6%	1,522	--	15.2%
2012-2017	1,009	31.7%	11.7%	1,321	18.0%	4.1%

Note:

*-- indicates not applicable, LOD was lower than 3.3 µg/dL in these years.

6.4.2 Comparison of BLLs by House Age

Table 21 shows that the majority of the BLLs greater than 5 µg/dL occurred in children who lived either in houses built before 1940 or in houses where the age of construction was not known. Even in the oldest houses built before 1940, the percentage of children with elevated BLLs has declined substantially since the Phase 1 study, with 26% elevated BLLs in the period from 2003-2010, and 10% in the period from 2012-2017). For this table, house age was stratified into 7 categories based on the decreasing likelihood of having lead paint in newer homes, as shown in Table 21 and as listed in Table 15, Option 1. However, the small number of samples in some of the house age categories suggested that broader categories would make better comparisons, especially when additional stratifying variables are considered.

The second grouping for house age, listed as Option 2 in Table 15 was used in a comparison of house age across neighborhood groups. The higher rate of elevated BLLs in Uptown versus the Flats persists even when considering house age. For example, from 2003-2010, 30.3% of Uptown children living in the oldest houses had elevated BLLs versus 21.5% in the Flats. In the current study period (i.e., 2012-2017), 13.3% of Uptown children living in the oldest houses had elevated BLLs versus 5.9% in the Flats. As can be seen in Table 22 and Figure 23, there is not much difference in the frequency of BLLs greater than 5 µg/dL between Uptown and the Flats for children living in houses built from 1940 to 1959. However, the average frequency of elevated BLLs over the period from 2012-2017 is higher in Uptown children living in houses built in 1960 or later. This result for Uptown children living in newer houses is unexpected, and could be related to the fact that relatively few Uptown children live in newer houses. When data for individual years is examined, the results for newer houses are highly variable and inconsistent.

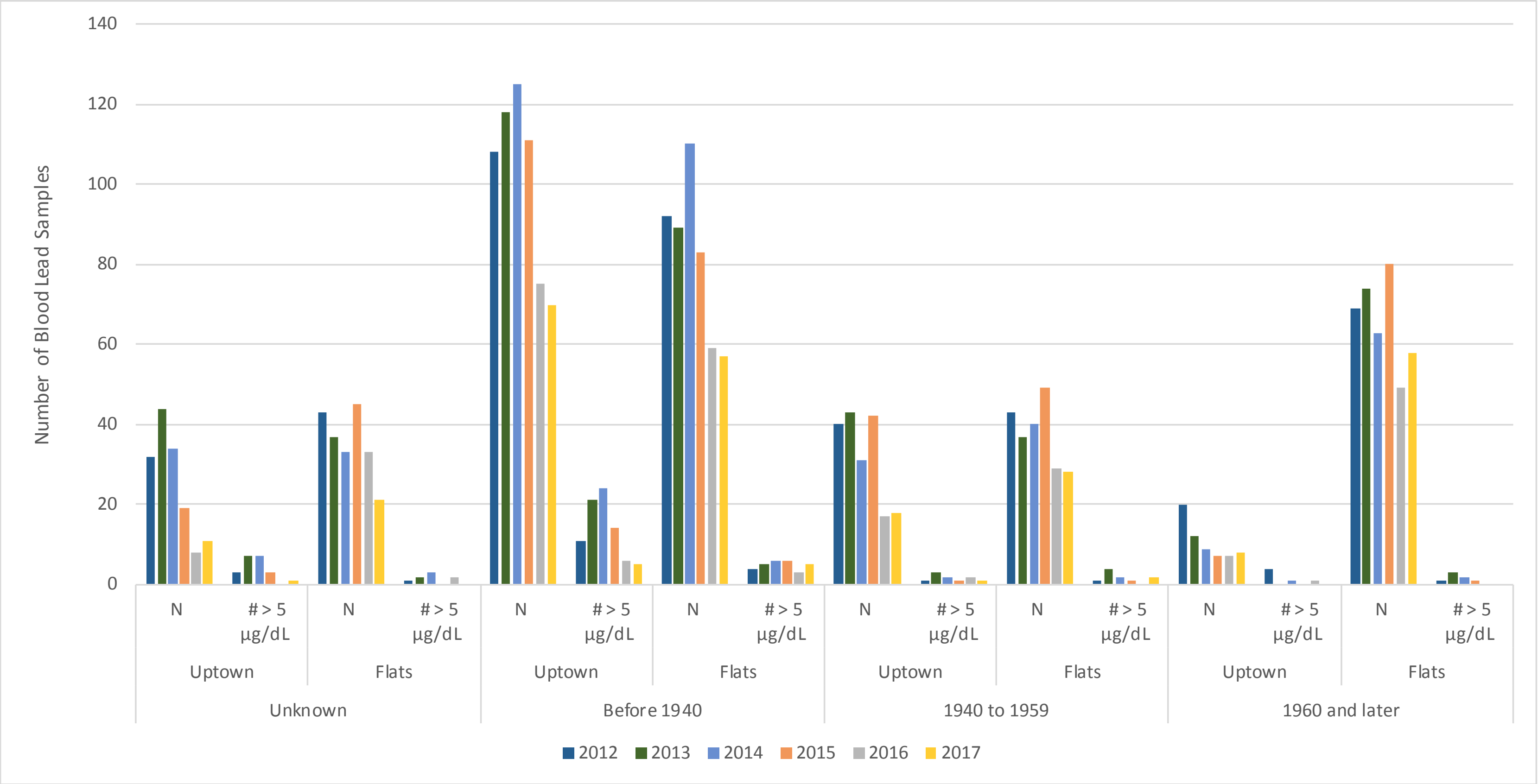
Table 21. Number of Samples and Percentage >5 µg/dL by House Age

Year	Unknown		Before 1940		1940 to 1949		1950 to 1959		1960 to 1977		1978 to 1989		1990 and later	
	N	% > 5 µg/dL	N	% > 5 µg/dL	N	% > 5 µg/dL	N	% > 5 µg/dL	N	% > 5 µg/dL	N	% > 5 µg/dL	N	% > 5 µg/dL
2003	165	59.4%	154	42.2%	33	24.2%	15	6.7%	22	27.3%	2	0.0%	5	0.0%
2004	156	67.9%	133	53.4%	28	32.1%	17	41.2%	18	27.8%	8	0.0%	4	75.0%
2005	169	52.7%	132	29.5%	23	13.0%	21	28.6%	15	13.3%	5	20.0%	2	0.0%
2006	178	44.4%	112	16.1%	18	16.7%	31	19.4%	24	12.5%	11	0.0%	1	100.0%
2007	186	41.4%	127	21.3%	33	15.2%	22	4.5%	14	0.0%	8	12.5%	5	0.0%
2008	172	35.5%	133	26.3%	32	28.1%	15	6.7%	16	0.0%	5	0.0%	6	0.0%
2009	181	27.1%	162	9.9%	29	10.3%	18	11.1%	18	5.6%	7	0.0%	7	28.6%
2010	201	22.4%	176	12.5%	48	4.2%	19	0.0%	25	8.0%	9	0.0%	11	0.0%
2011	221	20.4%	168	13.7%	46	6.5%	17	0.0%	37	8.1%	12	0.0%	14	0.0%
2012	198	19.7%	200	7.5%	44	2.3%	39	2.6%	45	8.9%	18	0.0%	26	3.8%
2013	217	24.9%	207	12.6%	50	4.0%	30	16.7%	51	5.9%	14	0.0%	21	0.0%
2014	211	23.2%	235	12.8%	32	6.3%	39	5.1%	33	3.0%	16	0.0%	23	8.7%
2015	232	32.8%	194	10.3%	42	4.8%	49	0.0%	45	2.2%	16	0.0%	26	0.0%
2016	135	23.7%	134	6.7%	18	11.1%	28	0.0%	24	0.0%	15	6.7%	17	0.0%
2017	148	19.6%	127	7.9%	24	4.2%	22	9.1%	38	0.0%	16	0.0%	12	0.0%
2003-2010	1,408	**42.9%**	1,129	**26.0%**	244	**17.2%**	158	**15.2%**	152	**12.5%**	55	**3.6%**	41	**14.6%**
2012-2017	1,141	**24.5%**	1,097	**10.0%**	210	**4.8%**	207	**4.8%**	236	**3.8%**	95	**1.1%**	125	**2.4%**

Table 22. Number of Samples and Percentage >5 µg/dL by House Age - Uptown vs. the Flats

Year	Unknown				Before 1940				1940 to 1959				1960 and later			
	Uptown		Flats		Uptown		Flats		Uptown		Flats		Uptown		Flats	
	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL
2003	42	40.5%	70	21.4%	82	46.3%	72	37.5%	30	23.3%	18	11.1%	4	25.0%	25	20.0%
2004	39	51.3%	61	36.1%	71	57.7%	62	48.4%	24	41.7%	21	28.6%	3	66.7%	27	22.2%
2005	33	42.4%	72	9.7%	65	33.8%	67	25.4%	24	29.2%	20	10.0%	4	25.0%	18	11.1%
2006	40	15.0%	82	13.4%	57	19.3%	55	12.7%	28	21.4%	21	14.3%	2	50.0%	34	8.8%
2007	46	23.9%	82	8.5%	58	29.3%	69	14.5%	32	12.5%	23	8.7%	4	0.0%	23	4.3%
2008	47	34.0%	65	6.2%	72	29.2%	61	23.0%	34	23.5%	13	15.4%	7	0.0%	20	0.0%
2009	50	16.0%	61	6.6%	76	13.2%	86	7.0%	23	17.4%	24	4.2%	7	28.6%	25	4.0%
2010	53	20.8%	102	3.9%	90	14.4%	86	10.5%	43	4.7%	24	0.0%	12	8.3%	33	3.0%
2011	76	17.1%	82	1.2%	76	18.4%	92	9.8%	42	4.8%	21	4.8%	16	0.0%	47	6.4%
2012	32	9.4%	43	2.3%	108	10.2%	92	4.3%	40	2.5%	43	2.3%	20	20.0%	69	1.4%
2013	44	15.9%	37	5.4%	118	17.8%	89	5.6%	43	7.0%	37	10.8%	12	0.0%	74	4.1%
2014	34	20.6%	33	9.1%	125	19.2%	110	5.5%	31	6.5%	40	5.0%	9	11.1%	63	3.2%
2015	19	15.8%	45	0.0%	111	12.6%	83	7.2%	42	2.4%	49	2.0%	7	0.0%	80	1.3%
2016	8	0.0%	33	6.1%	75	8.0%	59	5.1%	17	11.8%	29	0.0%	7	14.3%	49	0.0%
2017	11	9.1%	21	0.0%	70	7.1%	57	8.8%	18	5.6%	28	7.1%	8	0.0%	58	0.0%
2003-2010	350	**29.4%**	595	**12.4%**	571	**30.3%**	558	**21.5%**	238	**20.2%**	164	**11.0%**	43	**18.6%**	205	**9.3%**
2012-2017	148	**14.2%**	212	**3.8%**	607	**13.3%**	490	**5.9%**	191	**5.2%**	226	**4.4%**	63	**9.5%**	393	**1.8%**

Figure 23. Number of Samples and Number >5 µg/dL by House Age - Uptown vs. the Flats



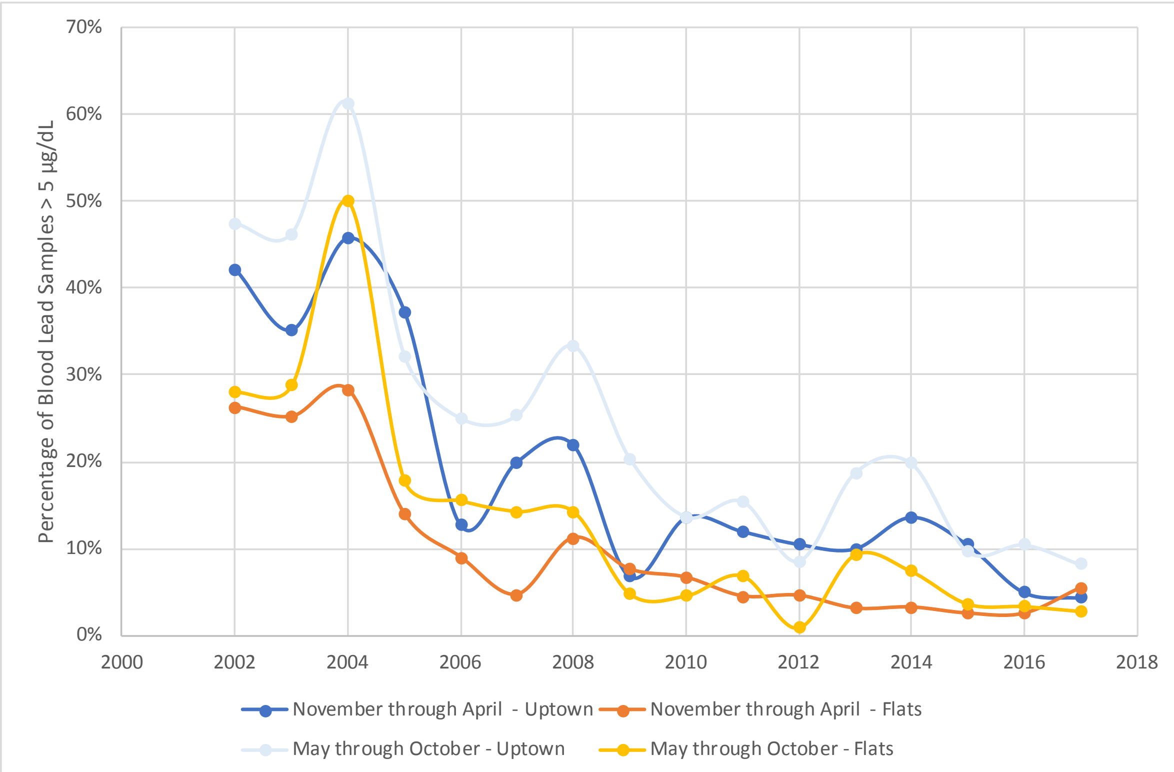
6.4.3 Comparison of BLLs by Season

Table 23 shows that samples are approximately equally split between seasons and that BLLs taken in the more temperate months (May through October) are more likely to be elevated than those taken in the months when snow is likely to be on the ground (November through April). BLLs are about 20-30% higher on average in the warm season. Uptown also continues to have more elevated BLLs than the Flats in each season. The percentage of blood lead values greater than 5 μg/dL has been consistently decreasing in both seasons over the two study periods, with warm season Uptown values falling from 30.1% elevated BLLs from 2003-2010 to 13.2% from 2012-2017. Similarly, warm season elevated BLLs in the Flats fell from 16.9% elevated BLLs from 2003-2010 to 4.6% from 2012-2017.

Table 23. Number and Percent of Samples >5 µg/dL by Season and Neighborhood Group

Year	November through April				May through October			
	Uptown		Flats		Uptown		Flats	
	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL	N	% >5 µg/dL
2003	91	35.2%	119	25.2%	67	46.3%	66	28.8%
2004	70	45.7%	99	28.3%	67	61.2%	72	50.0%
2005	67	37.3%	93	14.0%	59	32.2%	84	17.9%
2006	63	12.7%	89	9.0%	64	25.0%	103	15.5%
2007	65	20.0%	85	4.7%	75	25.3%	112	14.3%
2008	73	21.9%	89	11.2%	87	33.3%	70	14.3%
2009	58	6.9%	92	7.6%	98	20.4%	104	4.8%
2010	81	13.6%	135	6.7%	117	13.7%	110	4.5%
2011	100	12.0%	111	4.5%	110	15.5%	131	6.9%
2012	95	10.5%	131	4.6%	105	8.6%	116	0.9%
2013	110	10.0%	129	3.1%	107	18.7%	108	9.3%
2014	88	13.6%	124	3.2%	111	19.8%	122	7.4%
2015	86	10.5%	119	2.5%	93	9.7%	138	3.6%
2016	40	5.0%	80	2.5%	67	10.4%	90	3.3%
2017	46	4.3%	92	5.4%	61	8.2%	72	2.8%
2003-2010	568	**24.8%**	801	**13.6%**	634	**30.1%**	721	**16.9%**
2012-2017	465	**9.9%**	675	**3.6%**	544	**13.2%**	646	**4.6%**

Figure 24. Seasonal Variation in BLLs - Uptown vs. Flats



Note: During the Phase 1 study, it was noted that the increase in BLLs during the warmer months was greater in Uptown versus the Flats. Figure 24 shows these differences throughout the Phase 1 and Phase 2 study periods, and it shows the seasonal differences are becoming less pronounced.

6.5 Trends in Blood Lead Data

For comparison to the Phase 1 study, all analyses done on the Phase 2 data of the percentage of blood lead samples above the LeadCare II detection limit or reference value were also done using the Phase 1 database, as well as all data available from 2002 to 2017.

For a first look at trends over time, linear regression was performed on the data, with the year of sampling as the independent variable. This allows a general estimation of the change over time in the percentage of samples above the detection limit or reference value and allows comparison between the Butte data and a reference population, such as NHANES. With linear regression, the multiple descriptive parameters described in the section above can also be used to "adjust" the trend by the effect of the parameter.

As a second way of looking at trends over time, logistic regression was used to understand the relationship between the other parameters and the percentage of children with BLLs above the detection limit or reference value. As with the linear regression, the demographic and geographic parameters were used to "adjust" the model fits. With the logistic models, comparisons can then be made between the categories of the covariates to see if there are differences in the percentage of blood lead values greater than the detection limit or reference value across genders, ages, or neighborhoods or over time.

6.5.1 Relationship Between BLLs and Butte Population Variables

Linear and logistic regression analyses were used to examine the time trends for elevated BLLs for variables known to affect BLLs.

6.5.1.1 Univariate Regression – BLL Time Trends for Variables

For the first analysis by linear regression, the slopes of the equations looking at the percentage of BLLs greater than either the LOD (3.3 µg/dL) or the reference value (5 µg/dL) over the years were examined. The regressions were performed with year only and then with the year and additional covariates to see if adding in an adjustment for gender, age, year the housing was built, neighborhoods or neighborhood groups, or season would have a significant effect on the slope for year. In addition, a regression was run that included adjustment for gender, age category, and season, which are all the variables that can also be adjusted on the NHANES data when looking for a trend.

Table 24 shows the results for the slopes for all years, for Phase 1, and for Phase 2, and in every case the slope is negative, indicating that the percentages of samples above the LOD or reference value are decreasing over time. The slight differences in the slopes when additional covariates are adjusted for indicate no real effect of these covariates over time. However, the P values indicate that the slope parameter is significantly different from zero with values less than 0.05 (e.g., an indication that the slopes are significantly different from zero). All of the “All Years” and “Phase 1” slopes are significantly different from zero, but the “Phase 2” slopes are not. This points to a slowing down of the decrease in BLLs, with no statistically significant differences between the years of 2012 through 2017.

Table 24. Univariate Regression – BLL Time Trends for Variables

Cut Point for BLL	Variable	All Years 2002-2017 (N=5,584)		Phase 1 2003-2010 (N=2,724)		Phase 2 2012-2017 (N=2,330)	
		Slope	P value*	Slope	P value*	Slope	P value*
>LOD (3.3 µg/dL)	Year only	-0.0299	**<.0001**	-0.0657	**0.0008**	-0.0073	**0.6319**
	Year + adjusting for:						
	Gender	-0.0297	**<.0001**	-0.0656	**<.0001**	-0.0080	0.4862
	Age category	-0.0300	**<.0001**	-0.0544	**<.0001**	-0.0070	0.4855
	Year house built	-0.0338	**<.0001**	-0.0643	**<.0001**	-0.0062	0.3373
	Neighborhood groups	-0.0298	**<.0001**	-0.0543	**<.0001**	-0.0061	0.5523
	Neighborhood	-0.0287	**<.0001**	-0.0534	**<.0001**	-0.0068	0.2968
	Season	-0.0300	**<.0001**	-0.0548	**<.0001**	-0.0084	0.455
	Gender, age category, and season	-0.0304	**<.0001**	-0.0550	**<.0001**	-0.0102	0.1594

Cut Point for BLL	Variable	All Years 2002-2017 (N=5,584)		Phase 1 2003-2010 (N=2,724)		Phase 2 2012-2017 (N=2,330)	
		Slope	P value*	Slope	P value*	Slope	P value*
> Reference value (5 µg/dL)	Year only	-0.0223	**<.0001**	-0.0411	**0.0098**	-0.0064	0.3315
	Year + adjusting for:						
	Gender	-0.0220	**<.0001**	-0.0409	**0.0002**	-0.0068	0.2316
	Age category	-0.0224	**<.0001**	-0.0368	**<.0001**	-0.0058	0.2123
	Year house built	-0.0191	**<.0001**	-0.0320	**<.0001**	-0.0050	0.1703
	Neighborhood groups	-0.0227	**<.0001**	-0.0374	**<.0001**	-0.0062	0.2297
	Neighborhood	-0.0209	**<.0001**	-0.0349	**<.0001**	-0.0059	0.1170
	Season	-0.0226	**<.0001**	-0.0374	**<.0001**	-0.0067	0.2297
	Gender, age category, and season	-0.0226	**<.0001**	-0.0370	**<.0001**	-0.0069	0.087

Note:
*Statistically significant slopes are marked by bold P values.

6.5.1.2 Logistic Regression

Logistic regression is a regression analysis that is used to describe the relationship between a dependent binary variable (e.g., whether a BLL is greater than the reference value) and one or more independent variables. Results from logistic regression can be used to predict the probability of elevated BLLs (above the reference value based on the values of the independent variables, such as child's age, housing age, and season that the blood sample was taken). Logistic regression can also be used to determine if there are statistically significant differences in the probability of elevated BLLs between two values of an independent variable (e.g., if there is a higher probability of elevated BLLs in the population of children who live in houses built before 1940 vs. those built after 1990).

Univariate logistic regression was performed to see if there were significant differences across the categories of the descriptive variables (child's age, house age, neighborhood, season, and year sample was obtained) in the number of blood lead samples above the reference value. First, each descriptive variable was fit to the event of being above the reference level. The resulting ORs show the probability of a category having a statistically significant different number of events than the reference for that category. When the OR, the upper confidence limit (UCR), and the lower confidence limit (LCL) are all less than 1, then there is a statistically significant decrease in the number of events from the reference. If the OR, the UCL, and the LCL are all greater than 1, then that category has a statistically significant increase in events above the reference level. If the UCL and the LCL include 1, then any difference between that category and the reference is not statistically significant.

The reference categories used were male; 12 to 35 months; year of 2003 for "All Years," 2003 for "Phase 1" years, and 2012 for "Phase 2" years; housing built in 1990 or later; Uptown; neighborhood 8; and the months of November through April. Detailed results are presented in Appendix A, and a summary follows:

- A statistically significant difference was found in the number of occurrences where the BLL was greater than the reference value of 5 µg/dL among genders for “All Years” and “Phase 1” years but not “Phase 2” years.
- All three groupings of years show statistically significant differences in the child age categories, the season, and Uptown versus the Flats.
- The year that the subject’s housing was built shows a statistically significant difference between the number of elevated BLL events in samples from children living in housing built after 1990 and those living in housing in the Unknown category and before 1940 for both “All Years” and the “Phase 2” years, and also for 1940 to 1949 for “All Years.” However, no difference was seen in the number of events stratified by housing for “Phase 1” years.
- For the year of the sample, years 2004 to 2017 were different from the reference year in “All Years”; for the “Phase 1” years, the reference year of 2003 was different from all other years 2004 to 2010, but there was no significant difference between the reference for “Phase 2” years (2012) and any of the years from 2013 to 2017.
- Looking at the neighborhoods ungrouped, all years showed a statistically significant difference between the reference (N8) and neighborhoods 3, 4, 5, 6, and 7. “Phase 1” years showed differences between N8 and N5, N6, and N7, but no differences were seen among the neighborhoods compared with N8 for the “Phase 2” years.

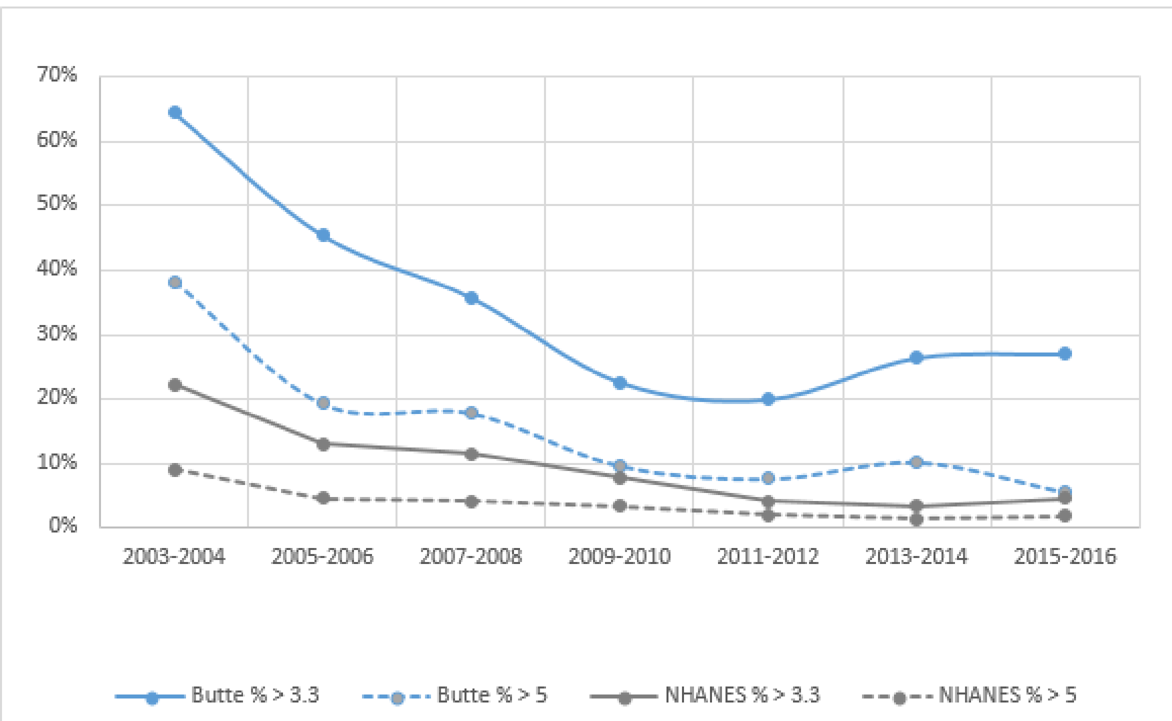
The multivariate logistic analysis performed on the events of BLLs being greater than the reference value (Table A 2) was a selection process where all the variables were allowed to enter the model but were retained only if the P value associated with their variable was less than 0.15. Since the grouped neighborhood and the individual neighborhoods are the same data, the individual neighborhoods only were included in this process. This selection process resulted in all variables being selected for the “All Years” and “Phase 1” categories, but gender was not selected as a significant variable for the “Phase 2” years’ multivariate analysis. Similar results to the univariate analyses were seen for the multivariate analysis. Season and age showed differences between the categories for “All Years” combinations. There were statistically significant differences between the reference year and later years, but more for “All Years” and “Phase 1” than for “Phase 2,” where only 2013 and 2014 were significantly different from 2012. The year the housing was built showed a significant difference for the “before 1940” group versus the “1990 and later” group for “All Years” and “Phase 2” years but not “Phase 1” years. The neighborhood variable showed a significant difference between N8 and N5, N6, and N7 for “All Years,” between N8 and N6 and N7 for “Phase 1,” and between N8 and N5 and N6 for “Phase 2.”

6.5.2 Comparison of Trends in Butte Elevated BLLs with NHANES

Linear regression analyses were used to examine the time trends for elevated BLLs for comparison with a reference population. The only reference blood lead data that were found to compare with the Butte blood lead data in Phase 1 were data from NHANES. As described in Section 4.2.2, during Phase 1 the NHANES data for the applicable years were weighted to match the Butte population for key variables known to affect BLLs. House age was the most influential variable, but information on house age is no longer collected as part of the more recent NHANES data. While this factor and the much higher detection limit for the Phase 2 Butte blood lead data prevent direct comparison of rates of elevated BLLs between NHANES and Butte, it is still relevant to compare the rates of change in the elevated BLLs between the two datasets.

Figure 25 shows a comparison between the percentage of NHANES BLLs greater than 3.3 µg/dL and 5 µg/dL reported between 2003 and 2016 and those reported in Butte. To make the values as consistent as possible, the Butte data were combined in 2-year groups to match the NHANES data. It is evident from this graph that the percentage of the BLL samples in Butte greater than 3.3 µg/dL and 5 µg/dL has descended at a faster rate than did the NHANES data. Both sets of data show a leveling off in the later years (2013 to 2016) with higher rates persisting in Butte. Given the very old housing stock in Butte, as well as higher poverty rate among the Butte study population as compared with the NHANES data (which are adjusted to reflect the U.S. population demographics), these differences in BLLs between Butte and NHANES reflect substantial differences in lead risk factors between the two populations, in addition to the influence of historical mining activities, and are likely to persist even when remediation is complete.

Figure 25. Comparison of Butte and NHANES Percentage of BLLs above the LOD for Butte or the Reference Value



Tables 25 and 26 show the comparisons of slopes for regressions performed on the percentage of samples greater than the detection limit and reference level for all years or broken into the years for Phase 1 and 2. For all years and the Phase 1 years, with any adjustment variables used, the slopes for the NHANES regression lines were statistically significantly different from the slopes for the regression lines for the Butte data. In these cases, the Butte data showed a stronger decrease over time than the NHANES data. However, when data from the Phase 2 years were considered, there was no statistically significant difference between the slopes of the NHANES and the Butte data, and although the Butte data had consistent negative slopes, in some cases the NHANES data had positive slopes. As with Table 24, this indicates that in the Phase 2 portion of the study and in the NHANES data from 2012 to 2016, there has been little change in the percentage of BLLs that are greater than the LOD or the reference point.

Table 25. NHANES vs. Butte Comparison Regression Slopes for BLLs >3.3 µg/dL

Variable	Grouping	NHANES			Butte			Test Statistic	P value* for H0 = slope 1 = slope 2
		N	Slope 1	SE	N	Slope 2	SE		
Year only	All 2002-2017	8	-0.01464	2.13E-03	16	-0.02989	5.07E-03	2.77	**0.006**
	Phase 1 2003-2010	5	-0.01938	3.68E-03	8	-0.06568	1.05E-02	4.18	**<0.001**
	Phase 2 2012-2017	3	0.00107	2.84E-03	6	-0.00734	1.42E-02	0.58	0.561
Year + gender	All 2002-2017	16	-0.01465	1.48E-03	32	-0.02972	3.82E-03	3.68	**<0.001**
	Phase 1 2003-2010	10	-0.01935	2.51E-03	16	-0.06559	0.008312	5.33	**<0.001**
	Phase 2 2012-2017	6	0.00106	1.98E-03	12	-0.00802	1.10E-02	0.81	0.418
Year + age category	All 2002-2017	16	-0.01420	1.72E-03	32	-0.03005	0.003677	3.90	**<0.001**
	Phase 1 2003-2010	10	-0.0186	3.45E-03	20	-0.05436	5.93E-03	5.21	**<0.001**
	Phase 2 2012-2017	6	0.00061	2.37E-03	12	-0.00698	9.60E-03	0.77	0.442
Year + season	All 2002-2017	16	-0.01463	1.98E-03	32	-0.02999	3.86E-03	3.54	**<0.001**
	Phase 1 2003-2010	10	-0.01939	3.86E-03	20	-0.05483	6.23E-03	4.83	**<0.001**
	Phase 2 2012-2017	6	0.00025	1.82E-03	12	-0.00838	1.07E-02	0.79	0.428
Year + gender, age category, and season	All 2002-2017	64	-0.01417	1.22E-03	128	-0.03041	2.33E-03	6.18	**<0.001**
	Phase 1 2003-2010	40	-0.01868	2.45E-03	80	-0.05504	4.31E-03	7.33	**<0.001**
	Phase 2 2012-2017	24	-0.00028	2.91E-03	48	-0.01019	7.12E-03	1.29	0.197

Note:

*Statistically significant slopes are marked by bold P values. SE = Standard error.

Table 26. NHANES vs. Butte Comparison Regression Slopes for BLLs >5 µg/dL

Variable	Grouping	NHANES			Butte			Test Statistic	P value* for H0 = slope 1 = slope 2
		N	Slope 1	SE	N	Slope 2	SE		
Year only	All 2002-2017	8	-0.00658	1.18E-03	16	-0.02233	3.57E-03	4.19	**<0.001**
	Phase 1 2003-2010	5	-0.01011	2.08E-03	8	-0.04105	1.10E-02	2.76	**0.006**
	Phase 2 2012-2017	3	-0.00045	1.74E-03	6	-0.00641	5.80E-03	0.98	0.325
Year + gender	All 2002-2017	16	-0.0066	0.00092	32	-0.02203	0.002789	5.26	**<0.001**
	Phase 1 2003-2010	10	-0.01	0.0018	16	-0.04089	0.007804	3.85	**<0.001**
	Phase 2 2012-2017	6	-0.0004	0.00149	12	-0.00676	0.005266	1.16	0.245
Year + age category	All 2002-2017	16	-0.0062	0.00127	32	-0.02236	0.002571	5.64	**<0.001**
	Phase 1 2003-2010	10	-0.0094	0.00295	20	-0.03679	0.005128	4.63	**<0.001**
	Phase 2 2012-2017	6	-0.0006	0.00139	12	-0.00581	0.004325	1.15	0.252
Year + season	All 2002-2017	16	-0.0066	0.00114	32	-0.02261	0.00278	5.33	**<0.001**
	Phase 1 2003-2010	10	-0.0101	0.00233	20	-0.03744	0.005605	4.50	**<0.001**
	Phase 2 2012-2017	6	-0.0009	0.00145	12	-0.00669	0.005196	1.07	0.285
Year + gender, age category, and season	All 2002-2017	64	-0.0062	0.00087	128	-0.02256	0.001766	8.30	**<0.001**
	Phase 1 2003-2010	40	-0.0093	0.00198	80	-0.03703	0.003757	6.53	**<0.001**
	Phase 2 2012-2017	24	-0.001	0.00174	48	-0.0069	0.003937	1.36	0.174

Note:
*Statistically significant slopes are marked by bold P values. SE = Standard error.

7. KEY FINDINGS AND RECOMMENDATIONS

This report presents the second RMAP public medical monitoring study for the BPSOU Superfund site. The study focuses on updated analyses of blood lead data compiled as part of the RMAP. The goal of the health studies is to support an evaluation of the effectiveness of ongoing remediation and residential metals abatement efforts, and to yield recommendations regarding whether future changes are needed to these efforts.

In addition to updating the blood lead analyses, this report includes summaries of the BPSOU HHRAs conducted by USEPA, reviews of the toxicity of the key metals evaluated in the risk assessments, and descriptions of the soil action levels guiding the remediation efforts. Prior exposure and health studies conducted in Butte are also described. An updated study of cancer incidence and mortality conducted by the Montana Department of Public Health and Human Services (MDPHHS) is included among these studies.

7.1 Key Findings

Key findings are briefly summarized in this section.

7.1.1 Butte Superfund History and Community Characteristics

Remediation of historical mine wastes in Butte began in the 1980s even before the Superfund site was designated. Altogether millions of cubic yards of mine waste and contaminated soil have been remediated in Butte Silver Bow County over the past 35 years. In residential areas, the RMAP, which began in 1994, is now more than half complete, having sampled 3,332 residential parcels (of a total of 3,646) and abated 1,351 properties and attics as of 2018 (BSBHD 2018).

While Superfund is one potential health concern in Butte, health studies must consider other factors that are important determinants of public health such as age, demographics, socioeconomics, access to health care, and behavioral factors like smoking and exercise. Butte's elevation and smoking history were identified as two factors that might increase the prevalence of some diseases that could also be related to metal contamination. High elevation and outdoor lifestyles are associated with higher incidence of skin cancers; however, in 2017 Butte's skin cancer rate was lower than rates in the rest of Montana. Higher smoking rates increase risk for a number of cancers. Historically, Butte has had a high smoking rate. Happily, the 2017 smoking rate in Butte had declined significantly from the 2014 rate.

While Superfund issues were not identified as key health concerns in the community needs assessments conducted by BSBHD and St. James Healthcare, a recent study on community risk perceptions related to Superfund revealed many misperceptions about the extent of remediation and potential for ongoing exposures. For example, there was a perception that drinking water might be contaminated even though the source of Butte's drinking water is outside areas affected by historical mining activities. The survey's findings about where people get information about Superfund-related remediation and health issues indicates that few rely on USEPA public meetings, and rely instead on local news media, family and friends and social media. This finding provides insights to approaches to more effectively engage the community on Superfund health issues.

7.1.2 Review of Toxicity, Risk Assessments and Action Levels

A preliminary HHRA for Butte was conducted by USEPA in 1991, with a series of more focused HHRAs conducted since that time. Lead, arsenic and mercury were identified as contaminants that were “risk drivers”, i.e., cleaning up areas with elevated levels of those metals would control health risks.

Soil action levels for lead, arsenic and mercury were based on the results of the USEPA HHRAs and research conducted on the bioavailability of lead and arsenic in soil, and from a comprehensive lead biomonitoring and exposure study conducted by the University of Cincinnati and BSBHD. The bioavailability of lead in Butte soil was found to be very low. No site-specific studies were conducted using Butte indoor dust, so the default assumptions were applied, i.e., assuming lead is more readily absorbed from dust than from soil. The protectiveness of these action levels was reviewed by USEPA in the BPSOU ROD and continues to be reviewed in ROD reviews conducted every 5 years. These reviews include reviews of new toxicological and epidemiological information about the key chemicals.

7.1.3 Review of Past Exposure/Biomonitoring Studies

Recent exposures to metals may be measured directly by analyzing the concentrations in biological samples collected from people. For lead, arsenic and mercury there are multiple common sources of exposures that are not related to mining affected soils in the BPSOU, with diet being a significant source of exposure to arsenic and mercury for most people. For lead there are many, varied sources of exposure in homes and the community, including imported spices, costume jewelry, ceramic dishes, painted toys, vinyl blinds, brass drinking water fixtures, and lead solder and pipes (lead pipes are not known to be present in Butte).

Because of these pervasive sources, the results of biological sampling for an individual seldom provides evidence of exposure from one specific source. For that reason, the use of biological testing as an adjunct to exposure assessment is usually done in the context of a more comprehensive community biomonitoring study. Biomonitoring studies may employ multiple biomarkers that vary based on the behavior of the chemical being studied. Common biomarkers include hair, urine, nails, and blood. Urine and blood are the most common matrices that are collected with blood being the most widely used method of assessing lead exposure, while urine is used to measure arsenic exposure. Hair and nails have been studied as potential indicators of longer-term exposure (Wolowiec et al. 2013, Davis et al. 2014), but standardizing sample preparation procedures has been challenging, especially washing to remove external contamination and mineralization methods.

Since 1990, two large exposure studies have been conducted in Butte, as well as several more focused studies.

Working with BSBHD, University of Cincinnati scientists conducted an extensive blood lead and urine arsenic exposure study (BSBHD/UC 1992) that also included measurements of arsenic and lead in soil, house dust, drinking water and lead in paint. The lead study included 294 children up to age six, plus 53 older children and 48 adults. There were 140 participants in the urine arsenic study. The geometric mean BLL among young children was similar to U.S. levels and lower than values from other mining communities tested at that time. Although the community BLLs were not elevated compared with national values, there was evidence of some influence of a combination of soil, dust, and paint lead on BLLs. The investigators concluded that 39% of the variability in soil lead concentrations was attributable to lead-based paint, while the remainder (61%) was attributable to “the heterogeneous distribution of lead in soil, and lead from other sources such as native lead in soil, mine waste and contaminates from ore processing.” Gardening or eating homegrown produce was shown not to contribute to elevated BLLs. In contrast, urine arsenic concentrations were not higher among participants with higher yard soil arsenic concentrations. The RMAP was an outgrowth of a recommendation made by the University of Cincinnati scientists.

The Phase 1 Superfund medical monitoring study focused on blood lead samples collected from 2003 through 2010 (ENVIRON 2014), including 2796 records from 1697 young children, most of whom were from low income families. No associated exposure data were available for this study. A reference population was created from national blood lead data to compare Butte BLLs with those expected in a comparable community that did not have the historical mining activity. When comparing geometric mean BLLs over four 2-year study periods, BLLs declined more rapidly over time in Butte versus the reference population and were comparable by the last period (2009-2010). BLLs greater than 5 µg/dL also declined more rapidly in Butte but were still higher than those in the reference population at the last study period. When comparing BLLs for children living in Uptown with those of children living in the Flats, average BLLs in Uptown were consistently higher than those in the Flats, although the difference was small and not statistically significant in all time periods. The difference was greatest in the summer months when children are expected to have more contact with soil.

The ATSDR (2002) also conducted a small blood lead and urine arsenic study targeting households that had elevated lead and arsenic in house dust. Most BLLs among the 23 participants were 1 µg/dL or less (including among the 9 children). The highest BLL as 5 µg/dL in a 70-year-old man. All 25 participants had undetectable urine arsenic levels.

Hailer et al. (2017) sought to establish baseline metal concentrations in hair and blood and possible routes of exposure for 116 adults living in Butte, Montana; these concentrations were compared with those in a control group of 86 individuals from Bozeman, Montana. The Butte participants were older than the Bozeman participants, with the median age being 20 years higher. The focus of this study was on current mining operations, which are unrelated to the historical mining operations that are the subject of the Phase 2 study. Air and soil samples were also collected. Lead concentrations were not elevated in hair of Butte participants, while 3 of the 35 other elements tested were higher in Butte participants when age, gender and smoking status were considered. Among the 11 elements tested in blood, only arsenic concentrations were higher in Butte participants.

The biomonitoring conducted in Butte to date is more extensive than that conducted in all but a handful of other mining communities in the U.S. The total available blood lead results from the last 15-20 years is over 6,000 records. While these records are not linked to exposure data, they provide a comprehensive view of the overall status of lead exposure from all sources in Butte supporting an evaluation of exposure trends over time and assessment of the effectiveness of the RMAP. The 1990 study of lead and arsenic exposures is an example of a comprehensive exposure study that supported identification of the relative contribution of specific sources of exposure. This study is the gold standard of such studies and continues to provide us with useful insights close to 30 years later. These studies have focused on the metals with the greatest potential to impact public health and have tested the population most vulnerable to exposures to metals in soil (i.e., young children).

7.1.4 Review of Disease Prevalence and Rate Studies

Five studies of disease prevalence in Butte were identified, beginning with an ecological study of skin cancer published in 1992, and followed by three surveillance studies of cancer incidence for the Butte population compared with state and/or national data in 2002, 2012 and 2018. The

2012 and 2018 studies also considered cancer mortality rates. The fifth study was an ecological study that examined mortality rates of a broad range of diseases.

Self-reported disease and risk factor prevalence studies were also conducted as part of the periodic community needs assessments conducted by BSBHD. The 2017 assessment reported that rates of diabetes, skin cancer and smoking were lower in Butte than in the rest of Montana or the U.S., while rates of asthma, chronic obstructive pulmonary disease, Alzheimer's and kidney disease were higher than the rest of Montana or the U.S. Rates for all kinds of cancer and for cardiovascular risk factors were the same as in the comparison groups. Rates of smoking and cardiovascular risk factors had declined significantly since the 2014 assessment.

Wong et al. (1992) conducted an early ecologic study of skin cancer for Silver Bow and Deer Lodge counties using case reports collected from health providers. Certain types of skin cancer have been associated with arsenic exposure. Contrary to their hypothesis, Wong et al. (1992) found higher age-adjusted annual skin cancer rates for the two control counties than for either Silver Bow and Deer Lodge counties. The control counties had a much higher rate of farming, and the high UV exposure of farm workers was hypothesized to be the cause of elevated skin cancer rates in those counties.

In contrast, ATSDR (2002), using the MCTR and national databases, found statistically significantly higher standardized incidence rates (SIR) of skin cancer among Silver Bow County residents compared to Montana and the U.S. The SIR in Butte-Silver Bow was highest for people 20 to 54 years old when using Montana as a reference, while the SIRs were highest among people 65 years old and older when using the U.S. as a reference. No other cancer rates were consistently elevated. Urinary bladder, kidney, and lung cancer had elevated rates in some age groups, but results were not consistent throughout the whole dataset. Liver and prostate cancer had no elevated rates.

MDPHHS (2012) examined both cancer incidence and mortality in Butte-Silver Bow from 1981 through 2010 data from Montana death records and the MCTR. The age-adjusted incidence rates among Silver Bow County residents for all cancers combined and for each of the four most common cancers were statistically the same or lower than for Montana and the U.S. The incidence rates for cancers known to be associated with arsenic exposure were statistically lower in Butte Silver Bow than for Montana and the U.S. MDPHHS also examined cancer mortality rates. Mortality rates for cancers of prostate, breast, bladder, and lung and bronchus were not elevated in Silver Bow County, while the mortality rate for colorectal cancers was elevated in all three time periods.

In 2018, the Montana Department of Public Health and Human Services (MDPHHS) updated the 2012 Silver Bow County cancer mortality and incidence analysis extending the analysis through 2016. Age-adjusted incidence rates for all cancers combined were statistically the same as rates for other Montana residents from 2002 through 2016. Age-adjusted mortality rates for all cancers combined were significantly higher among Silver Bow County residents compared to other Montana residents from 2012 to 2016, whereas from 2002 through 2011 the rate of cancer deaths was the same among Silver Bow County residents as other among other Montana residents. The rate of new breast, bladder, kidney, colorectal, and lung and bronchus cancer cases and the rate of deaths were statistically[7] the same in Silver Bow County and the rest of Montana from 2007-2016. The rate of new prostate cancer cases in men in Silver Bow County

[7] There were too few kidney cancer deaths to allow for statistical comparison.

has been declining and was significantly lower from 2007-2016 compared with the rest of Montana. Liver cancer incidence was not statistically elevated, but mortality was statistically elevated among Silver Bow County residents compared to other Montana residents from 2007-2016.

Davis et al. (2019) used mortality data obtained from the CDC WONDER site to examine the hypothesis that elevated exposures to metals in Deer Lodge and Silver Bow counties might be associated with certain diseases. Deer Lodge and Silver Bow had overall higher mortality compared to the rest of Montana from 2000 to 2015 for cancers, cerebrovascular and cardiovascular conditions, and organ failures. Neurological conditions mortality was not elevated compared to the rest of Montana. From 2000 to 2015 mortality due to cancer, cerebrovascular and cardiovascular, and neurological conditions decreased among Silver Bow and Deer Lodge county residents. The organ failure mortality remained the same over the study period. No exposure data were linked to the cases to support the assertion that different mortality rates were associated with metal exposures, and no analysis of remediation timelines was presented to support the hypothesis that reduced rates were associated with remediation.

The best way to assess the effects of environmental exposure on cancer risk is to measure cancer incidence which measures the number of newly diagnosed cancer cases in a population each year. Cancer mortality, the number of deaths that occur each year from cancer, reflects both the risk of getting cancer and the ability to get effective diagnosis and medical treatment. Therefore, incidence rates are the best way to compare the risk of getting a disease and mortality rates are a way to compare access to care and treatment after people become ill.

None of the Butte studies included individual level exposure data or occupational history. Such surveillance and ecological studies are hypothesis generating studies primarily used to suggest future studies that should be done. So, none of these studies can be linked to causes of observed elevated incidence or mortality. They are all valuable for use in identifying areas of focus for future studies.

MDPHHS (2012, 2018) and ATSDR (2002) defined cancer-related mortality using underlying cause of death (i.e., the immediate cause of death) recorded on the death certificate rather than using multiple cause of death (i.e., intermediate causes), as Davis et al. (2018) did. MDPHHS's approach to defining cancer-related mortality in this way is a standard surveillance method used by state and federal public health agencies. Studies have shown that the two methods of defining cause-specific mortality can yield greatly different results, with the multiple cause definition counting more deaths than underlying cause (Redelings et al. 2006). The different methods in defining cancer-related mortality may account for the different conclusions of the MDPHHS analysis and Davis et al. study the immediate cause of death, and not intermediate causes, underlying causes, or other health disorders a person had at the time of death, is used by state health departments in calculating mortality rates.

7.1.5 Phase 2 Blood Lead Data Analysis

Blood lead data from 2011 through 2017 and summary statistics were compiled, and exposure trends over time, by Butte neighborhood, and (to the extent supported by available data) in comparison to a defined reference population were evaluated. There were a total of 3,077 BLL records for all age categories. Among the infants less than 12 months old, 20 of 373 tested (or 5.4%) had BLLs greater than 5 µg/dL. Among children 12 to 60 months of age, 172 of 2,330 (or 7.4%) had BLLs greater than 5 µg/dL. Only 3 of the 326 (0.9%) adults tested had BLLs greater than 5 µg/dL. Consistent with the Phase 1 study, these data confirm that it is appropriate to focus the Phase 2 study on children from 12 to less than 60 months of age. For the young children, 76% of the blood lead samples in the dataset were below the LOD (3.3 µg/dL), meaning that the Phase 2 study could not replicate the approach used in the Phase 2 study of focusing on trends in the geometric mean BLLs. For the Phase 2 assessment, demographic and geographic parameters similar to those used in the Phase 1 study (including the child's age and gender, the neighborhood and age of housing, and the season in which the blood samples were collected) were used to determine if these variables had a significant effect on the BLLs.

The Uptown neighborhoods continue to show higher percentages of samples greater than the 5 µg/dL throughout both study periods, but in both Uptown and the Flats the percentage of elevated BLLs declined from the 2003-2010 period to the 2012-2017 period. The differences between Uptown and the Flats likely primarily reflect both the older housing stock Uptown and the greater extent of mine waste affecting soil concentrations, both factors being addressed by the RMAP. The higher rate of elevated BLLs in Uptown versus the Flats persists even when considering house age. For example, from 2012-2017, 13.3% of Uptown children living in the oldest houses built before 1940 had elevated BLLs versus 5.9% in the Flats. In both study periods BLLs are about 20-30% higher on average in the warmer half of the year. Uptown also continues to have more elevated BLLs than the Flats in each season.

Another factor to consider in assessing seasonal variation in BLLs is seasonal variation in lead in drinking water. Several studies have demonstrated that lead concentrations in drinking water increase during warm weather when lead service lines are present (Deshommes et al. 2013, Ngueta et al. 2014). This phenomenon occurs because warmer water is more acidic and more effectively leaches lead from plumbing fixtures. The 1990 Blood Lead and Urine Arsenic Study (BSBDH/UC 1992) documented elevated tap water concentrations across all Butte neighborhoods, a finding that is not consistent with current conditions which include management of pH and addition of corrosion controls to reduce lead leaching potential.

Linear regression analyses were used to examine the time trends for elevated BLLs for variables known to affect BLLs. For all variables and years during Phase 1 and for Phase 2, in every case the slope is negative, indicating that the percentages of samples above the LOD or reference value are decreasing over time. All of the "All Years" and "Phase 1" slopes are significantly different from zero, but the "Phase 2" slopes are not. This points to a slowing down of the decrease in BLLs, with no statistically significant differences between the years of 2012 through 2017. Logistic regression was performed to see if there were significant differences across the categories of the descriptive variables (child's age, house age, neighborhood, season, and year sample was obtained) in the number of blood lead samples above the reference value. All three groupings of years (all years, 2003-2010 and 2012-2017) show statistically significant differences in the child age categories, the seasons, and Uptown versus the Flats.

During the Phase 1 study the NHANES data for the applicable years were weighted to match the Butte population for key variables known to affect BLLs. House age was the most influential variable, but information on house age is no longer collected as part of the more recent NHANES data. While this factor and the much higher detection limit for the Phase 2 Butte blood lead data prevent direct comparison of rates of elevated BLLs between NHANES and Butte, it is still relevant to compare the rates of change in the elevated BLLs between the two datasets.

A comparison between the percentage of NHANES BLLs greater than 3.3 µg/dL and 5 µg/dL reported between 2003 and 2016 and those reported in Butte shows that the percentage of the BLLs in Butte greater than 3.3 µg/dL and 5 µg/dL has descended at a faster rate than did the

NHANES data. Both sets of data show a leveling off in the later years (2013 to 2016) with higher rates persisting in Butte. Given the very old housing stock in Butte, as well as higher poverty rate among the Butte study population as compared with the NHANES data (which are adjusted to reflect the U.S. population demographics), these differences in BLLs between Butte and NHANES reflect substantial differences in lead risk factors between the two populations, in addition to the influence of historical mining activities. The greatest risk factor is potential lead paint exposures due to the very old housing stock in much of Butte. Because the RMAP only addresses lead paint when necessary to protect soil that has been remediated or when investigating a reported elevated BLL, this risk factor is likely to persist even when remediation is complete.

The percent of Butte children with elevated BLLs is still higher than the average reported in a national survey of BLLs. There are several possible reasons for this difference. One reason could be continuing exposures to lead in soil that hasn't yet been cleaned up or to lead paint in homes not yet abated. Another reason could be related to the method used to collect blood samples in Butte. The national survey used samples collected by venipuncture. The Butte samples are collected by a finger stick. The venous samples usually provide a more reliable indication of elevated BLLs (Wang et al. 2019). For example, in Michigan (MDHHS 2017), which has a state-wide blood lead surveillance program with samples collected by finger stick, 3.4% of the children had elevated BLLs in 2015. Only half of those children were confirmed to have elevated BLLs when tested by venipuncture.

The percent of elevated BLLs in Butte is also lower than in many U.S. counties (often those with a high percentage of older housing). Looking again to Michigan, in 2015 the three counties with the highest percent of elevated BLLs had rates of 10.1%, 6.5% and 6.2%, as compared to the 6% rate found in Butte in 2015. And finally, the percent of elevated BLLs are higher among low income children such as those tested in Butte. The national survey is representative of children at all income levels, whereas the Butte data are mostly from children whose families have income low enough to qualify for the Women, Infants and Children (WIC) program. For example, in Michigan, the rate of elevated BLLs statewide was 3.4%, but among children enrolled in Medicaid, the rate was 4.2%, more than 20% higher.

7.2 Recommendations

Based on this study, recommendations are provided in four categories: RMAP operations, future exposure/biomonitoring studies, future epidemiology/disease studies, and public outreach and communication. One general recommendation is that the Working Group be maintained as an active group, meeting at least several times per year to facilitate implementation of the recommendations and to plan for the next study.

7.2.1 RMAP Operations

The Phase 1 study concluded "Given that Butte BLLs for the most recent time period evaluated are no longer statistically different from the reference population, but differences were identified in earlier years, we conclude that the RMAP has been effective and should be continued. Coupled with other extensive source remediation activities in Butte, the RMAP has been an important community-wide mechanism for identifying and reducing lead exposures." Continued declines in elevated BLLs observed in the Phase 2 study provides continued support for this conclusion.

Two key recommendations from the Phase 1 study were that focused on BSBHD outreach activities:

1. To the extent possible, build upon community interactions via the RMAP to further promote exposure reduction education and outreach, including exposure reduction related to non-Superfund sources (e.g., house paint). It is crucial that outreach efforts be maintained at a consistently high level because the population of concern continues to change as children grow and as families move into the community.
2. Continue to seek opportunities to promote community participation in the RMAP, particularly among residents of Uptown where increased exposures and risk factors are evident. We understand that some "information fatigue" may be occurring in Butte, but continued efforts are needed to reach new residents and longer term residents who may have changed circumstances.

Based on the RMAP annual reports, these recommendations have been implemented. Excerpts from the 2018 Annual Report below detail outreach activities for the year, and are typical of past and ongoing outreach activities:

> "During the calendar year of 2018 the RMAP distributed program specific posters and brochures to various local businesses and agencies and worked with the Butte-Silver Bow Community Enrichment Program to provide outreach to the public. The RMAP was represented at the Wellbeing Fair conducted at the Butte Civic Center. The program was also represented at the Career Fair conducted at Butte High School. The program also made informative presentations to multiple real estate agencies. Soil specific and attic dust specific public service announcements public service announcements were aired in the spring, mid-summer, and early fall. Program specific mailers which offered environmental assessments to property owners within the BPSOU were also distributed in the spring, mid-summer, and early fall. Program staff was also available at the CTEC office periodically throughout 2018 to provide program information to the general public. RMAP partnered with CTEC to provide program specific information to the general public at a booth during the Butte Farmers' Market. The RMAP continues to work in conjunction with the medical community, particularly pediatricians and the WIC program to inform the public about risk, health monitoring, nutritional information, the program's activities, and to ensure clientele are offered environmental assessments.
>
> The education and outreach program materials specifically address portions of the homes that pose a risk for potential exposure and encourage property owners to participate in the program's activities. The portions of the home addressed are the attic space, interior living space, and exterior yard areas. The program relies on educational materials and face-to-face consultations to ensure that homeowners, remodeling contractors, home inspectors, electricians, potential buyers, and weatherization workers are aware of the following:
>
> (1) The potential presence of lead, arsenic, and/or mercury in attics or earthen basements;
>
> (2) The importance of restricting access to those areas by sensitive populations and taking the appropriate measures to ensure that dust is not tracked into the interior living space when infrequent access occurs; and

(3) The proper contact information prior to implementing any remodeling project and/or landscaping project to ensure that dust and soil are appropriately handled and disposed of by a responsible entity and/or by approved contractors.

The educational materials shall be provided to all participants of the program at the time an environmental assessment of the home is implemented (whether interior or exterior) as well as when applicable building permits are sought for remodeling projects. Recommendations made to each resident will be based on the results of the environmental assessment performed at their home and specific information collected by program staff about daily habits and activities."

In addition to these activities, RMAP staff send out on average 500 direct mailers yearly which offer free environmental assessments for properties that are known to have not been sampled. These yearly direct mailers should address the concerns mentioned above regarding the need to reach new property owners or longer-term residents whose circumstances might have changed.

Two new recommendations for RMAP operations are now added:

1. Concerns have been raised about landlord participation in RMAP. It is recommended that BSBHD staff assess these participation rates and determine if additional outreach or alternate approaches are needed to increase landlord participation rates.
2. It is recommended that a position be established within the BSBHD for an environmental health clinician specializing in pediatrics. This is consistent with a recommendation first made by BSBHD/UC (1992). Establishment of this position would facilitate tracking and follow up for cases with elevated BLLs and would also assist with the recommended outreach to other clinicians in Butte (see below).

7.2.2 Recommendations for Future Exposure/Biomonitoring Studies

Primary recommendations for future exposure/biomonitoring studies and RMAP operations include the following:

- Continued focus on lead biomonitoring,
- Increased tracking and refined follow-up for individuals with elevated BLLs,
- Increased outreach to local pediatricians and clinics to augment the available blood lead data.

These and other recommendations are elaborated below.

Lead biomonitoring has been and should continue to be the focus of the Superfund health studies. The Phase 1 study report recommended that BSBHD re-initiate blood lead testing procedures that produce reliable results at a detection limit of 1 µg/dL or lower. BLLs in Butte are now low enough that trends in BLLs cannot be discerned using testing procedures with higher detection limits. Despite that limitation, the clinical advantages of using the LeadCare II kits that provide immediate results need to be considered and a return to testing procedures with a lower detection limit is not recommended at this time.

At the beginning of the Phase 1 study, blood lead data were stored in individual patient records, and a primary recommendation was the addition of blood lead data to the BSBHD electronic database. Since the Phase 1 study, this recommendation has been successfully implanted by BSBHD with electronic capture of blood lead data. It is recommended that BSBHD staff document the procedures and instructions they follow for blood lead sampling and data handling to ensure consistency over time and with staff changes. Consistency will support better tracking and follow up of individuals who have confirmed BLLs exceeding the CDC reference value.

Given that geometric mean Butte BLLs had already declined to the levels of the reference population during 2009-2010, combined with the fact that a comparable reference population can no longer be created from the NHANES database due to dropping house age information, it may be more useful to focus recommendations on refining follow up for individuals with elevated BLLs. Changes in procedures to increase the number of venous confirmation samples that are collected within several weeks of a reported elevated BLL is more likely to provide insights regarding the true rate of elevated BLLs in Butte. The results of the confirmation testing should be included in the blood lead database to ensure that appropriate follow up occurs and should also be coded in such a way that those records can be linked to the original results for use in the next medical monitoring study. The Phase 1 study also recommended that to the extent legally possible, additional information from blood lead tested individuals be collected to improve interpretation of community BLL trends going forward (e.g., race, maternal education, household income level). Given the lack of a suitable reference population for comparison, this recommendation is now a lower priority than the recommendation for more venous confirmation testing and documentation of case follow up and lead exposure sources. The need to collect such demographic data would need to be tied to a specific study goal.

The recent Anaconda study (ATSDR 2019a) included a recommendation that primary healthcare providers should continue to improve understanding of lead screening and ways to reduce exposure to site contaminants and lead paint. This recommendation should also be applied to Butte and could be supported by the new BSBHD staff position. ATSDR (2019a) notes that ATSDR's Case Studies in Environmental Medicine (CSEM) provide a self-instructional primer. The lead and arsenic CSEMs are available at:

https://www.atsdr.cdc.gov/csem/csem.asp?csem=34&po=0
https://www.atsdr.cdc.gov/csem/csem.asp?csem=1&po=0.

Currently, very little blood lead data are available from sources other than BSBHD/WIC. Increased outreach to local pediatricians and clinics would augment the available blood lead data. The American Academy of Pediatrics (AAP 2016) recommends that "pediatricians and other primary care health providers should conduct targeted screening of children for elevated blood lead concentrations if they are 12 to 24 months of age and live in communities or census block groups with ≥25% of housing built before 1960 or a prevalence of children's blood lead concentrations ≥5 µg/dL (≥50 ppb) of ≥5%." The percentage of BPSOU houses built before 1960 is much greater than 25%, likely greater than 80%, indicating that this recommendation would apply to Butte even in the absence of the historical mining lead sources. In addition, based on the BSBHD surveillance data, the more than 5% of Butte children in the WIC program has BLLs ≥5 µg/dL. The Phase 1 study recommended a program to ensure that records are obtained regularly from all doctors and clinics to provide a more robust view of BLLs in Butte and to facilitate tracking of children tested multiple times; however, a means of implementing this program was not proposed. Such an effort could be developed by the new environmental health clinician if that position is created.

The American College of Obstetricians and Gynecologists (ACOG 2012) recommends that "risk assessment of lead exposure should take place at the earliest contact with pregnant or lactating women, and blood lead testing should be performed if a single risk factor is identified". One of the risk factors is "living near a point source of lead—examples include lead mines, smelters, or battery recycling plants (even if the establishment is closed).” Data from St. James Medical Center (considered during the Phase 1 study) showed very low BLLs among pregnant women at delivery, and the routine testing was discontinued. It is recommended that the new environmental health clinician conduct outreach to Butte primary healthcare providers to encourage including lead risk assessment in prenatal visits.

Two arsenic biomonitoring studies conducted in Butte have not found any evidence of elevated arsenic exposure due to arsenic in soil (ATSDR 2002 and BSBHD/UC 1992). The 1992 study included evaluation of soil concentrations and did not find any correlation between those and urine arsenic concentrations, while the 2002 study preferentially selected people with the highest reported house dust arsenic concentrations and in most cases found undetectable urine arsenic. A third study (Hailer et al. 2017) reported higher arsenic in hair and blood of Butte residents as compared with Bozeman residents, but soil arsenic levels for the Butte residents were reported to be much less than the soil action level, while air concentrations were reported to be higher than ambient levels. Dietary sources of arsenic were not reported to have been controlled prior to sampling.

Given these findings, another arsenic exposure study in Butte is not likely to yield useful information about soil remediation effectiveness. Based on the recent study in Anaconda (ATSDR 2019a), regular access to un-remediated attics could be a source of exposure. Additional engagement is needed to address expressed concerns about arsenic exposure from the community. One initial step might be development of a flyer describing the uses and limitations of arsenic exposure studies and describing the results of the prior studies. This flyer could be coupled with a summary of the results of recent Anaconda ATSDR study, as well as describing what would be needed to support a successful exposure study in Butte.

7.2.3 Recommendations for Future Epidemiology/Disease Studies

Periodic updates by MDPHHS of cancer incidence and mortality in Butte-Sliver Bow versus Montana and the U.S. should continue and will provide useful information for the community health needs assessments, as well as for Superfund. Hypothesis-generating studies that have been conducted so far do not support concerns about elevated cancer rates in Butte. Arsenic is the primary carcinogen with elevated soil concentrations, but there is no evidence of increased exposures to soil arsenic that support the need for case control or cohort studies that could examine such a link. Elevated skin cancer rates could signal a need to investigate arsenic exposure further; however, two of three studies that have looked at skin cancer do not find elevated rates in Butte, including the most recent health needs assessment. Skin cancer is not a reportable disease, so MDPHHS has not been able to evaluate that cancer using the MCTR. The Wong et al. (1992) study provides an example of a method to study skin cancers but given their negative findings and the major confounding by high exposure to sunlight among farm workers in the control communities, an effective approach for further study is not readily apparent.

Rates of diseases other than cancer are difficult to study because there are no registries that reliably document incidence. The community health needs assessments have provided the most useful source of information on prevalence of major disease categories. The findings of these assessments should be reviewed to determine if they provide indications of possible environmental exposures related to Superfund or other sources within the community. Neurological diseases, and especially multiple sclerosis are a continuing community concern; however, the CDC has stated that a study of this disease is not feasible or needed (Bryesse 2017).

7.2.4 Recommendations for Public Outreach and Risk Communication

The NIH-funded pilot study reported by Nagisetty et al. (2019) confirmed the existence of a health risk perception gap between BPSOU residents and the regulatory agencies. The primary message for Superfund is that few residents rely on USEPA public meetings as a source of information and rely instead on local news media, family and friends and social media. This finding suggests that USEPA and responsible parties (i.e., AR and Butte-Silver Bow) need to supplement public meetings and flyers with regular communications via local news media and social media. In addition to added communication methods, methods of more proactively engaging members of the public should be developed.

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APPENDIX A
LOGISTIC REGRESSION –
BLL TIME TRENDS FOR VARIABLES

Table A 1. Univariate Logistic Regression for BLLs >5 µg/dL

Variable	Categories	All Years 2002-2017 (N=5,584)			Phase 1 2003-2010 (N=2,724)			Phase 2 2012-2017 (N=2,330)		
		Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)
Gender	Male	ref			ref			ref		
	Female	-0.1044	0.0063	**0.81 (0.70,0.94)**	-0.1398	0.0034	**0.76 (0.63,0.91)**	0.0785	0.324	1.17 (0.86,1.60)
Age category	12 to 35 months	ref			ref			ref		
	36 to 60 months	-0.1053	0.0068	**0.81 (0.70,0.94)**	-0.1018	0.0343	**0.82 (0.68,0.99)**	-0.2028	0.0148	**0.67 (0.48,0.92)**
Year	2002	1.3933	<.0001	1.29 (0.78,2.14)						
	2003	ref			ref					
	2004	1.6416	<.0001	**1.65 (1.20,2.27)**	1.1985	<.0001	**1.65 (1.20,2.27)**			
	2005	0.6976	<.0001	**0.64 (0.45,0.91)**	0.2544	0.0463	**0.64 (0.45,0.91)**			
	2006	0.1324	0.388	**0.37 (0.25,0.54)**	-0.3108	0.0321	**0.37 (0.25,0.54)**			
	2007	0.1621	0.2741	**0.38 (0.26,0.55)**	-0.2811	0.0452	**0.38 (0.26,0.55)**			
	2008	0.5004	0.0003	**0.53 (0.37,0.75)**	0.0572	0.662	**0.53 (0.37,0.75)**			
	2009	-0.3089	0.0704	**0.24 (0.16,0.36)**	-0.752	<.0001	**0.24 (0.16,0.36)**			
	2010	-0.4196	0.0087	**0.21 (0.14,0.31)**	-0.8625	<.0001	**0.21 (0.14,0.31)**			
	2011	-0.3892	0.013	**0.22 (0.15,0.32)**						
	2012	-0.9212	<.0001	**0.13 (0.08,0.20)**				ref		
	2013	-0.3437	0.0254	**0.23 (0.16,0.33)**				0.4145	0.0078	**1.78 (1.08,2.94)**
	2014	-0.273	0.0711	**0.24 (0.17,0.36)**				0.4852	0.0016	**1.91 (1.16,3.15)**
	2015	-0.8947	<.0001	**0.13 (0.08,0.21)**				-0.1365	0.4659	1.03 (0.59,1.80)
	2016	-1.0698	<.0001	**0.11 (0.06,0.20)**				-0.3116	0.1956	0.86 (0.44,1.68)
	2017	-1.0467	<.0001	**0.11 (0.06,0.20)**				-0.2885	0.231	0.88 (0.45,1.72)

Variable	Categories	All Years 2002-2017 (N=5,584)			Phase 1 2003-2010 (N=2,724)			Phase 2 2012-2017 (N=2,330)		
		Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)
Year house built	Unknown	0.6627	<.0001	**2.78 (1.49,5.21)**	0.3599	0.0166	1.34 (0.56,3.25)	0.7197	0.0038	**3.56 (1.07,11.91)**
	Before 1940	0.8955	<.0001	**3.51 (1.89,6.52)**	0.7791	<.0001	2.04 (0.85,4.91)	0.9604	<.0001	**4.53 (1.42,14.49)**
	1940 to 1949	0.3171	0.0453	**1.97 (1.01,3.85)**	0.2569	0.1885	1.21 (0.48,3.07)	0.1588	0.6324	2.03 (0.55,7.53)
	1950 to 1959	0.1085	0.5477	1.60 (0.80,3.22)	0.1077	0.6389	1.05 (0.40,2.75)	0.1739	0.6004	2.06 (0.56,7.65)
	1960 to 1977	-0.0343	0.8503	1.39 (0.69,2.79)	-0.1184	0.6305	0.83 (0.31,2.24)	-0.0732	0.8311	1.61 (0.43,6.07)
	1978 to 1989	-1.5885	0.0016	0.29 (0.08,1.07)	-1.4492	0.02	0.22 (0.04,1.15)	-1.3888	0.1105	0.43 (0.04,4.23)
	1990 and later	ref			ref			ref		
Neighborhood groups	Flats	-0.4156	<.0001	**0.44 (0.37,0.51)**	-0.3787	<.0001	**0.47 (0.39,0.57)**	-0.5669	<.0001	**0.32 (0.23,0.45)**
	Uptown	ref			ref			ref		
Neighborhood	1	0.5141	<.0001	1.03 (0.71,1.50)	0.448	<.0001	0.95 (0.61,1.49)	0.715	<.0001	2.14 (0.76,6.06)
	2	0.7251	<.0001	1.28 (0.87,1.88)	0.7414	<.0001	1.27 (0.79,2.04)	0.9518	<.0001	2.71 (0.95,7.77)
	3	0.00392	0.976	**0.62 (0.40,0.96)**	0.0391	0.8032	0.63 (0.37,1.06)	-0.0624	0.8313	0.98 (0.30,3.20)
	4	0.00126	0.9908	**0.62 (0.41,0.93)**	0.0862	0.5218	0.66 (0.40,1.08)	-0.3224	0.2095	0.76 (0.24,2.36)
	5	-0.4411	0.0045	**0.40 (0.25,0.64)**	-0.3865	0.0411	**0.41 (0.23,0.73)**	-0.447	0.1801	0.67 (0.20,2.30)
	6	-0.4026	0.0002	**0.41 (0.28,0.62)**	-0.3843	0.0024	**0.41 (0.26,0.67)**	-0.5894	0.0212	0.58 (0.19,1.80)
	7	-0.8828	0.0008	**0.26 (0.13,0.50)**	-1.0455	0.0026	**0.21 (0.09,0.51)**	-0.199	0.6307	0.86 (0.22,3.31)
	8	ref			ref			ref		
Season	May 1 through Oct 31	0.142	0.0002	**1.33 (1.14,1.54)**	0.148	0.0019	**1.35 (1.12,1.62)**	0.1799	0.0255	**1.43 (1.05,1.97)**
	Nov 1 through Apr 30	ref			ref			ref		

Note:
*Statistically significant differences between the reference category and other categories are marked by bold ORs.

Table A 2. Multivariate Regression Using Selection by Phases and Overall for BLLs >5 µg/dL

Variable	Categories	All Years 2002-2017 (N=5,584)			Phase I 2003-2010 (N=2,724)			Phase II 2012-2017 (N=2,330)		
		Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)
Age category	12 to 35 months	ref			ref					
	36 to 60 months	-0.132	0.0018	**0.77 (0.65,0.91)**	-0.133	0.0109	**0.77 (0.63,0.94)**	-0.213	0.0124	**0.65 (0.47,0.91)**
Gender	Male	ref			ref					
	Female	-0.081	0.05	**0.85 (0.72,1.00)**	-0.128	0.0134	**0.78 (0.63,0.95)**	Not Selected		
Year	2002	1.378	<.0001	1.19 (0.70,2.04)						
	2003	ref			ref					
	2004	1.760	<.0001	**1.74 (1.25,2.43)**	1.291	<.0001	**1.73 (1.24,2.41)**			
	2005	0.763	<.0001	**0.64 (0.45,0.92)**	0.300	0.0233	**0.64 (0.45,0.92)**			
	2006	0.184	0.2448	**0.36 (0.24,0.54)**	-0.283	0.059	**0.36 (0.24,0.53)**			
	2007	0.163	0.2868	**0.35 (0.24,0.52)**	-0.308	0.0329	**0.35 (0.24,0.51)**			
	2008	0.469	0.001	**0.48 (0.33,0.69)**	0.011	0.9342	**0.48 (0.33,0.69)**			
	2009	-0.382	0.028	**0.21 (0.13,0.31)**	-0.852	<.0001	**0.20 (0.13,0.31)**			
	2010	-0.442	0.0068	**0.19 (0.13,0.29)**	-0.904	<.0001	**0.19 (0.13,0.29)**			
	2011	-0.416	0.0092	**0.20 (0.13,0.29)**						
	2012	-0.949	<.0001	**0.12 (0.07,0.19)**				ref		
	2013	-0.352	0.0249	**0.21 (0.14,0.31)**				0.426	0.008	**1.85 (1.10,3.08)**
	2014	-0.346	0.0257	**0.21 (0.14,0.31)**				0.442	0.0051	**1.87 (1.13,3.12)**
	2015	-0.912	<.0001	**0.12 (0.08,0.19)**				-0.137	0.473	1.05 (0.59,1.86)
	2016	-1.098	<.0001	**0.10 (0.06,0.18)**				-0.319	0.194	0.88 (0.44,1.73)
	2017	-1.024	0.0001	**0.11 (0.06,0.20)**				-0.226	0.3575	0.96 (0.49,1.90)

Variable	Categories	All Years 2002-2017 (N=5,584)			Phase I 2003-2010 (N=2,724)			Phase II 2012-2017 (N=2,330)		
		Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)	Parameter	P value	OR* (LCL, UCL)
Year House Built	Unknown	0.427	0.0008	1.86 (0.96,3.60)	0.366	0.0209	1.34 (0.52,3.45)	0.550	0.0339	3.09 (0.90,10.60)
	Before 1940	0.685	<.0001	**2.41 (1.26,4.61)**	0.637	<.0001	1.76 (0.69,4.51)	0.740	0.0009	**3.74 (1.14,12.30)**
	1940 to 1949	-0.127	0.4662	1.07 (0.53,2.18)	-0.085	0.6919	0.85 (0.31,2.33)	-0.255	0.4709	1.38 (0.36,5.34)
	1950 to 1959	0.226	0.2399	1.52 (0.73,3.19)	0.235	0.3391	1.18 (0.41,3.34)	0.388	0.2581	2.63 (0.69,9.98)
	1960 to 1977	0.223	0.2455	1.52 (0.73,3.17)	-0.037	0.8868	0.90 (0.31,2.58)	0.264	0.4582	2.32 (0.61,8.93)
	1978 to 1989	-1.240	0.0156	0.35 (0.09,1.32)	-1.188	0.0626	0.28 (0.05,1.58)	-1.107	0.207	0.59 (0.06,5.84)
	1990 and later	ref			ref			ref		
Neighbor-hood	1	0.579	<.0001	1.43 (0.95,2.15)	0.472	<.0001	1.13 (0.70,1.84)	0.707	<.0001	2.49 (0.87,7.15)
	2	0.757	<.0001	1.71 (1.12,2.60)	0.741	<.0001	1.48 (0.89,2.47)	0.815	<.0001	2.78 (0.96,8.03)
	3	-0.187	0.1833	0.66 (0.41,1.06)	-0.189	0.2624	0.58 (0.33,1.02)	-0.195	0.5153	1.01 (0.31,3.31)
	4	-0.050	0.6653	0.76 (0.49,1.18)	0.054	0.705	0.74 (0.44,1.26)	-0.444	0.088	0.79 (0.25,2.47)
	5	-0.310	0.0643	**0.59 (0.35,0.98)**	-0.228	0.2686	0.56 (0.30,1.05)	-0.359	0.3006	0.86 (0.24,3.03)
	6	-0.323	0.0053	**0.58 (0.37,0.90)**	-0.290	0.0354	**0.53 (0.31,0.89)**	-0.293	0.2866	0.92 (0.29,2.96)
	7	-0.690	0.0117	**0.40 (0.20,0.82)**	-0.908	0.011	**0.29 (0.11,0.71)**	-0.024	0.9549	1.20 (0.30,4.81)
	8	ref			ref			ref		
Season	May 1 through Oct 31	0.203	<.0001	**1.50 (1.27,1.77)**	0.225	<.0001	**1.57 (1.28,1.92)**	0.175	0.035	**1.42 (1.03,1.96)**
	Nov 1 through Apr 30	ref			ref			ref		

Note:
*Statistically significant differences between the reference category and other categories are marked by bold ORs.